L'essentiel de l'année en rythmologie
Devices

ELECTRA & RHYTHM

20/06/2022

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CHU GRENOBLE ALPES

L’essentiel de l’année en rythmologie : Devices

- ***Recommandations 2021 CRT et stimulation physiologique***

- ***APAF-CRT***

- ***Développement du leadless pacing***
  - *Simple chambre*
  - *Double chambre*
  - *Resynchronisation*
  - *»all leadless »*

- ***Défibrillateur sous cutané***

Quoi de neuf en resynchronisation ESC 2021
Nouvelles recommandations ESC

ESC European Society of Cardiology
European Heart Journal (2021) 00, 1–128
doi:10.1093/eurheartj/ehab368
ESC GUIDELINES

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

With the special contribution of the Heart Failure Association (HFA) of the ESC

Authors/Task Force Members: Theresa A. McDonagh* (Chairperson) (United Kingdom), Marco Metra * (Chairperson) (Italy), Marianna Adamo (Task Force Coordinator) (Italy), Roy S. Gardner (Task Force Coordinator) (United Kingdom), Andreas Baumbach (United Kingdom), Michael Böhm (Germany), Haran Burri (Switzerland), Javed Butler (United States of America), Jelena Čelutkienė (Lithuania), Ovidiu Chioncel (Romania), John G.F. Cleland (United Kingdom), Andrew J.S. Coats (United Kingdom), Maria G. Crespo-Leiro (Spain), Dimitrios Farmakis (Greece), Martine Gilard (France), Stephane Heymans

ESC European Society of Cardiology
European Heart Journal (2021) 00, 1–94
doi:10.1093/eurheartj/ehab364
ESC GUIDELINES

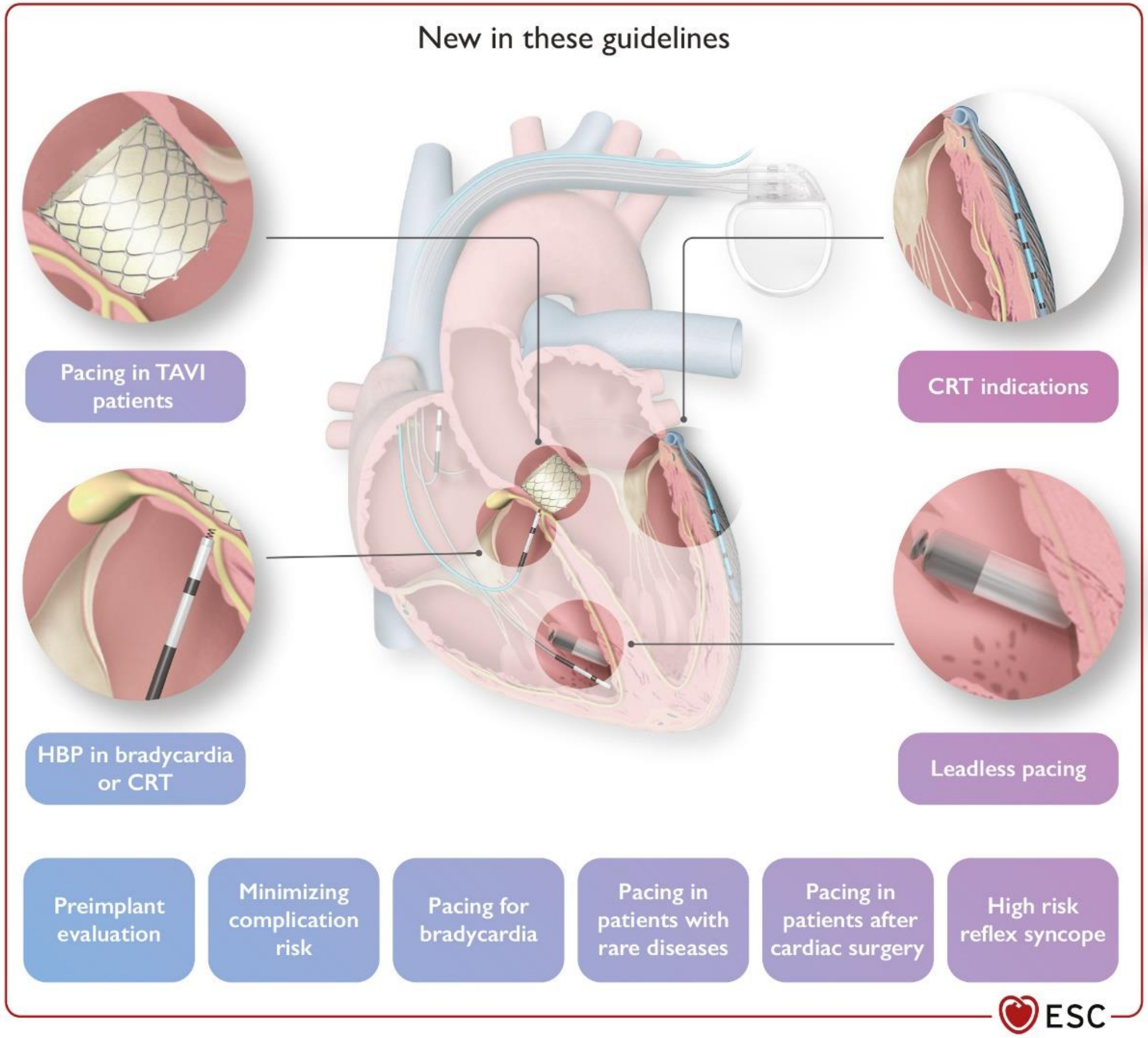
2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

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)

