3èmes JOURNÉES de STIMULATION & DÉFIBRILLATION
GROUPE DE RYTHMOLOGIE ET DE STIMULATION CARDIAQUE DE LA SOCIÉTÉ FRANÇAISE DE CARDIOLOGIE
16 et 17 MARS 2023 SFC Paris

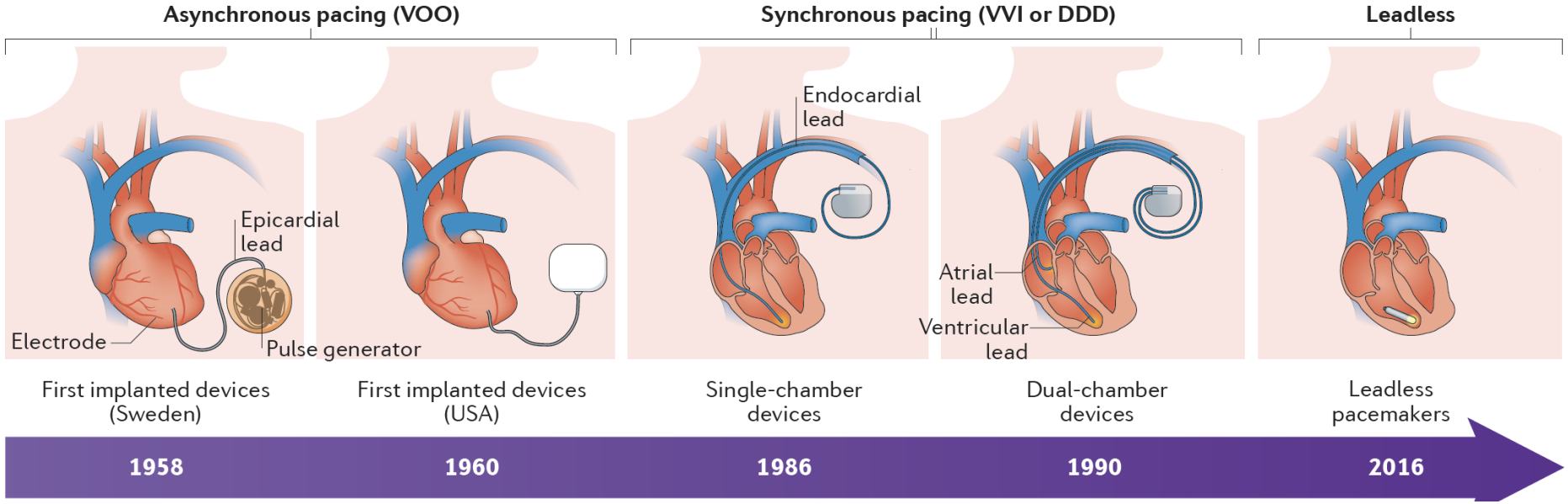
Stimulation cardiaque sans sonde: Pour tout le monde??

Mars 2023

Pascal DEFAYE

CHU GRENOBLE ALPES
UGA Université Grenoble Alpes

Stimulation sans sondes : du simple au double et triple chambre



>2022

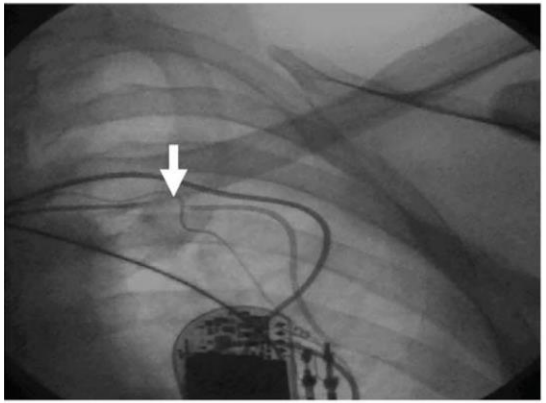
????

Why leadless? Unmet needs in cardiac pacing

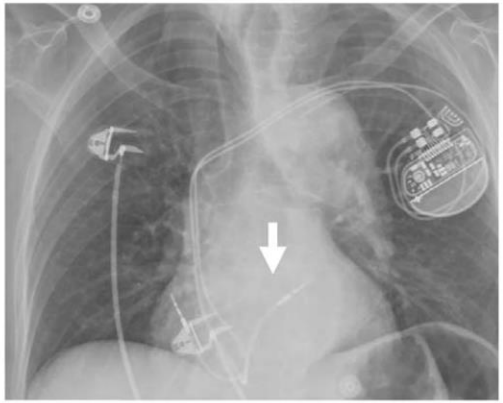
Complications of transvenous pacing

- Acute complications/ access issues
  - Pneumothorax
  - Hematoma
  - Venous access issues (dialysis, congenital heart disease)

- Long-term complications
  - Lead reliability (fracture, insulation)
  - Device pocket (erosion, discomfort)
  - Tricuspid regurgitation
  - Infection



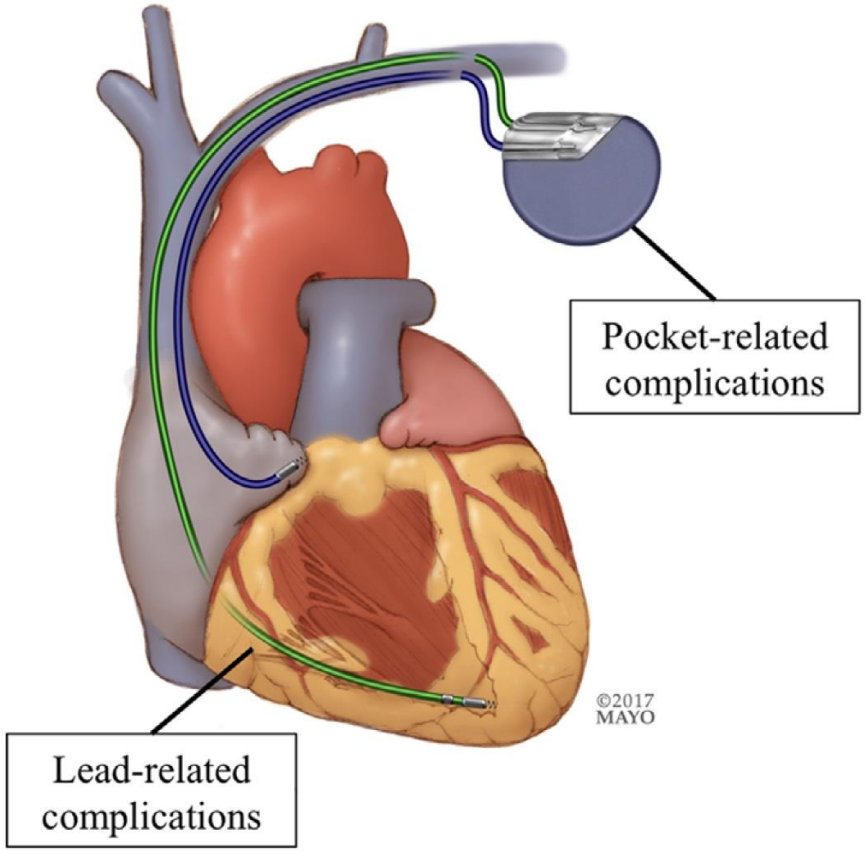
Lead fracture



Lead dislodgment

Pocket infection

Hematoma



Transvenous pacemaker complications	Rate (%)
Immediate complications	
Pneumothorax	0.6-0.9 [3, 24]
Cardiac perforation	0.1 - 0.3 [3, 27]
Hematoma	0.2 – 0.7 [3, 26]
Intermediate complications	
Lead dislodgement	0.4 – 1.7 [3, 25]
Pocket revision because of pain	0.4 [3]
Late complications	
Lead-related re-intervention • Conductor fracture • Insulation break	1.7 - 2.4 [3, 25]
Pacemaker infections	1.8-1.9 per 1000 pacemaker years [4, 5]

Lee JZ et al.Trends in CV Medicine 2019

Pacing implantations / CHU Grenoble Alpes

- 1st Implantation : November 19th, 2013

- ***Total : 63 Nanostim/***
  390 Micra /
  10 EBR Wyse CRT
  7 AVEIR/ 10 AVEIR DR

Total = 633 implantations

- Complications :
  - ***1 tamponade with Nanostim : pericardiocentesis only***
  - ***1 tamponade with Micra : sternotomy/ RV apical repair (2016)***

<0,2%

			2019	2020	2021
PM	VVI	PRIMO-IMPL	65	67	29
		Changement Boit	9	6	8
		MICRA	25	45	101
		sous total	**99**	**118**	7
					145
	DDD	PRIMO-IMPL	200	191	190
		Changement Boit	46	64	77
		sous total	**246**	**255**	**267**
	CRT	PRIMO-IMPL	60	69	85
		Changement Boit	6	12	74
		WISE	3	0	0
		sous total	**69**	**81**	**159**
	EPI	PRIMO-IMPL	0	0	1
		Changement Boit	0	0	0
		sous total	**0**	**0**	**1**
	TOTAL		**414**	**454**	**572**

2022

31

Micra 161

AVEIR DR : 10

Grenoble experience with Micra : patients >75 y.o.

130 pts

- 84 ± 5.6 years old, male 66.2%
- Fluo : 4.3±2.9 minutes

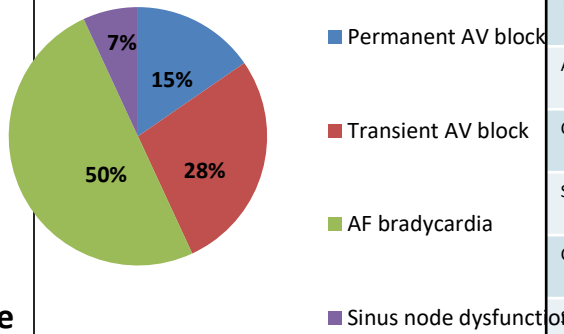
Number of device deployments 1.5±1 (1-7)

- Threshold : 0.5±0.4 at 0.24ms
  (only 4 pts (3%) threshold >1.0 V).
- Complications:
  - 1 myocardial perforation among the first implantations/ apical device position multiple comorbidities.
  - 1 cardiogenic shock/very fragile patient

- Total rate of major complications: 2.3%

1 femoral complication

Indications



Choice for Leadless system pacing	(%)
Transvenous pacemaker extractions	20%
Active systemic infection	20%
Complex conventional approach	21.6%
Severe tricuspid valve disease	1.5%
Clinical frailty	22.3%
Shortly after TAVR	8.5%

- Median time from implantation to discharge : 5±6.5 D (55.6% ≤72 hours)
- Follow-up :17± 15 M / mortality rate of 12.3%:
- 92.2% of pts : thresholds <1V during FU;
- No infections;
- No device dislodgement

Conclusion: *Elderly pts are at higher risk of complications; our experience confirms their clinical frailty and underlines the favorable safety profile of leadless system pacing with a low rate of complications and stable pacing thresholds.*