Authors/Task Force Members: Michael Glikson * (Chairperson) (Israel), Jens Cosedis Nielsen* (Chairperson) (Denmark), Mads Brix Kronborg (Task Force Coordinator) (Denmark), Yoav Michowitz (Task Force Coordinator) (Israel), Angelo Auricchio (Switzerland), Israel Moshe Barbash (Israel), José A. Barrabés (Spain), Giuseppe Boriani (Italy), Frieder Braunschweig (Sweden), Michele Brignole (Italy), Haran Burri (Switzerland), Andrew J. S. Coats (United Kingdom), Jean-Claude Deharo (France), Victoria Delgado (Netherlands), Gerhard-Paul Diller (Germany), Carsten W. Israel (Germany), Andre Keren (Israel), Reinoud E. Knops (Netherlands), Dipak Kotecha (United Kingdom), Christophe Leclercq (France),

McDonagh TA. Eur Heart J 2021
Glickson M. Eur Heart J 2021,



The 2021 ESC guidelines on cardiac pacing and CRT

New and updated recommendations for treatments in relevant patient populations

2021 ESC Guidelines on Cardiac Pacing and CRT. Glikson M. et al. Eur Heart J 2021

Morphologie du QRS	ESC stimulation 2021		ESC stimulation 2013	
BBG	QRS > 150 ms	Classe I	QRS>150 ms	Classe I
	130 ms<QRS<150 ms	Classe IIa	120 ms<QRS<150 ms	Classe I
	QRS<130 ms sans indication de stimulation	Classe III	QRS < 120 ms	Classe III
Non-BBG	QRS > 150 ms	Classe IIa	QRS > 150 ms	Classe IIa
	130 ms<QRS<150 ms	Classe IIb	120 ms<QRS<150 ms	Classe IIb

FA et ablation de la jonction AV

<table>
<tr><th colspan="3">ESC stimulation 2021</th><th colspan="2">ESC stimulation 2013</th></tr>
<tr><td>FEVG<35%</td><td>CRT</td><td>Classe I</td><td rowspan="4">FE diminuée</td><td rowspan="4">Classe IIa</td></tr>
<tr><td>35%<FEVG<50%</td><td>CRT</td><td>Classe IIa</td></tr>
<tr><td rowspan="2">FE > 50%</td><td>CRT</td><td>Classe IIb</td></tr>
<tr><td>Stimulation VD conventionnelle</td><td>Classe IIa</td></tr>
</table>

AV junction ablation and cardiac resynchronization for patients with permanent atrial fibrillation and narrow QRS: the APAF-CRT mortality trial

Michele Brignole[1,2*], Francesco Pentimalli[3], Pietro Palmisano[4], Maurizio Landolina[5], Fabio Quartieri[6], Eraldo Occhetta[7], Leonardo Calò[8], Giuseppe Mascia[9], Lluis Mont[10], Kevin Vernooy[11], Vincent van Dijk[12], Cor Allaart[13], Laurent Fauchier[14], Maurizio Gasparini[15], Gianfranco Parati[2,16], Davide Soranna[17], Michiel Rienstra[18], and Isabelle C. Van Gelder[18]; for the APAF-CRT Trial Investigators[†]

APAF-CRT

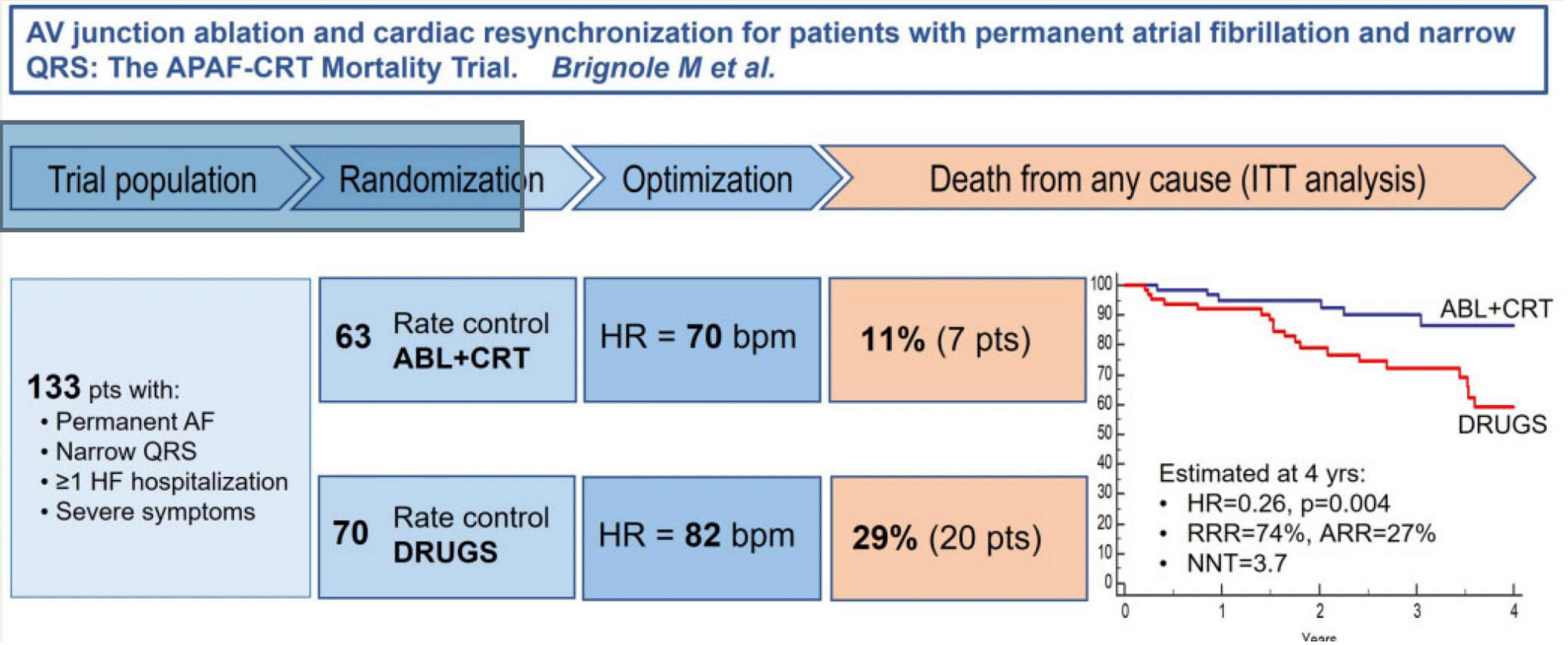
- **International, open-label, blinded outcome trial,**
- **Severely symptomatic permanent AF >6 months, narrow QRS (≤110 ms) and at least one HF hospitalization in the previous year randomized to**
  - **Ablation + CRT or**
  - **Pharmacological rate control.**
- **Hypothesis : Ablation + CRT >in reducing the primary endpoint of all-cause mortality.**
- **133 patients randomized.**
- **Mean age was : 73 ± 10 y, and 47% females.**
- **The trial was stopped for efficacy at interim analysis after 29 M of follow-up per pt**

European Heart Journal September 2021

AV junction ablation and cardiac resynchronization for patients with permanent atrial fibrillation and narrow QRS: the APAF-CRT mortality trial

Michele Brignole[1,2*], Francesco Pentimalli[3], Pietro Palmisano[4], Maurizio Landolina[5], Fabio Quartieri[6], Eraldo Occhetta[7], Leonardo Calò[8], Giuseppe Mascia[9], Lluis Mont[10], Kevin Vernooy[11], Vincent van Dijk[12], Cor Allaart[13], Laurent Fauchier[14], Maurizio Gasparini[15], Gianfranco Parati[2,16], Davide Soranna[17], Michiel Rienstra[18], and Isabelle C. Van Gelder[18]; for the APAF-CRT Trial Investigators[†]

- Mean LV EF = 41%



European Heart Journal September 2021

Recommendations for using His bundle pacing

Recommendations	Class[a]	Level[b]
In CRT candidates in whom coronary sinus lead implantation is unsuccessful, HBP should be considered as a treatment option along with other techniques such as surgical epicardial lead.[318,424,440,443]	IIa	B
HBP may be considered as an alternative to RV pacing in patients with AVB and LVEF >40%, who are anticipated to have >20% ventricular pacing.[42,433]	IIb	C

7.3 Left bundle branch area pacing

With left bundle branch area pacing, the lead is implanted slightly distal to the His bundle and is screwed deep in the LV septum, ideally to capture the left bundle branch.[442] Advantages of this technique are that electrical parameters are usually excellent, it may be successful in blocks that are too distal to be treated with HBP, and it also facilitates AVJ ablation, which may be challenging with HBP. However, although the technique is very promising, data on this modality are still scarce (*Supplementary Table 11*), and there is concern regarding long-term lead performance and feasibility of lead extraction. Recommendations for using left bundle branch area pacing cannot therefore be formulated at this stage. However, conduction system pacing (which includes HBP and left bundle branch area pacing) is very likely to play a growing role in the future, and the current recommendations will probably need to be revised once more solid evidence of safety and efficacy (from randomized trials) is published. A comparison of RV pacing, HBP, and left bundle branch area pacing is provided in *Supplementary Table 12*.