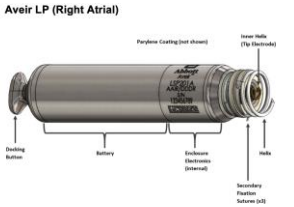
Benkilani M, EHRA 2022

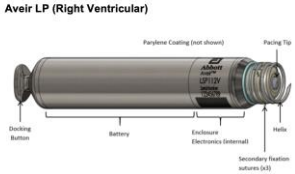
Leadless pacemakers

LCP™ Nanostim/Abbott

41 mm

December 2012





January 2021

Aveir/38 mm

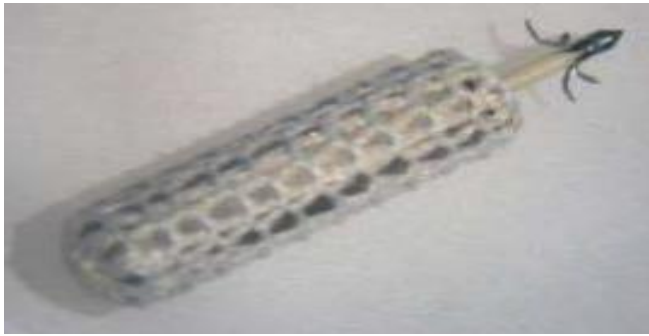
Micra™ Medtronic

25 mm

December 2013

Micra AV™ 2020

WICS™ EBR



9mm

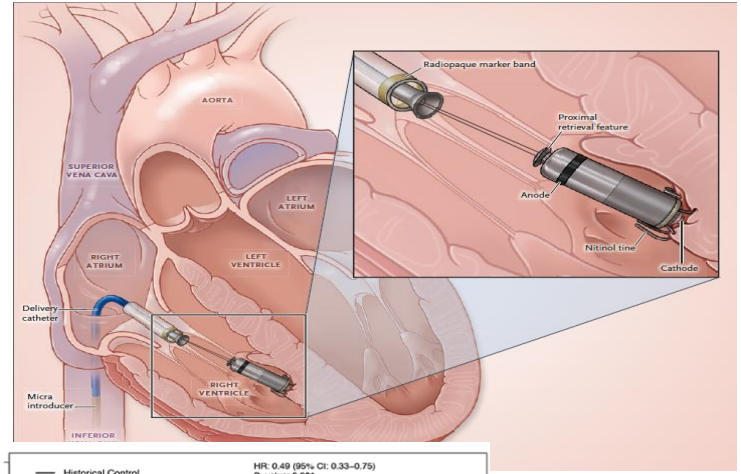
May 2011

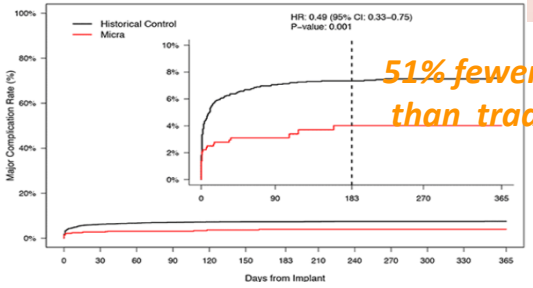
A Leadless Intracardiac Transcatheter Pacing System

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*

725 patients

Micra TPS study





51% fewer major complications than traditional pacemakers

N Engl J Med 2016

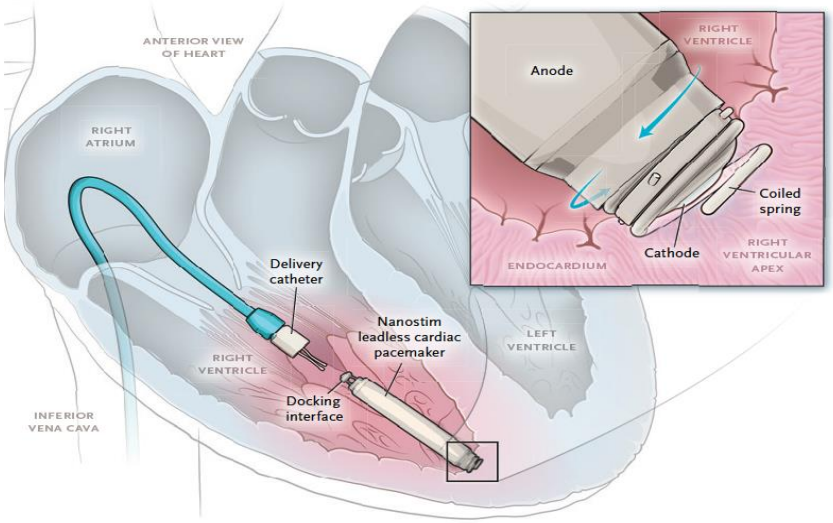
ORIGINAL ARTICLE

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*

526 patients

Leadless II



N Engl J Med 2015

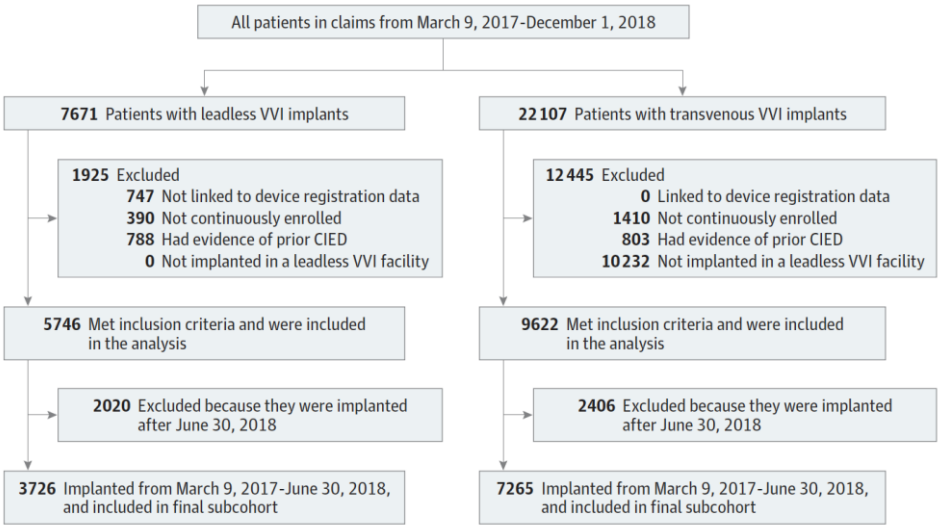
JAMA Cardiology | Original Investigation

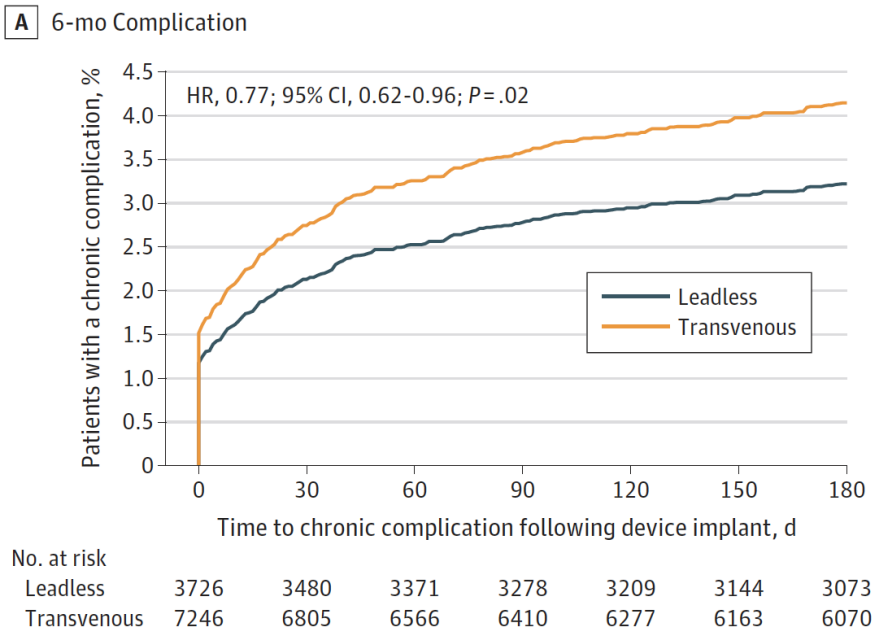
Contemporaneous Comparison of Outcomes Among Patients Implanted With a Leadless vs Transvenous Single-Chamber Ventricular Pacemaker

Jonathan P. Piccini, MD, MHS; Mikhael El-Chami, MD; Kael Wherry, PhD; George H. Crossley, MD; Robert C. Kowal, MD, PhD; Kurt Stromberg, MS; Colleen Longacre, PhD; Jennifer Hinnenthal, MPH; Lindsay Bockstedt, PhD

33% lower rate of chronic complications / transvenous VVI

Figure 1. Cohort Formation Flowchart





JAMA Cardiol. 2021;6:1187-1195.

JAMA Cardiology | Original Investigation

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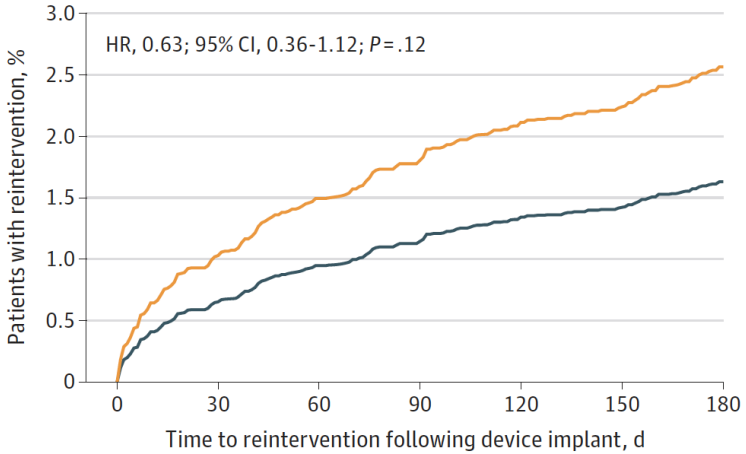
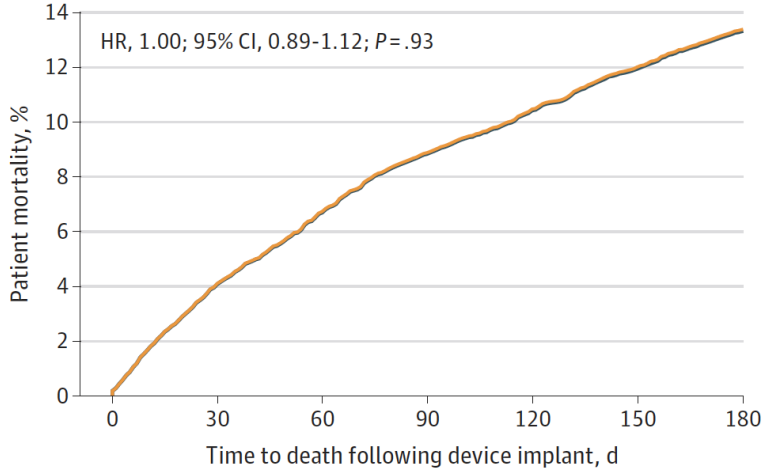
B 6-mo Revision



No. at risk

Leadless	3726	3536	3430	3335	3266	3202	3131
Transvenous	7246	6914	6670	6501	6371	6251	6149

C Patient mortality rates



No. at risk

Leadless	3726	3564	3459	3365	3295	3234	3166
Transvenous	7246	6972	6767	6615	6507	6393	6311

38% lower rate of reinterventions

JAMA Cardiol. 2021;6(10):1187-1195.