2021 ESC Guidelines on Cardiac Pacing and CRT. Glikson M. et al. Eur Heart J 2021

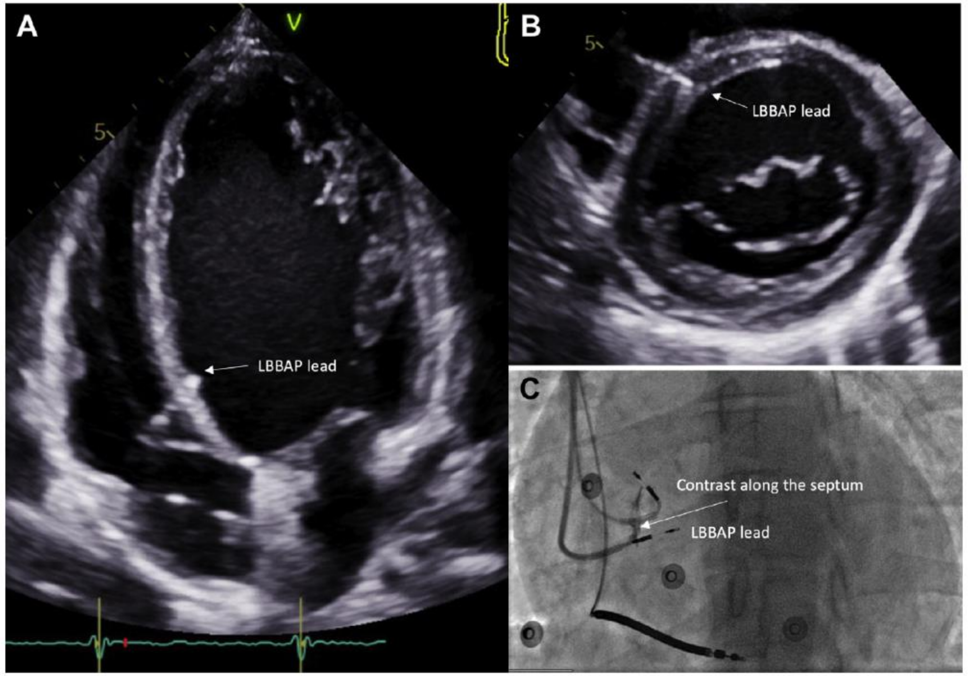
CIED: PHYSIOLOGICAL PACING

Left Bundle Branch Area Pacing for Cardiac Resynchronization Therapy

Results From the International LBBAP Collaborative Study Group

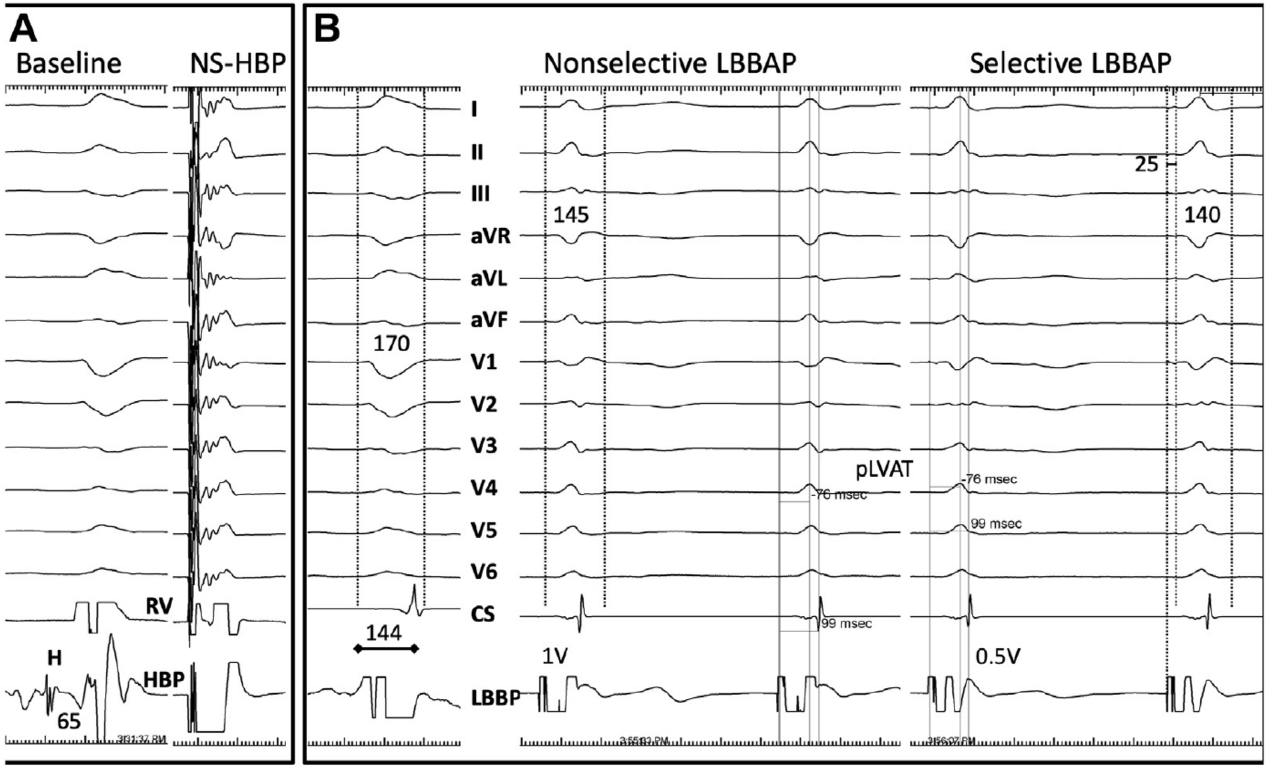
Pugazhendhi Vijayaraman, MD,[a] ShunmugaSundaram Ponnusamy, MD, DM,[b] Óscar Cano, MD, PhD,[c] Parikshit S. Sharma, MD, MPH,[d] Angela Naperkowski, RN, CEPS, CCDS,[a] Faiz A. Subsposh, MD,[a] Pawel Moskal, MD, PhD,[a] Agnieszka Bednarek, MD, PhD,[e] Alexander R. Dal Forno, MD,[f] Wilson Young, MD, PhD,[a] Sudip Nanda, MD,[g] Dominik Beer, DO,[a] Bengt Herweg, MD,[h] Marek Jastrzebski, MD, PhD[e]

FIGURE 2 Echocardiographic and Fluoroscopic Visualization of LBBAP Lead



(A) Apical 4-chamber echocardiographic view shows the location of the left bundle branch area pacing (LBBAP) lead in the proximal interventricular septum. **(B)** Short-axis view demonstrating the lead tip in the basal septum. **(C)** Fluoroscopic view in left anterior oblique projection at 30° shows contrast delineating the right ventricular septum and the depth of the LBBAP lead.

FIGURE 1 LBBAP in a Patient With LBBB



Twelve-lead electrocardiogram and intracardiac electrograms are shown at a sweep speed of 100 mm/s. **(A)** Left bundle branch block (LBBB) is corrected by nonselective His bundle pacing (NS-HBP) at high output. **(B)** At baseline, the surface QRS onset to left ventricular activation (Q-LV) in the coronary sinus (CS) lead was 144 ms. During decremental, asynchronous left bundle branch area pacing (LBBAP) from 1 to 0.5 V, transition from nonselective LBBAP (left ventricular [LV] septal + left bundle branch [LBB] capture) to selective LBBAP (LBB-only capture) is seen. Note that the stimulus to LV activation time in the CS lead and peak LV activation time (pLVAT) in leads V_4 to V_6 remain unchanged at 99 and 76 ms, respectively. QRS duration decreased from 170 ms at baseline to 145 ms with nonselective LBBAP and 140 ms during selective LBBAP with stimulus to QRS onset of 25 ms. RV = right ventricle.

J Am Coll Cardiol 2021

NEW RESEARCH PAPERS

CIED: PHYSIOLOGICAL PACING

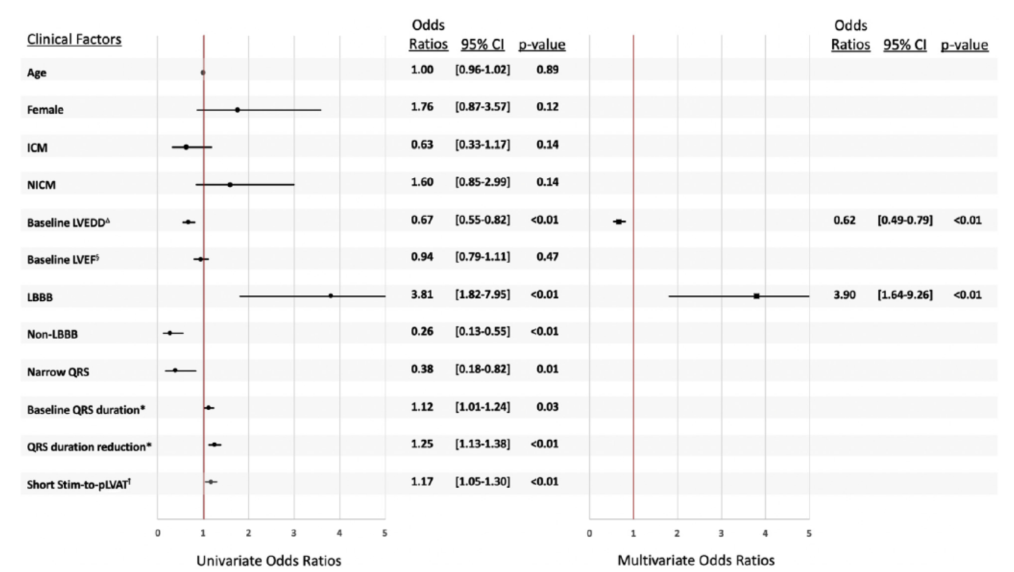
Left Bundle Branch Area Pacing for Cardiac Resynchronization Therapy

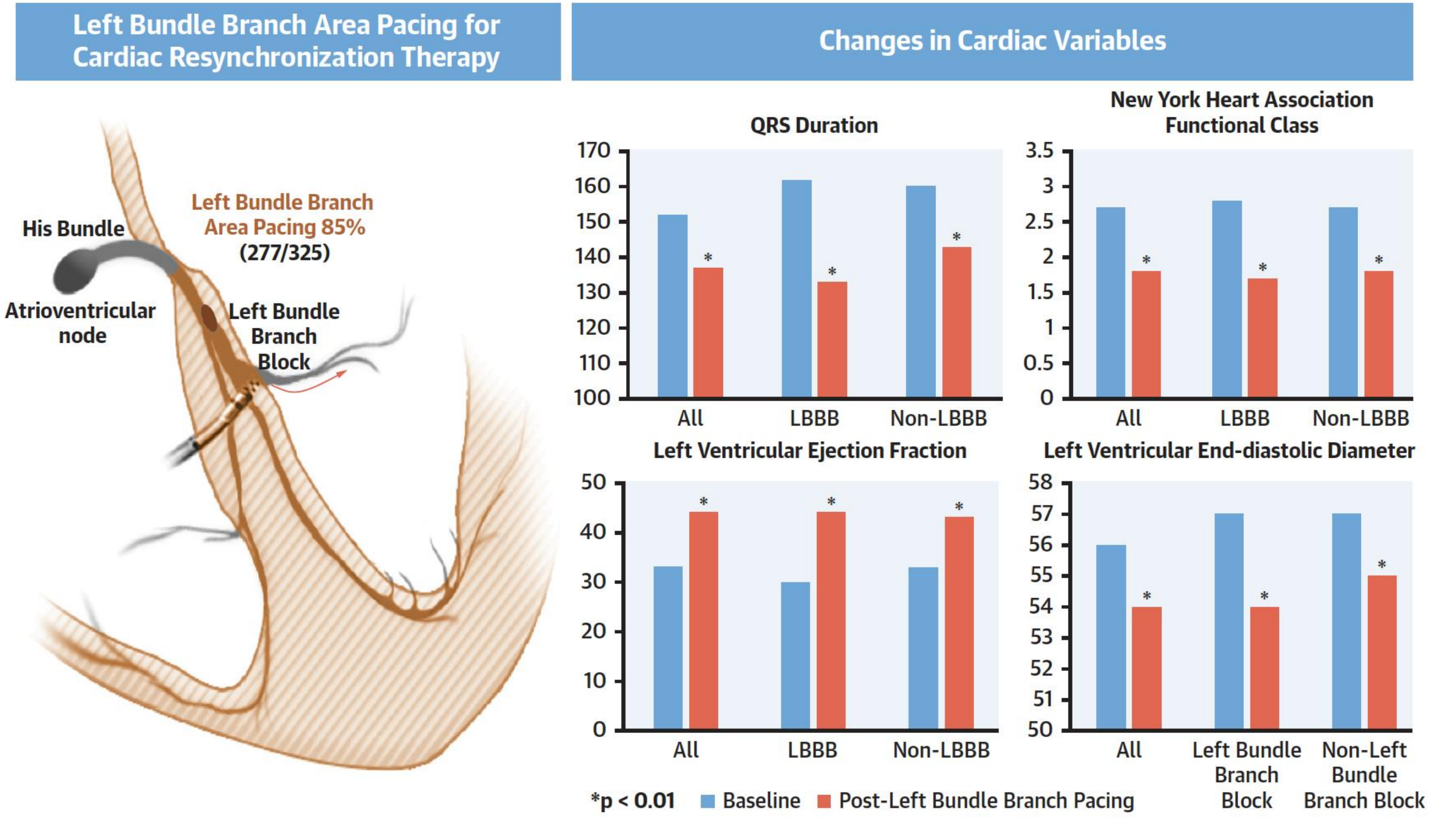
Results From the International LBBAP Collaborative Study Group