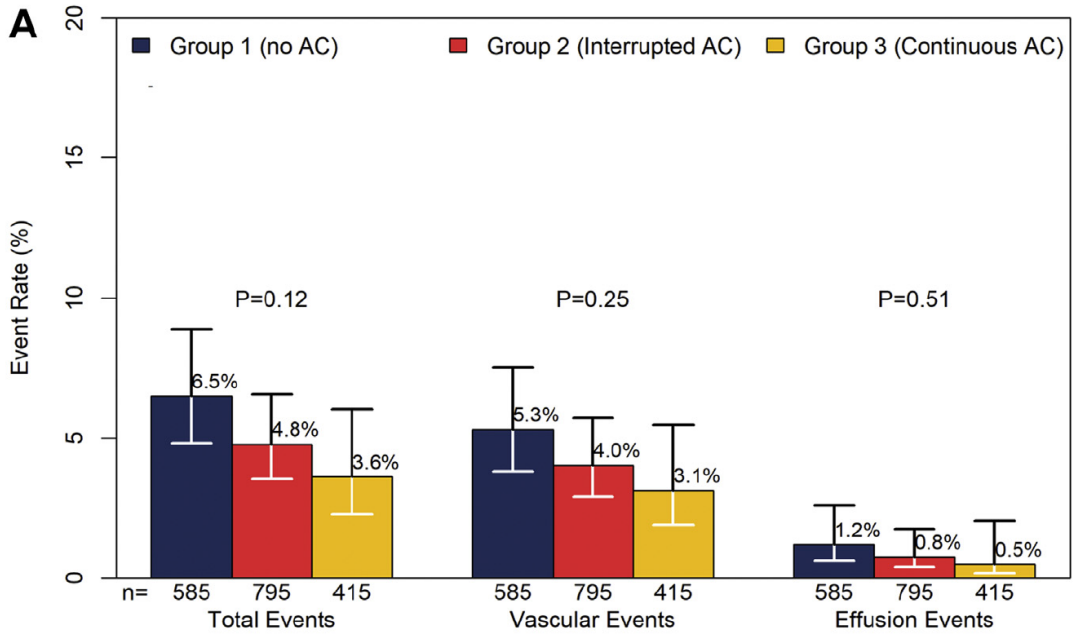
Leadless pacemaker implant, anticoagulation status, and outcomes: Results from the Micra Transcatheter Pacing System Post-Approval Registry

Mikhael F. El-Chami, MD, FHRS,* Christophe Garweg, MD, PhD,† Saverio Iacopino, MD,‡ Faisal Al-Samadi, MD, FHRS,§ Jose Luis Martinez-Sande, MD,¶ Claudio Tondo, MD, PhD, FHRS,‖ Jens Brock Johansen, MD,** Xavier Viñolas Prat, MD,†† Jonathan P. Piccini, MD, MHS, FHRS,‡‡ Yong Mei Cha, MD, FHRS,§§ Eric Grubman, MD, FHRS,¶¶ Pierre Bordachar, MD, PhD,‖‖ Paul R. Roberts, MD,*** Kyoko Soejima, MD,††† Kurt Stromberg, MS,‡‡‡ Dedra H. Fagan, PhD,‡‡‡ Nicolas Clementy, MD, PhD§§§

Table 3 Acute major complications by oral AC strategy

Adverse event	Group 1 (no AC) (n = 585)	Group 2 (interrupted AC) (n = 795)	Group 3 (continuous AC) (n = 415)	Omnibus *P* value*
Total major complications	19 (18, 3.08)	25 (21, 2.64)	6 (6, 1.45)	.29
Cardiac effusion/perforation	4 (4, 0.68)	2 (2, 0.25)	2 (2, 0.48)	.52
Events at groin puncture site	2 (2, 0.34)	7 (7, 0.88)	1 (1, 0.24)	.38
Thrombosis	0 (0, 0.00)	2 (2, 0.25)	0 (0, 0.00)	.62
Pacing issues†	8 (7, 1.20)	8 (8, 1.01)	1 (1, 0.24)	.36
Cardiac rhythm disorder	0 (0, 0.00)	0 (0, 0.00)	1 (1, 0.24)	.46
Infection	1 (1, 0.17)	3 (3, 0.38)	0 (0, 0.00)	.64
Other‡	4 (4, 0.68)	3 (3, 0.38)	1 (1, 0.24)	.62

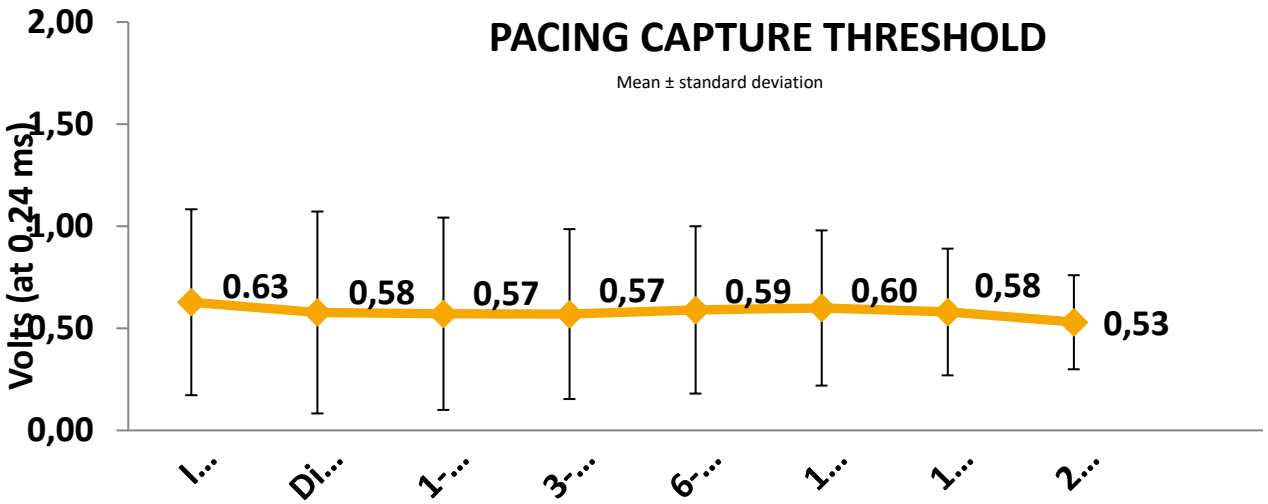
Implant of Micra is safe and feasible regardless of an interrupted or continued periprocedural oral AC strategy, with no increased risk of perforation or vascular complications.



Heart Rhythm 2021

Low and stable pacing thresholds

Estimation of the battery longevity : 12.1 years

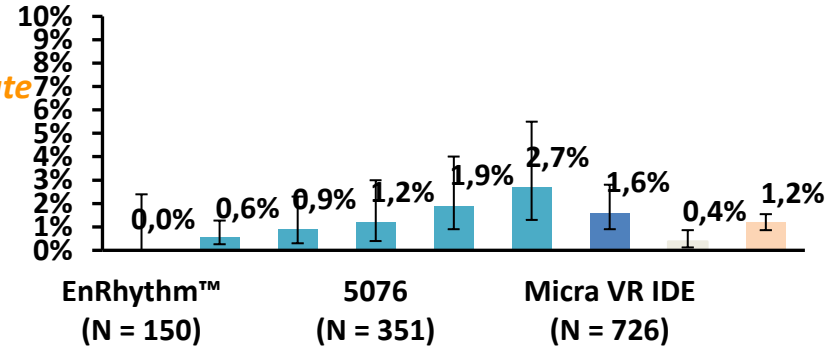


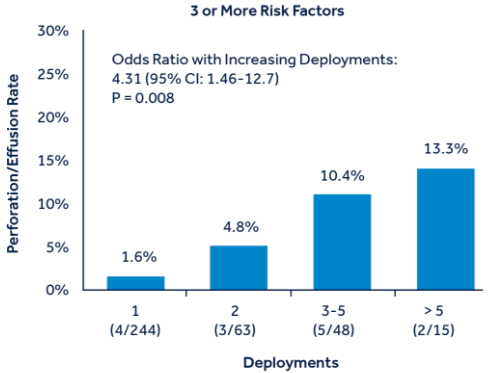
All patients Micra™ VR with Perforation/Effusion : ≥ 1 risk factor

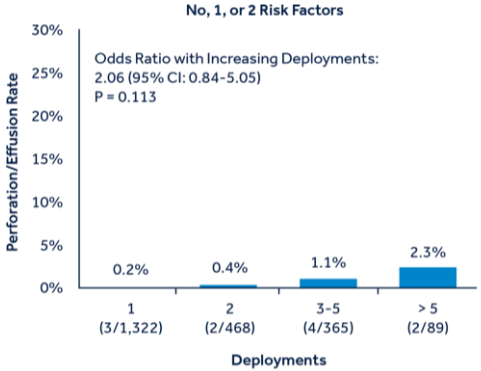
Known risk factors for complications of transvenous leads

Patients characteristics	No pericardial effusion (n = 712)	Pericardial effusion (n = 13)	P value
Mean age (years),	75.8 ± 11.0	81.7 ± 8.6	0.053
BMI	27.6 ± 5.3	24.5 ± 4.0	0.032
Woman, n (%)	290 (40.7%)	9 (69.2%)	0.048
Chronic lung disease, n (%)	203 (28.5%)	8 (61.5%)	0.025

Perforation /effusion rate



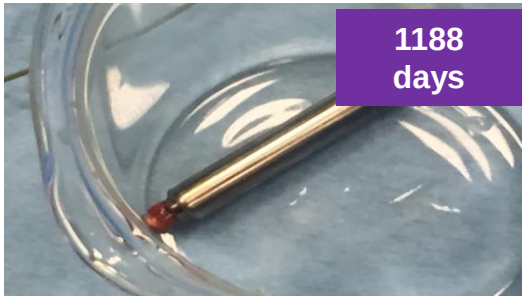




A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker

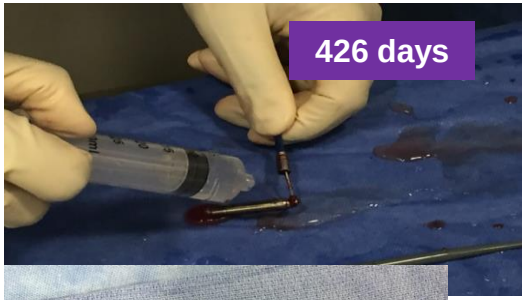
Dhanunjaya Lakkireddy, MD, FACC, FHRS,* Reinoud Knops, MD,† Brett Atwater, MD,‡ Petr Neuzil, MD,§ John Ip, MD,‖ Elkin Gonzalez, MD,¶ Paul Friedman, MD, FHRS,** Pascal Defaye, MD,†† Derek Exner, MD,‡‡ Kazutaka Aonuma, MD,§§ Rahul Doshi, MD, FHRS,‖‖ Johannes Sperzel, MD,¶¶ Vivek Reddy, MD***

Possibility of leadless retrieval (Nanostim™/Aveir™)



Nanostim Retrieval

Gross Pathology



90.4% success retrieval/implant duration range: 0.2–4.0 years

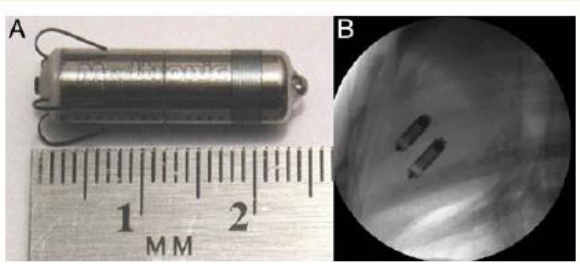
Heart Rhythm 2017;14:1756–1763

Multiple leadless pacemakers implanted in the right ventricle of swine

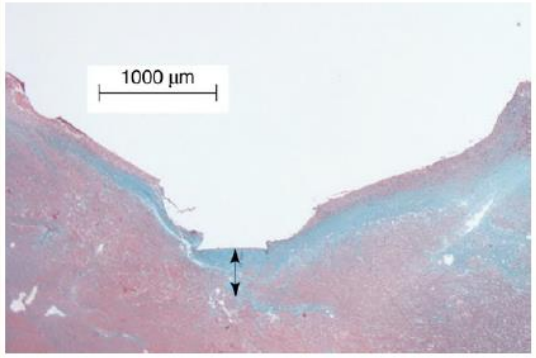
Keping Chen[1†], Xiaolin Zheng[1†], Yan Dai[1], Hao Wang[2], Yue Tang[3], Tingyu Lan[2], Jinping Zhang[2], Yi Tian[3], Baojie Zhang[3], Xiaohong Zhou[4], Matthew Bonner[4], and Shu Zhang[1*]

Multiple implantations possible

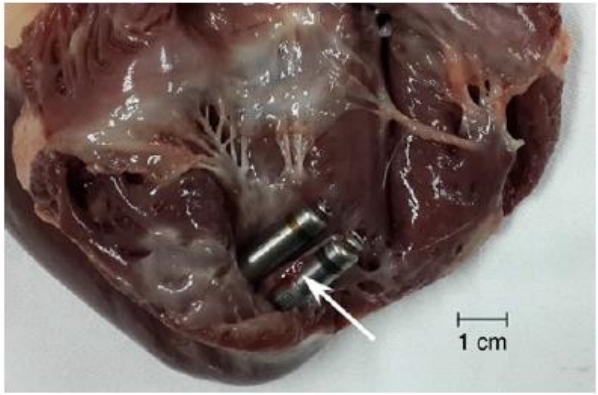
14 mini pigs received 2 leadless
1month interval between



Micra device and fluoroscopic imaging with Micra devices: (A) an example of the Micra device and (B) fluoroscopic imaging of two Micra devices implanted in the RV.



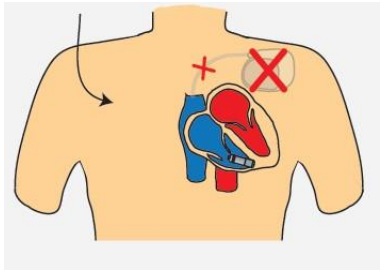
Tissue fibrosis beneath the Micra pacing electrode. Arrow indicates the thickness of the fibrosis measured from the endocardium where the device was placed.



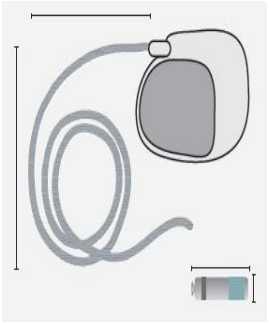
Fibrous tissue attaching around Micra devices observed at necropsy. Arrow indicates the fibrous tissue attachment.

Europace 2016 ; 18, 1748–1752

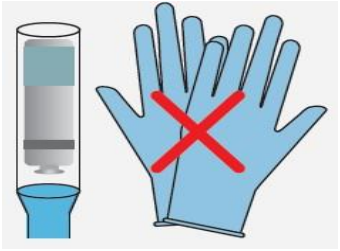
Low infection rate with leadless PM



No lead, no pocket



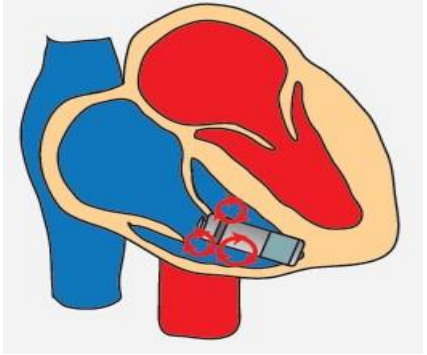
Small size



Reduced handling

Encapsulation

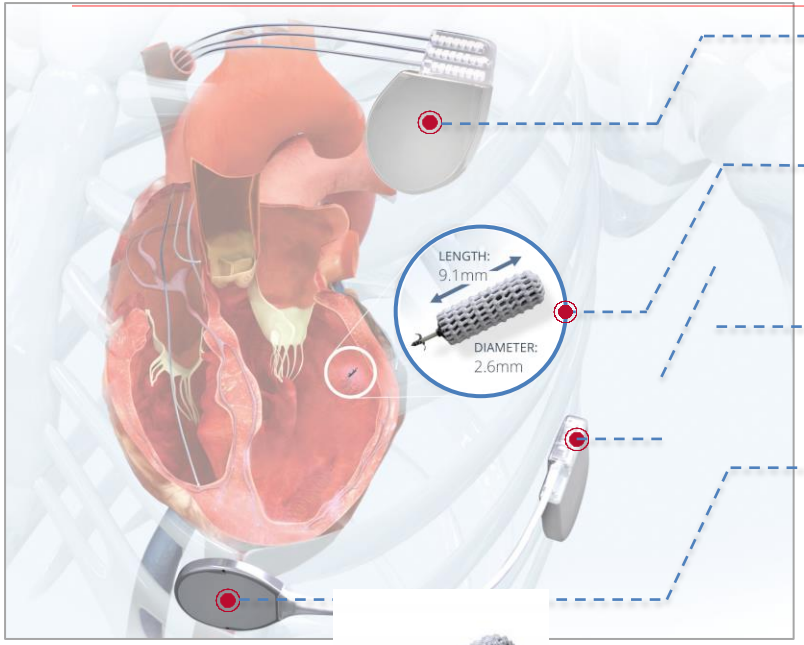
Protective covering



Turbulent flow

WiSE CRT system

Total : 383 patients worldwide



CO-IMPLANT DEVICE

Co-implanted pacemaker, ICD or CRT paces the right ventricle.

RECEIVER ELECTRODE

Implanted onto the endocardium, the receiver electrode converts ultrasound energy into electrical energy to pace the left ventricle.

BATTERY

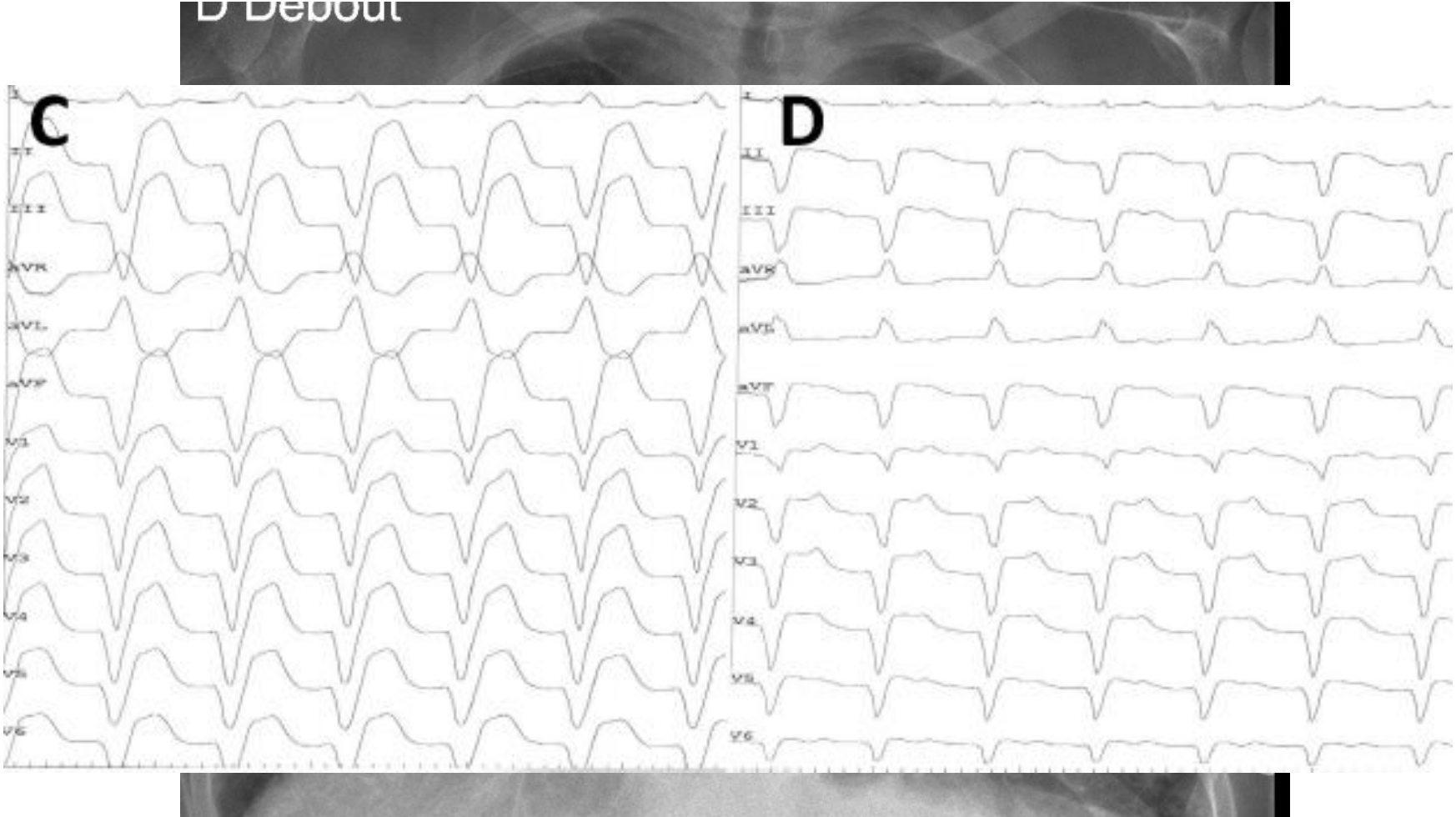
Implanted subcutaneously on the left mid axillary line, powers the transmitter.

TRANSMITTER

Phased array ultrasound transmitter is implanted sub-muscular over a cardiac echo window. Synchronizes with an RV pacing pulse to transmit ultrasound energy to the receiver electrode to provide Bi-V endocardial pacing.

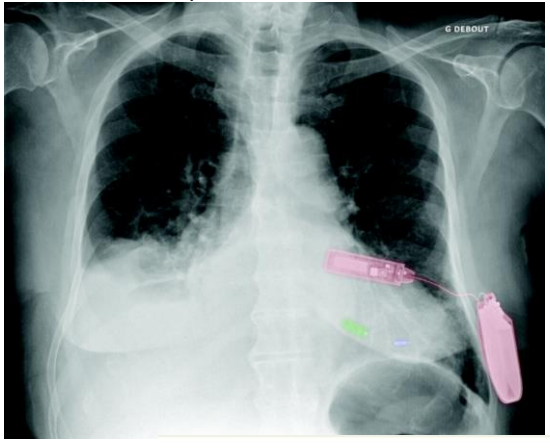
Very Small: 9.1mm x 2.7mm, 0.05cc (Micra .8cc)

“Leadless CRT”

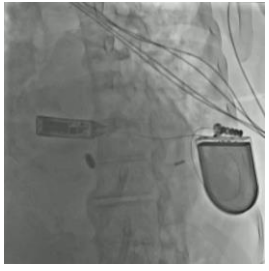


European experience with a first totally leadless cardiac resynchronization therapy pacemaker system

Adrien Carabelli [1], Mariem Jabeur[1], Peggy Jacon[1], Christopher Aldo Rinaldi[2], Christophe Leclercq[3], Giovanni Rovaris [4], Martin Arnold[5], Sandrine Venier[1], Petr Neuzil[6], and Pascal Defaye[1]*



8 patients



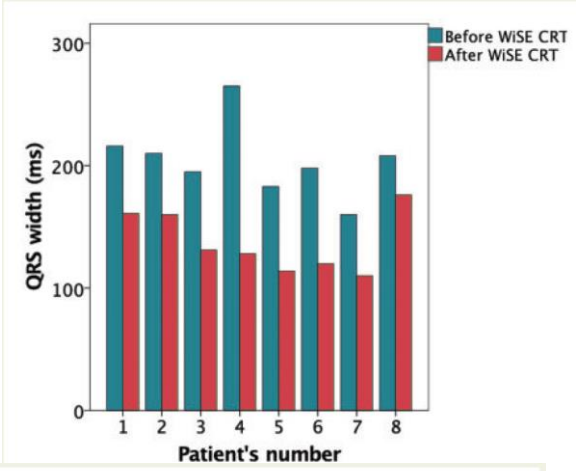
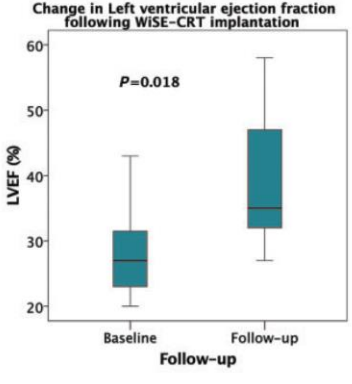
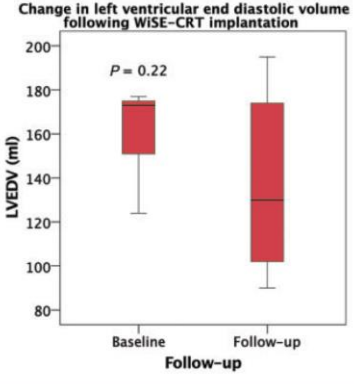
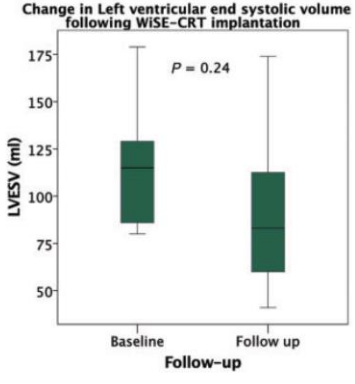