Pugazhendhi Vijayaraman, MD,[a] ShunmugaSundaram Ponnusamy, MD, DM,[b] Óscar Cano, MD, PhD,[c] Parikshit S. Sharma, MD, MPH,[d] Angela Naperkowski, RN, CEPS, CCDS,[a] Faiz A. Subsposh, MD,[a] Pawel Moskal, MD, PhD,[e] Agnieszka Bednarek, MD, PhD,[e] Alexander R. Dal Forno, MD,[f] Wilson Young, MD, PhD,[a] Sudip Nanda, MD,[g] Dominik Beer, DO,[a] Bengt Herweg, MD,[h] Marek Jastrzebski, MD, PhD[e]

325 patients

FIGURE 6 Forest Plot of Predictors of Echocardiographic Response





Vijayaraman, P. et al. J Am Coll Cardiol EP. 2021;7(2):135-47.

J Am Coll Cardiol 2021

Etude LBBP-RESYNC :
Étude randomisée comparant la stimulation de la branche gauche (LBBP-CRT) à la resynchronisation (BIVP-CRT)

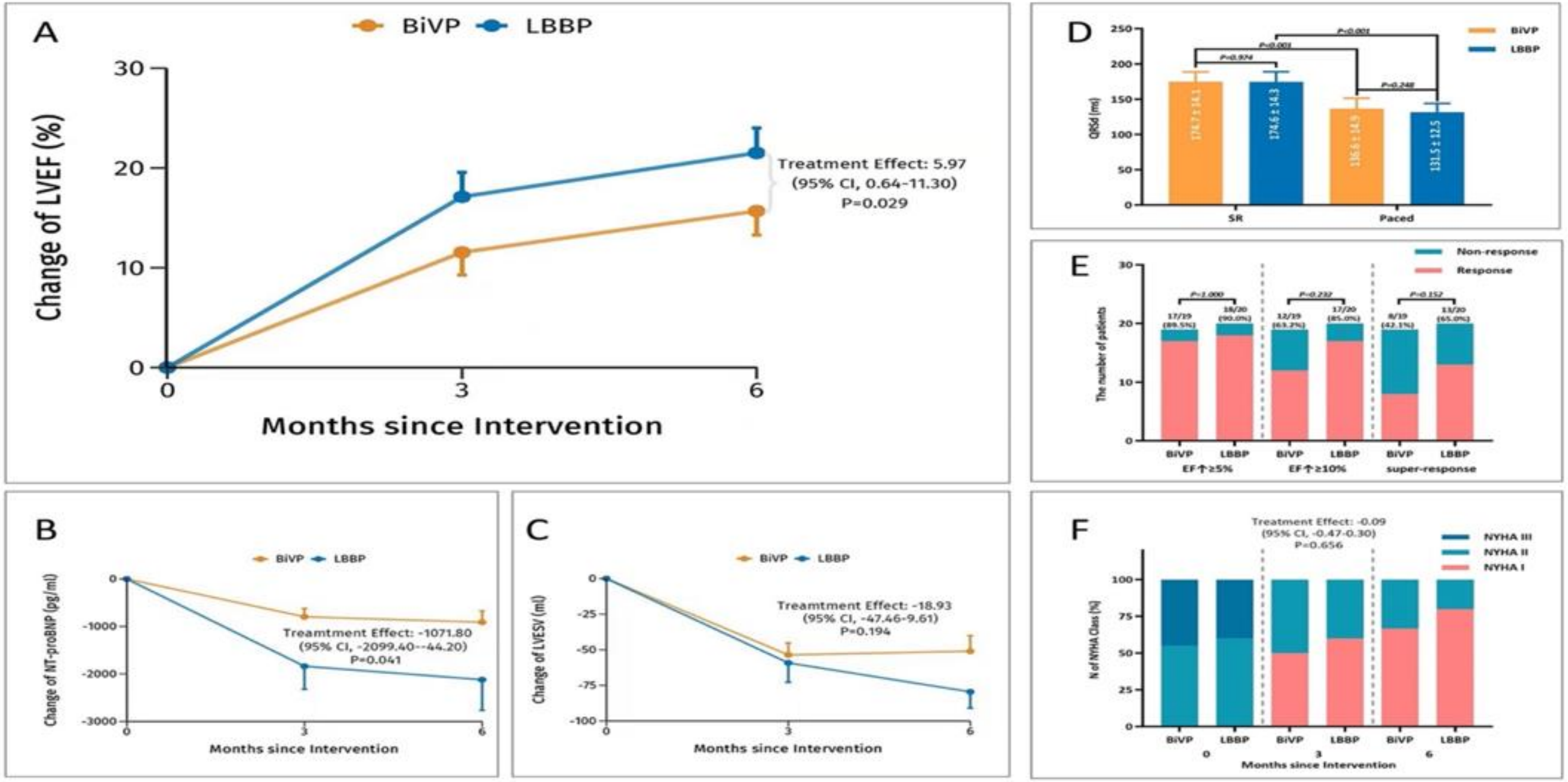


Figure 1 The primary and secondary endpoints of LBBP-CRT and BiVP-CRT

A: The primary endpoint: change in LVEF.
B-F: The secondary endpoints: change in NT-proBNP, LVESV, and QRSd, response rate and NYHA class.