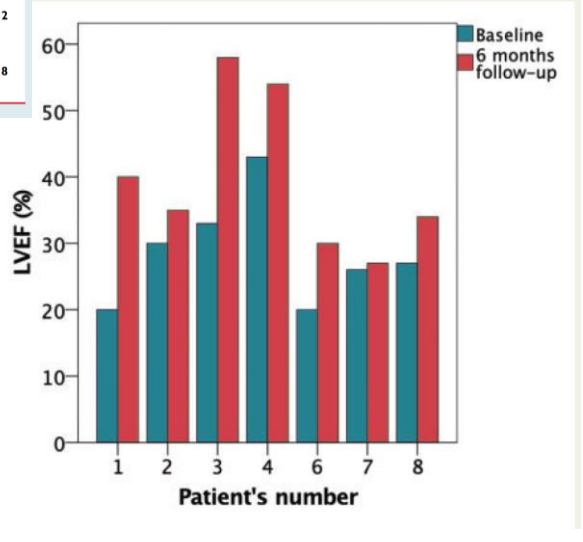
Table 2 Left ventricle function and volumes following WiSE-CRT implantation

Variables	Before WiSE-CRT implantation	After WiSE-CRT implantation	Change	*P*-value
QRS duration (ms)	204.37 ± 30.26	137.50 ± 24.75	−66.88 ± 31.58	**0.012**
LVESV (mL)	117.33 ± 35.61	91.86 ± 48.43	−23 ± 27.77	0.24
LVEDV (mL)	160 ± 22.69	129.4 ± 40.70	−30.60 ± 29.30	0.22
LVEF (%)	28.43 ± 8.01	39.71 ± 11.89	+11.29 ± 8.46	**0.018**
NYHA	2.63 ± 0.51	2.29 ± 0.95		0.18







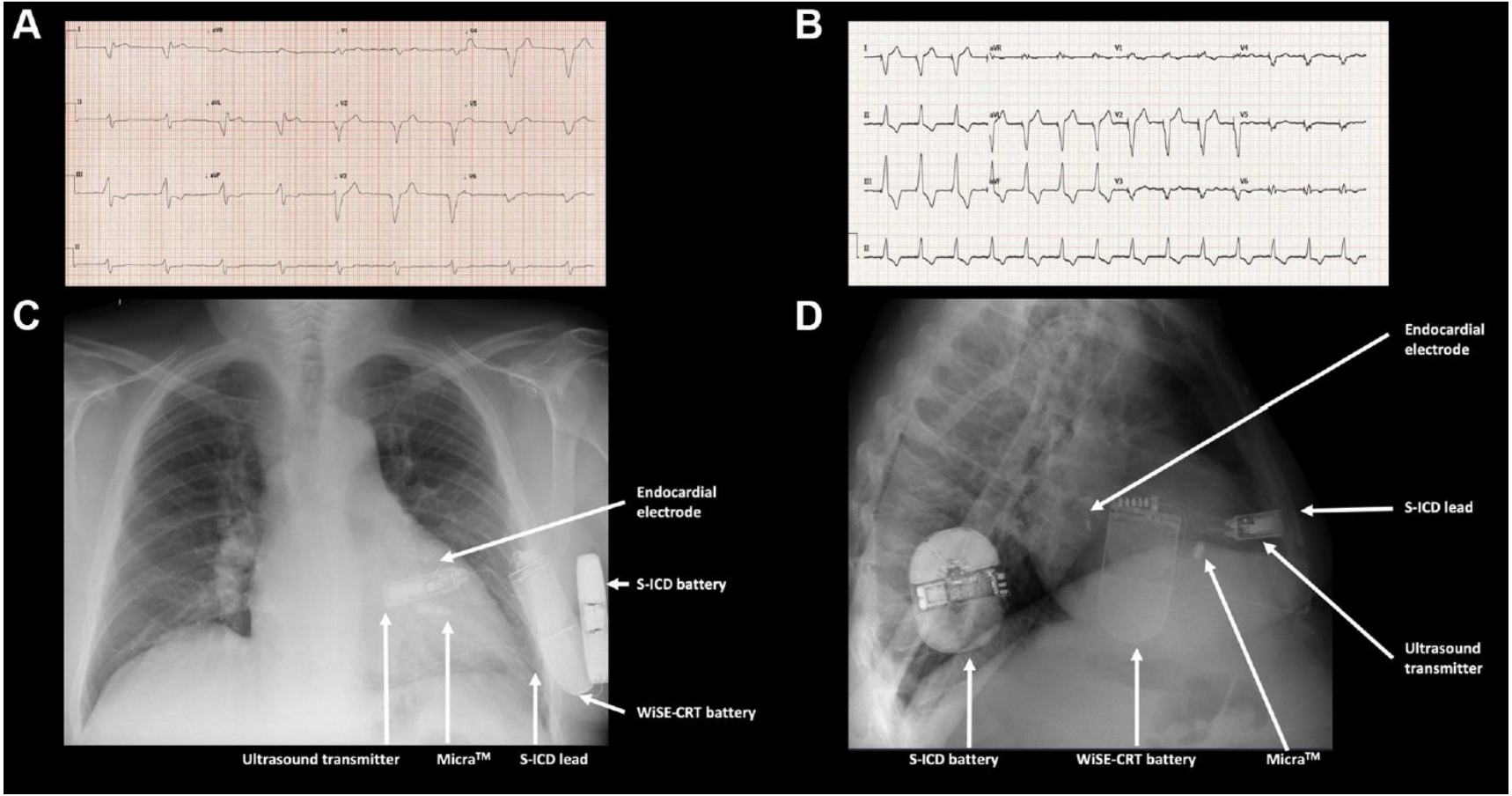


Europace 2021; 21;740-747

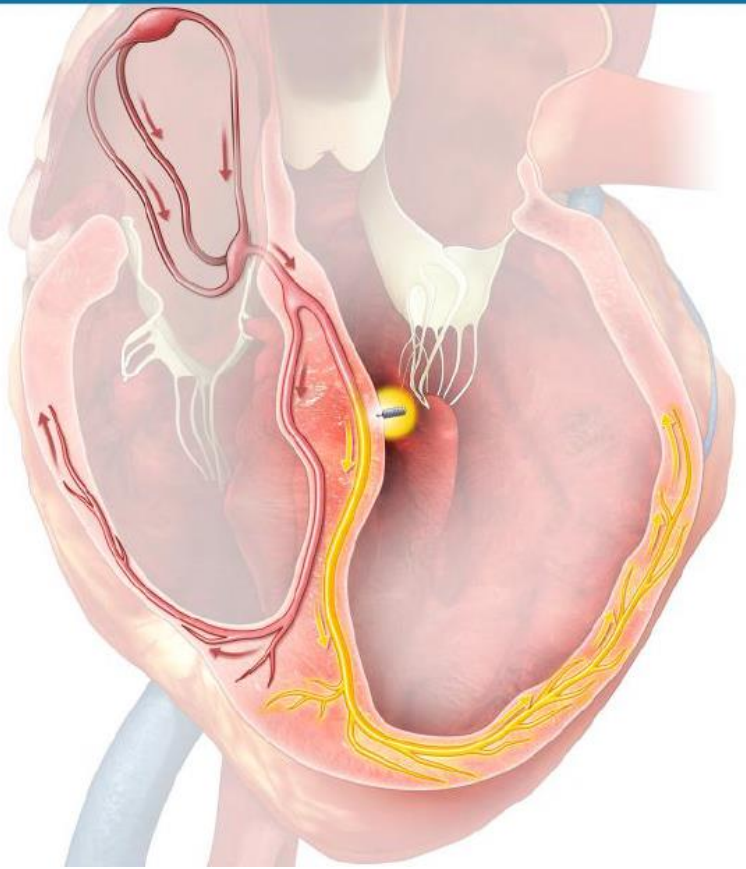
Completely Leadless Cardiac Resynchronization Defibrillator System

Baldeep S. Sidhu, BM,[a,b] Justin Gould, MBBS, PhD,[a,b] Bradley Porter, MBChB, PhD,[a,b] Mark Elliott, MBBS,[a,b] Vishal Mehta, MBBS,[a,b] Steven Niederer, DPhil,[a] Christopher A. Rinaldi, MD[a,b]

JACC EP 2020

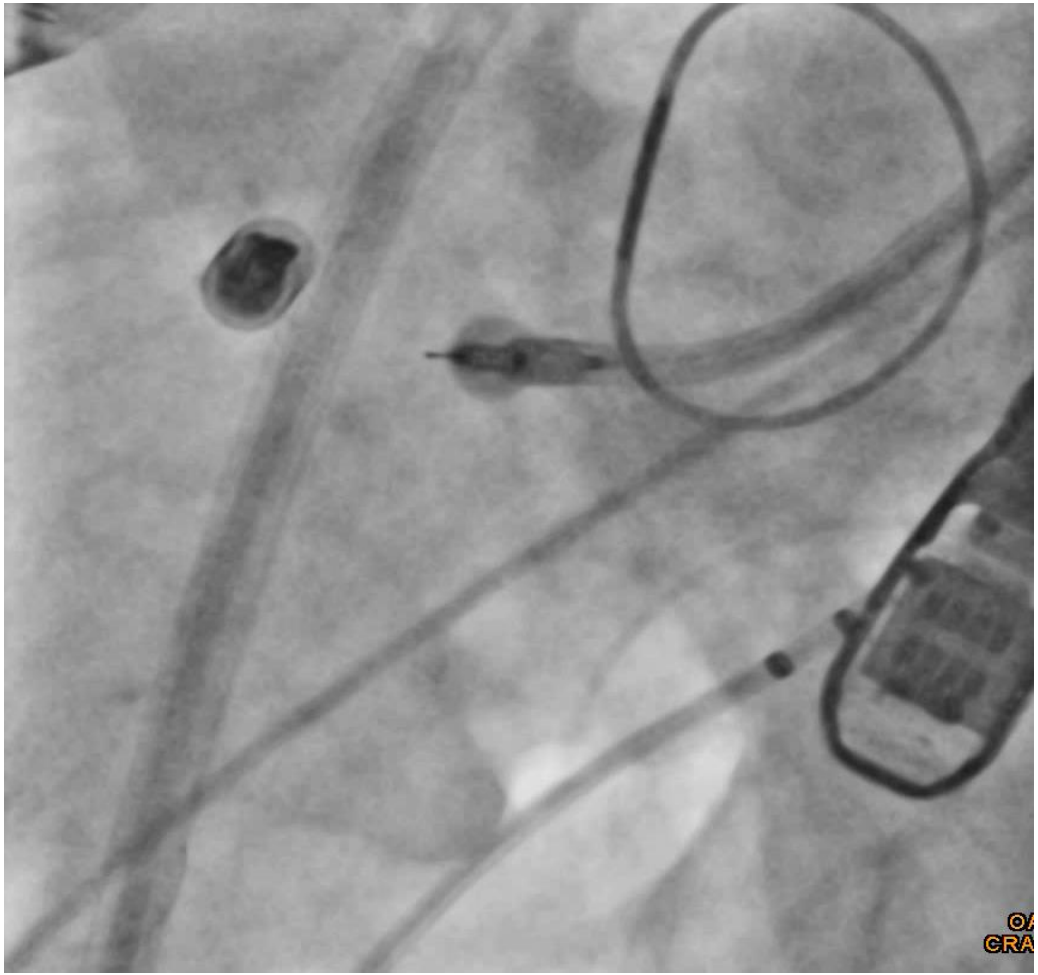


Leadless left bundle branch pacing

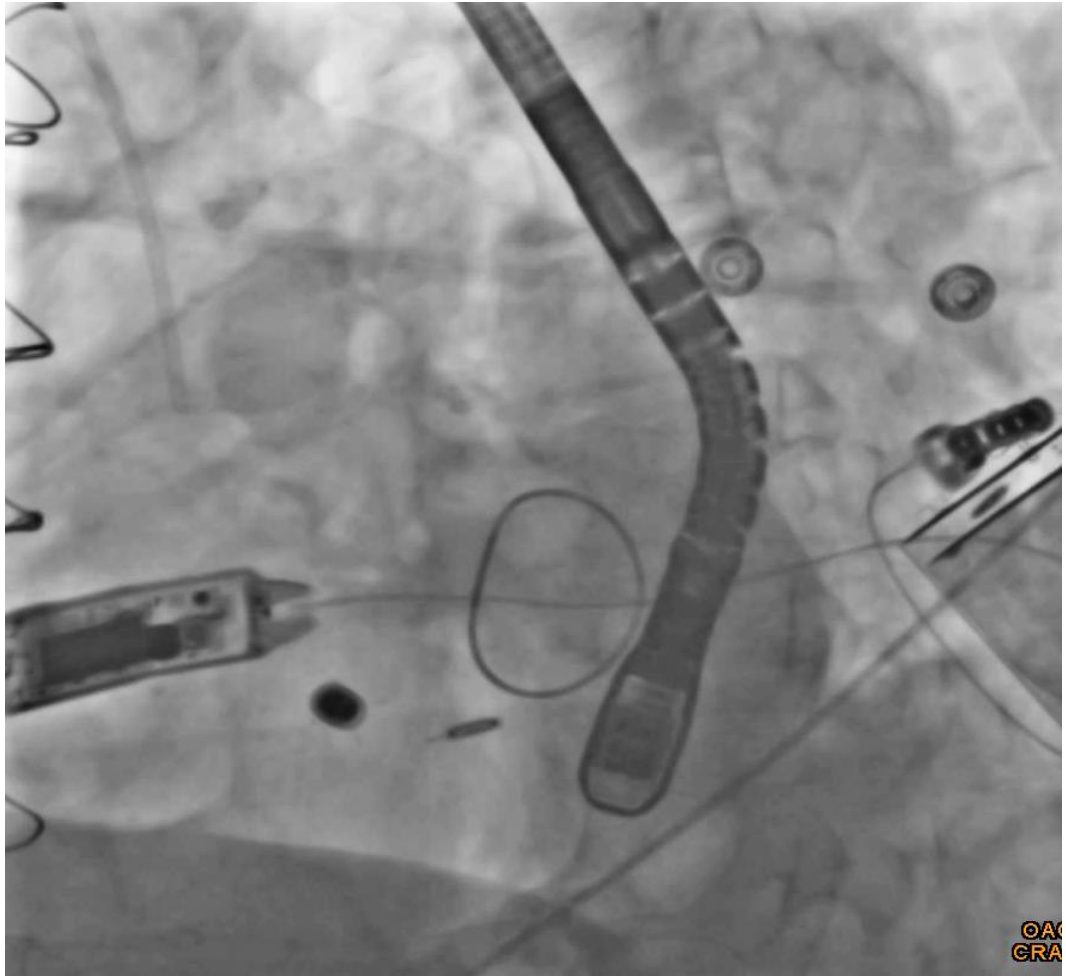


Potential advantages:

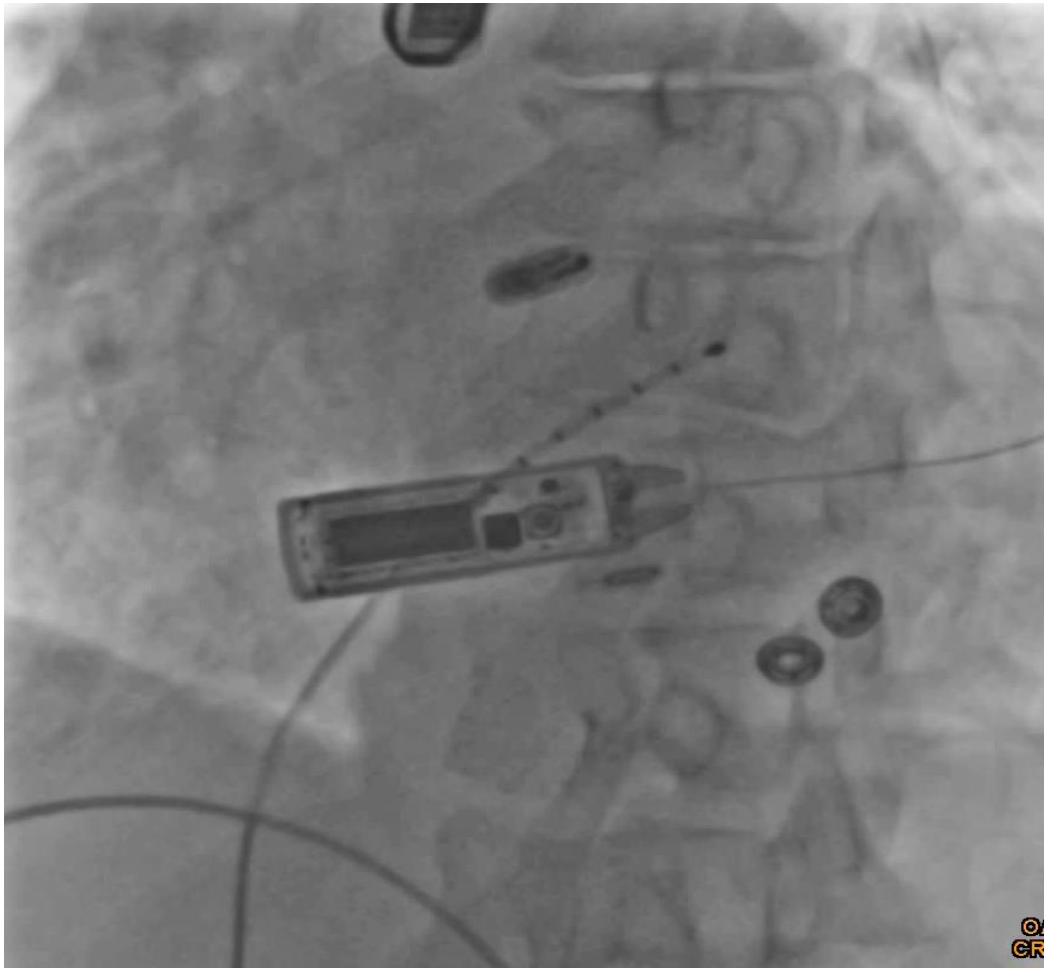
- Physiologic pacing
- Low pacing threshold
- No need for deep penetration into interventricular septum
- Negligible damage to conductive tissue
- Low risk of endocarditis



6/04/2022



6/04/2022



12/04/2022

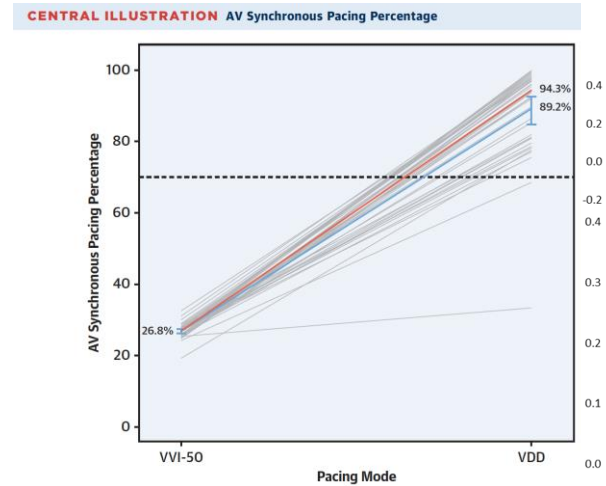
Atrioventricular Synchronous Pacing Using a Leadless Ventricular Pacemaker

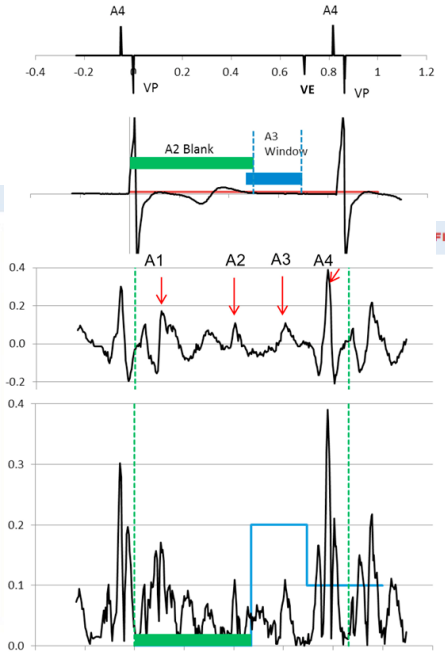
Results From the MARVEL 2 Study

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]

75 patients

AV conduction mode switch





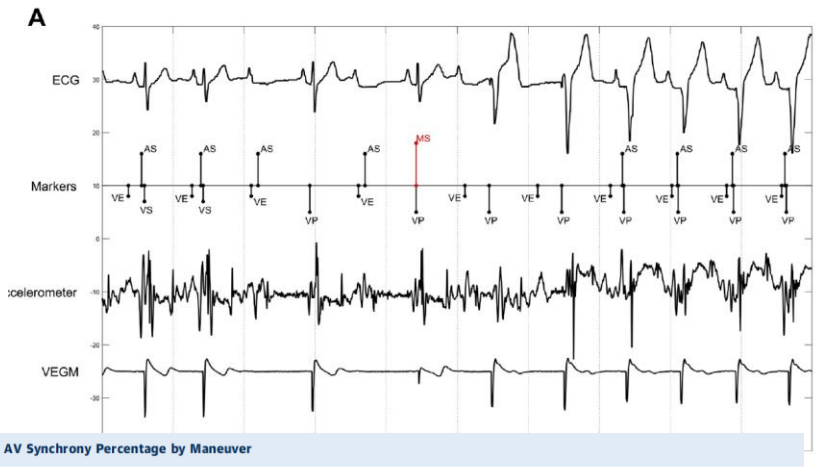
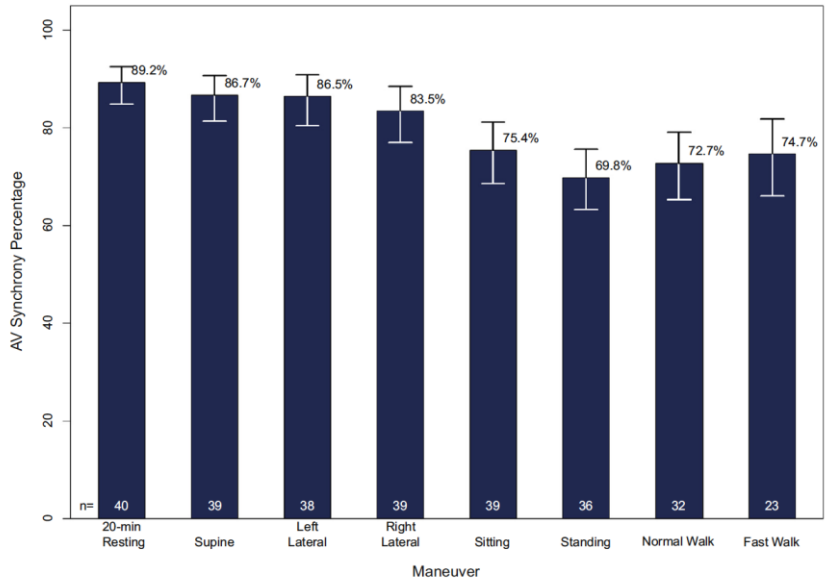