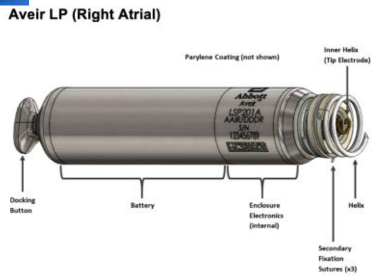
Zou J et al. HRS 2022

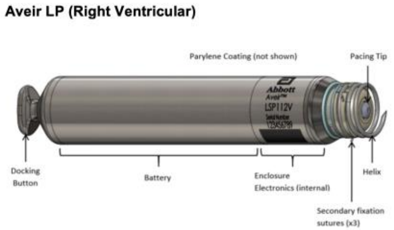
Leadless pacemakers

LCP™ Nanostim/Abbott

41 mm

December 2012





January 2021
Aveir/38 mm
March 2022
Aveir DR

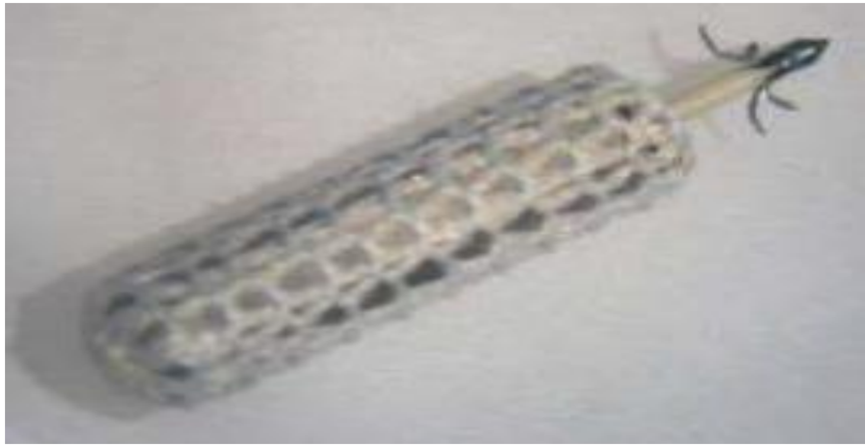
Micra™ Medtronic

25 mm

December 2013

Micra AV™ 2020

WICS™ EBR



9mm

May 2011

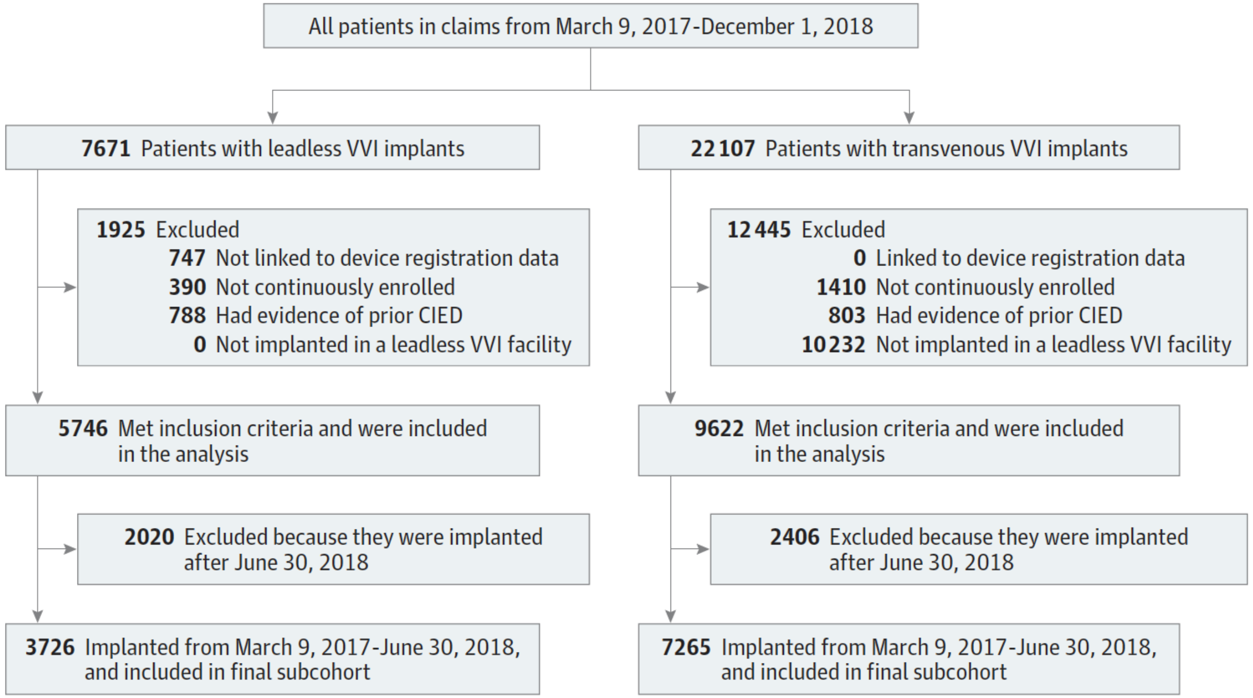
JAMA Cardiology | Original Investigation