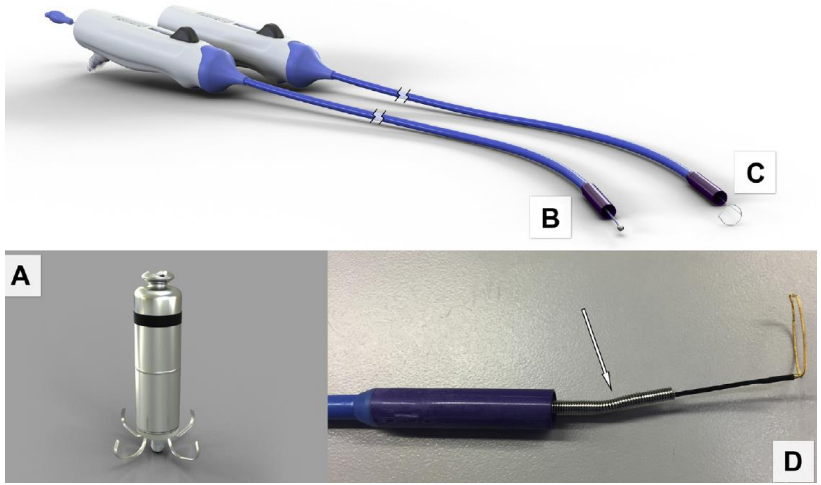
FIGURE 2 AV Synchrony Percentage by Maneuver



J Am Coll Cardiol EP 2020;6:94–106

Implant, performance, and retrieval of an atrial leadless pacemaker in sheep

Pierce J. Vatterott, MD,* Michael D. Eggen, PhD,† Katie E. Hilpisch, BS,†
Ron A. Drake, BS,† Vladimir Grubac, BS,† Tom A. Anderson, AAS,† Brian P. Colin, BS,†
Kevin R. Seifert, MS,† Mary Lauren Mesich, DVM,† Luis C. Ramon, DVM†



Heart Rhythm 2021;18:288–296

Micra AR (AAIR) or DDD (DDDR)

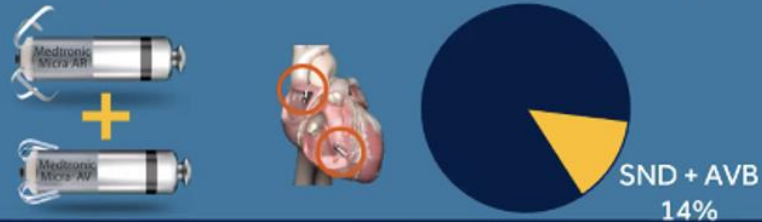
Modular Design provides flexible implant strategies

Single Device Use Case:

- Modular approach allows independent AR implant
- Option to upgrade to DDD later if necessary

Dual Device Use Case:

Implant Micra AR + Micra AV for DDDR pacing

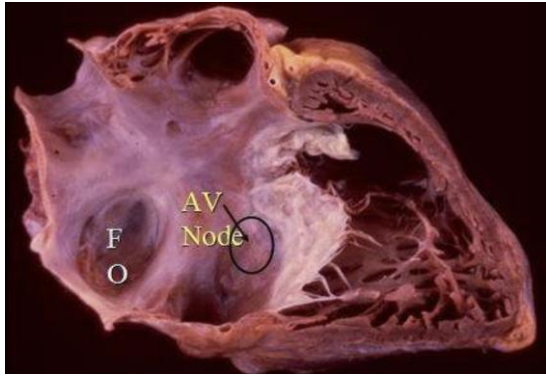


Focus on safe and effective implant procedure

Focus on optimized workflow for DDD pacing

Dual chamber leadless pacemaker

Abbott Aveir



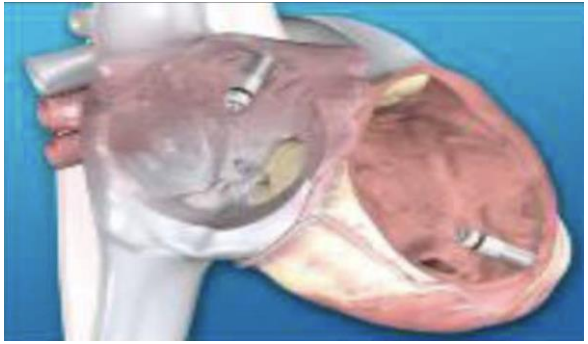
Requirements :

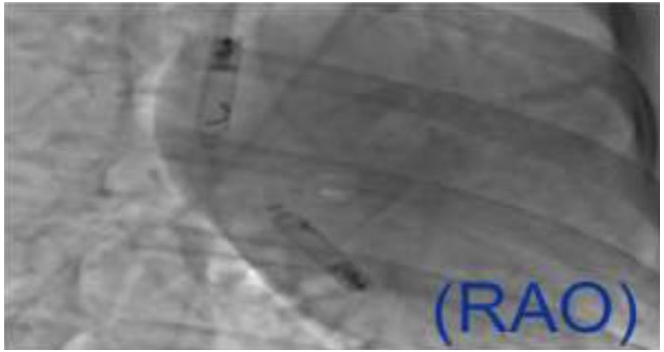
- ➢ **Safe atrial implant**
- **Wall thickness vs fixation mechanism**
- **Angle of implant/retrieval**
- **>18 F catheter femoral**

- ➢ **Sufficient longevity**

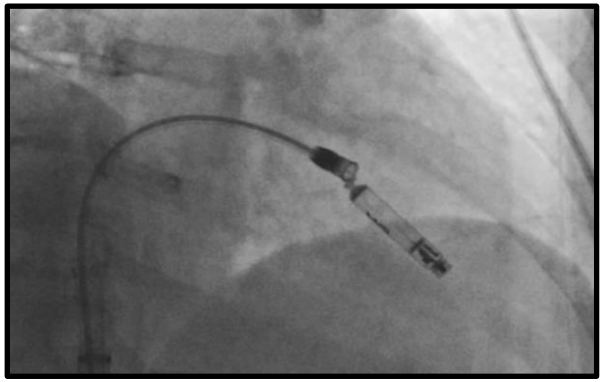
- ➢ **Intrabody communication**
- **Beat to beat communication**
- **Programmable AV delay**
- **Minimize V pacing**

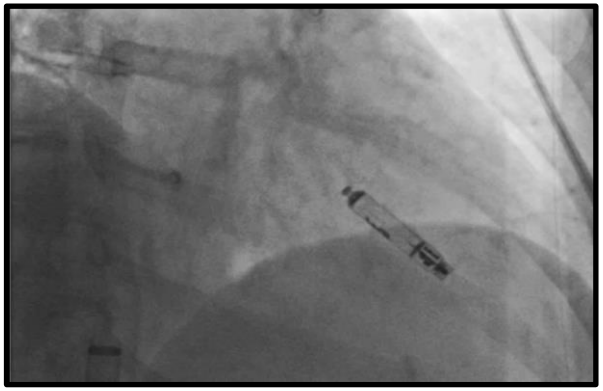
IMM Montsouris/2015



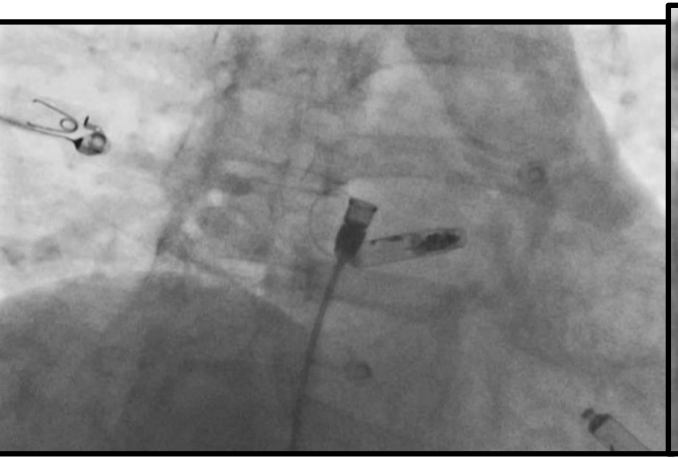


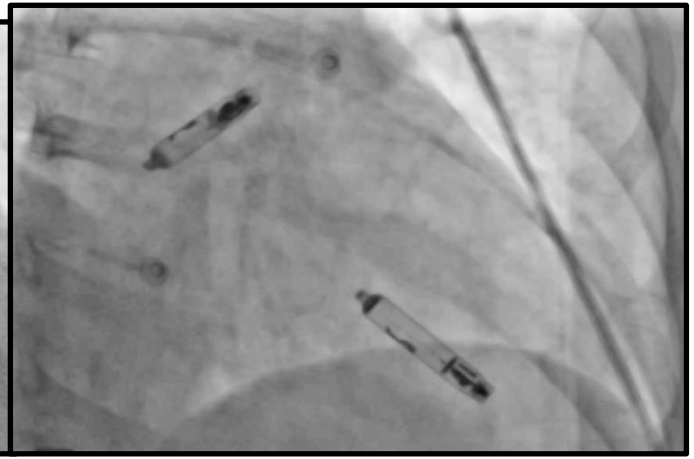
Clinical study 2022

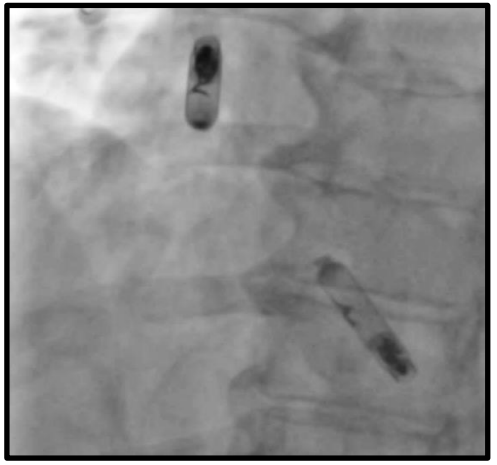




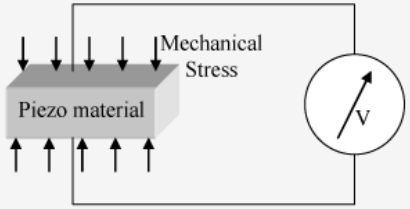
AVEIR™ DR







Kinetic energy harvesting system.



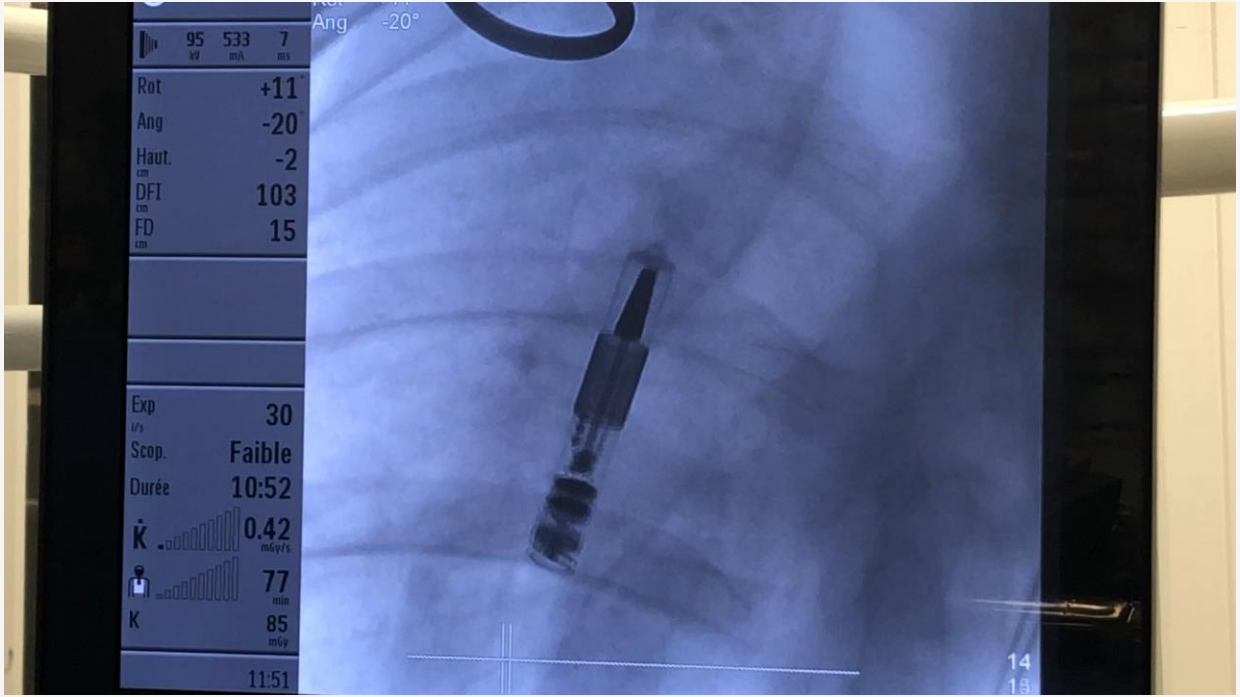
A closed-loop energy cycle.

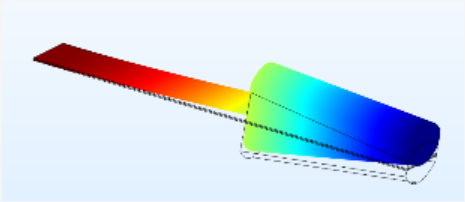
Improving **the patient's conditions** with a unique leadless pacemaker concept.

CAIRDAC

The kinetic energy is **HARVESTED** with every heartbeat and **RESTORED** for cardiac stimulation.

Kinetic energy harvesting system.





- *X-ray video of leadless capsule with harvester fixed at the APEX of pig*

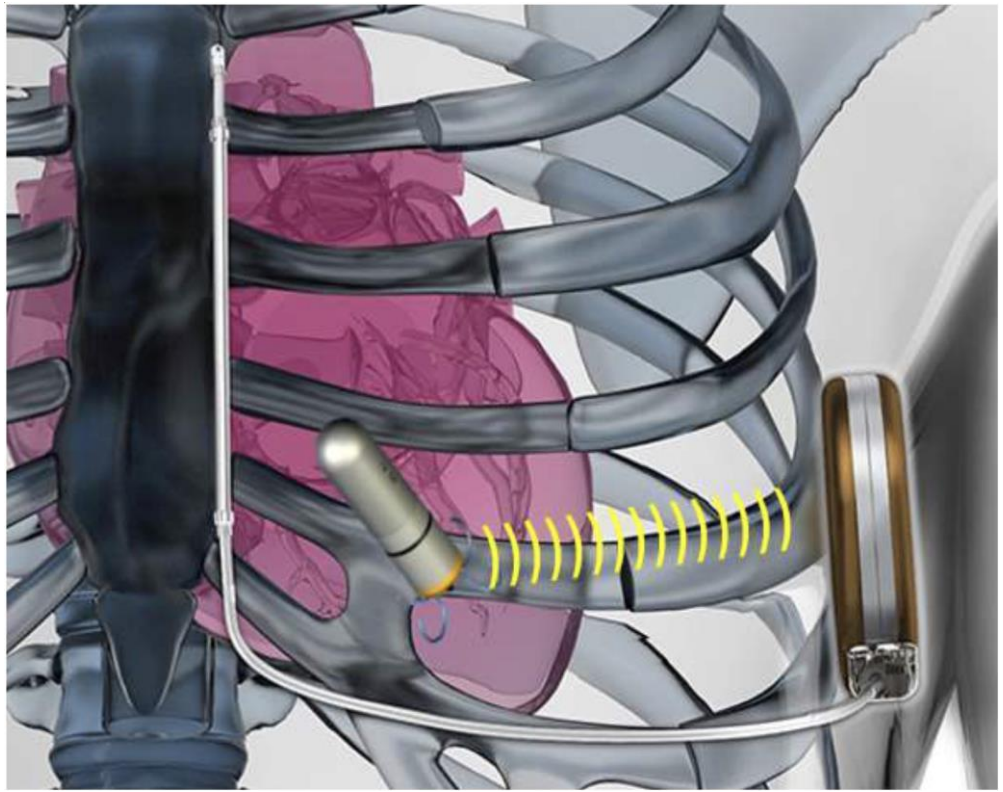
CAIRDAC

Future Directions

Limitations of the S-ICD :

S-ICD patients may develop a need for:

- **Pacing support** (0.06%-2.4%/year)
- **ATP** for recurrent monomorphic VT (0.4%-1.8% /year)



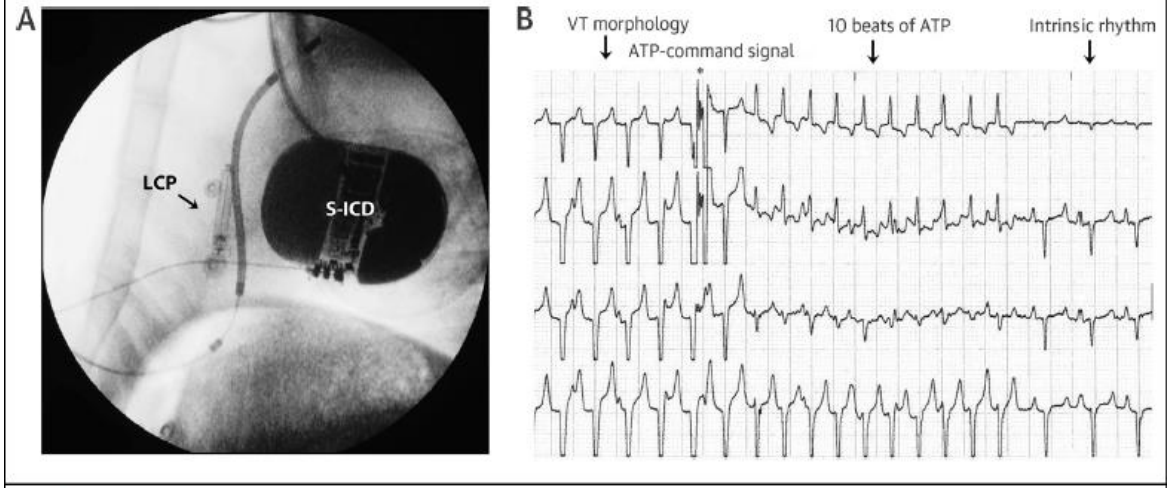
Burke MC .
J Am Coll Cardiol. 2015; 65(16):1605–1615
Poole JE.
Circ Arrhythm Electrophysiol. 2013;6:1236-1245.

Communicating Antitachycardia Pacing-Enabled Leadless Pacemaker and Subcutaneous Implantable Defibrillator

*Fleur V.Y. Tjong, MD
Tom F. Brouwer, MD
Kirsten M. Kooiman, PA
Lonneke Smeding, PhD
Brendan Koop, PhD
Brian Soltis, MSc
Allan Shuros
Arthur A.M. Wilde, MD, PhD
Martin Burke, DO
Reinoud E. Knops, MD

2 sheeps

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).

➢ December 2021 : first implantation in the *MODULAR ATP clinical trial*

Evaluation of the safety, performance and effectiveness of the mCRM™ Modular Therapy System

- EMBLEM™ MRI S-ICD System
- and the EMPOWER™ Modular Pacing System (MPS),

first leadless pacemaker capable of delivering both bradycardia pacing support and ATP

J Am Coll Cardiol 2016

Stimulation cardiaque sans sonde : conclusion

- ***Undoubtedly, Leadless pacing will become cardiac stimulation of the 3rd millenium***

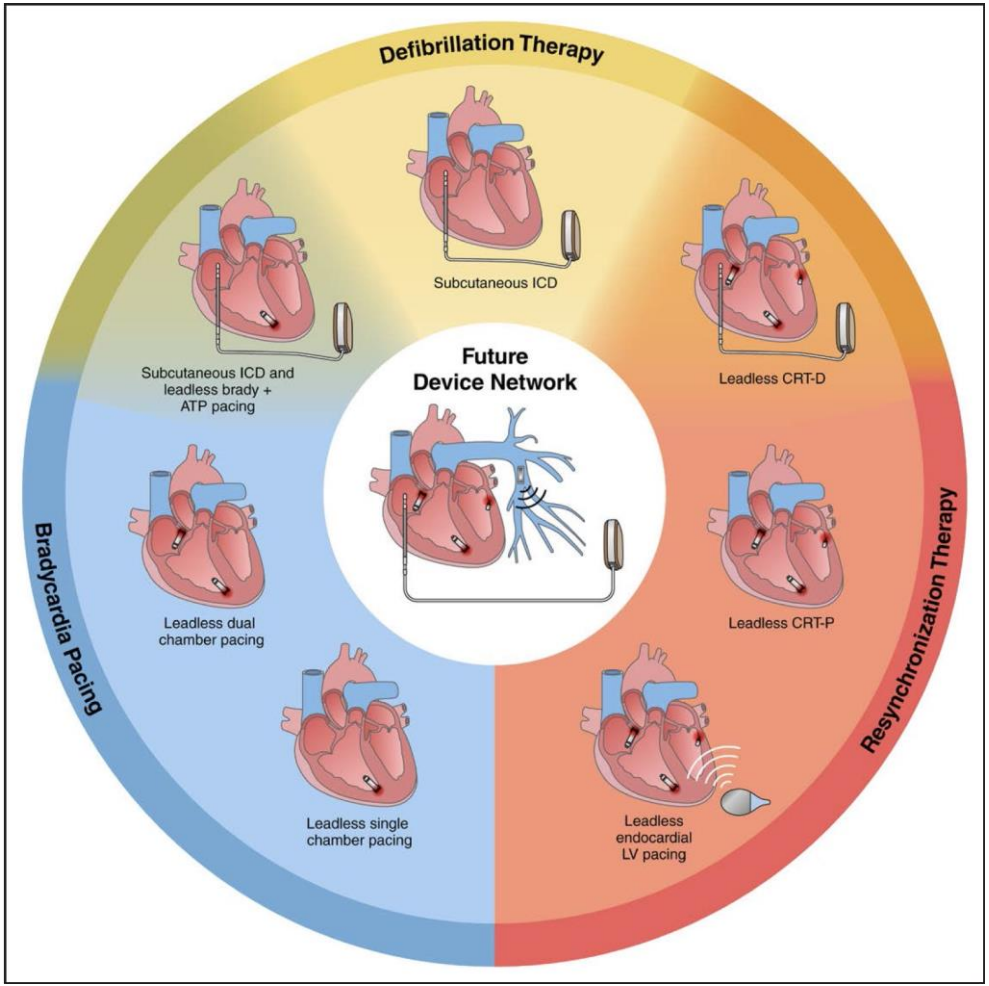
- ***Progressive replacement of VVIR TV pacing by leadless PM in reference centers***

- ***Today, expanded indications to syncope, post-infection, congenital heart disease***

- ***LPMs provide safe & efficient VVI pacing***
  - ***Compared to conventional PMs, 50% risk reductions***
  - ***But : limitations of leadless pacing***
    - ***particularly how to handle the generator at end of system life :***
      Retrieval or multiple implantations??

- ***Future of leadless pacing :***
  - ***DDD leadless, leadless CRT…., Harvester..***
  - ***Biological pacemakers but still in early development and preclinical phase***

Role of leadless pacing : overcome the unmet needs in cardiac pacing…..


Defibrillation Therapy
Subcutaneous ICD
Subcutaneous ICD and leadless brady + ATP pacing
Future Device Network
Leadless CRT-D
Leadless dual chamber pacing
Leadless CRT-P
Bradycardia Pacing
Resynchronization Therapy
Leadless single chamber pacing
Leadless endocardial LV pacing