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

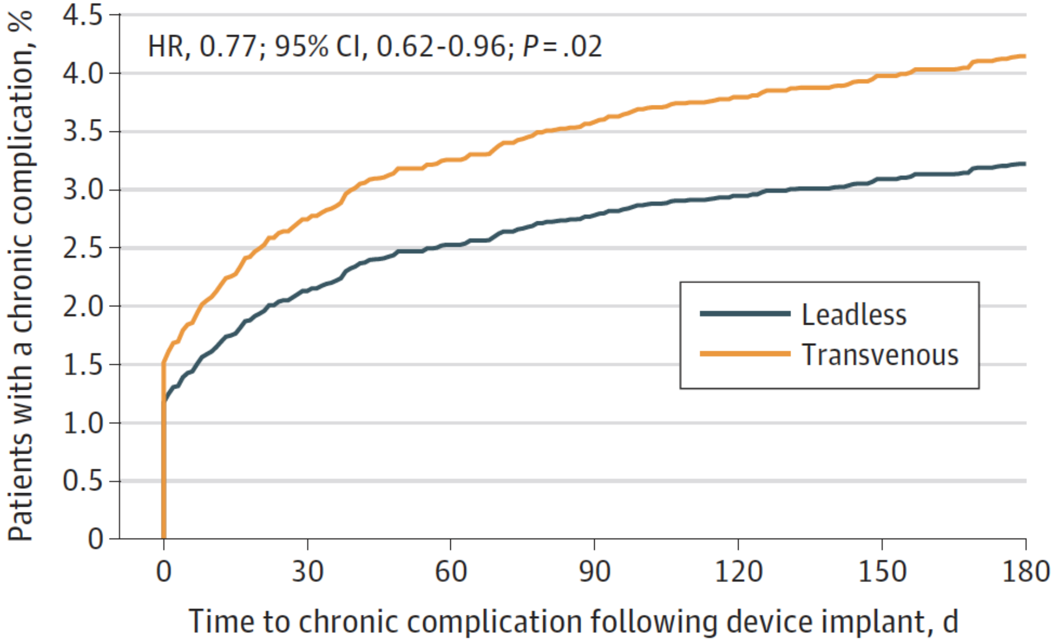
Jonathan P. Piccini, MD, MHS; Mikhael El-Chami, MD; Kael Wherry, PhD; George H. Crossley, MD; Robert C. Kowal, MD, PhD; Kurt Stromberg, MS; Colleen Longacre, PhD; Jennifer Hinnenthal, MPH; Lindsay Bockstedt, PhD

33% lower rate of chronic complications / transvenous VVI

Figure 1. Cohort Formation Flowchart



A 6-mo Complication



No. at risk							
Leadless	3726	3480	3371	3278	3209	3144	3073
Transvenous	7246	6805	6566	6410	6277	6163	6070

JAMA Cardiol. 2021;6:1187-1195.

JAMA Cardiology | Original Investigation

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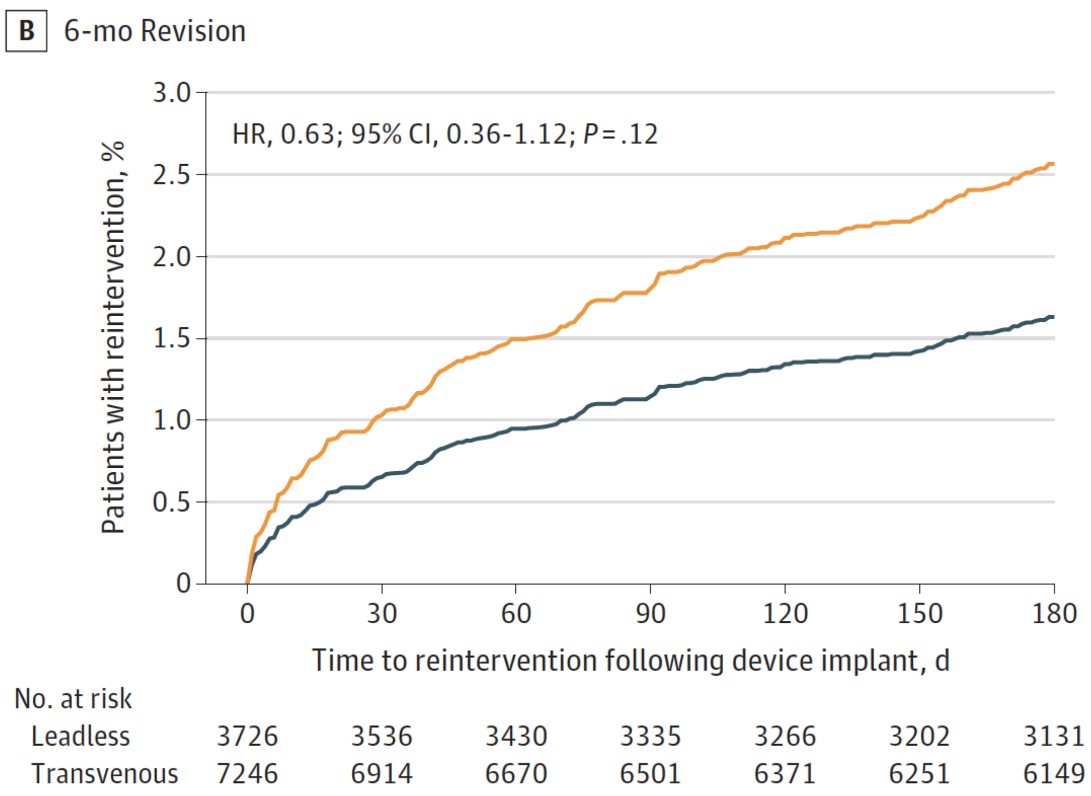
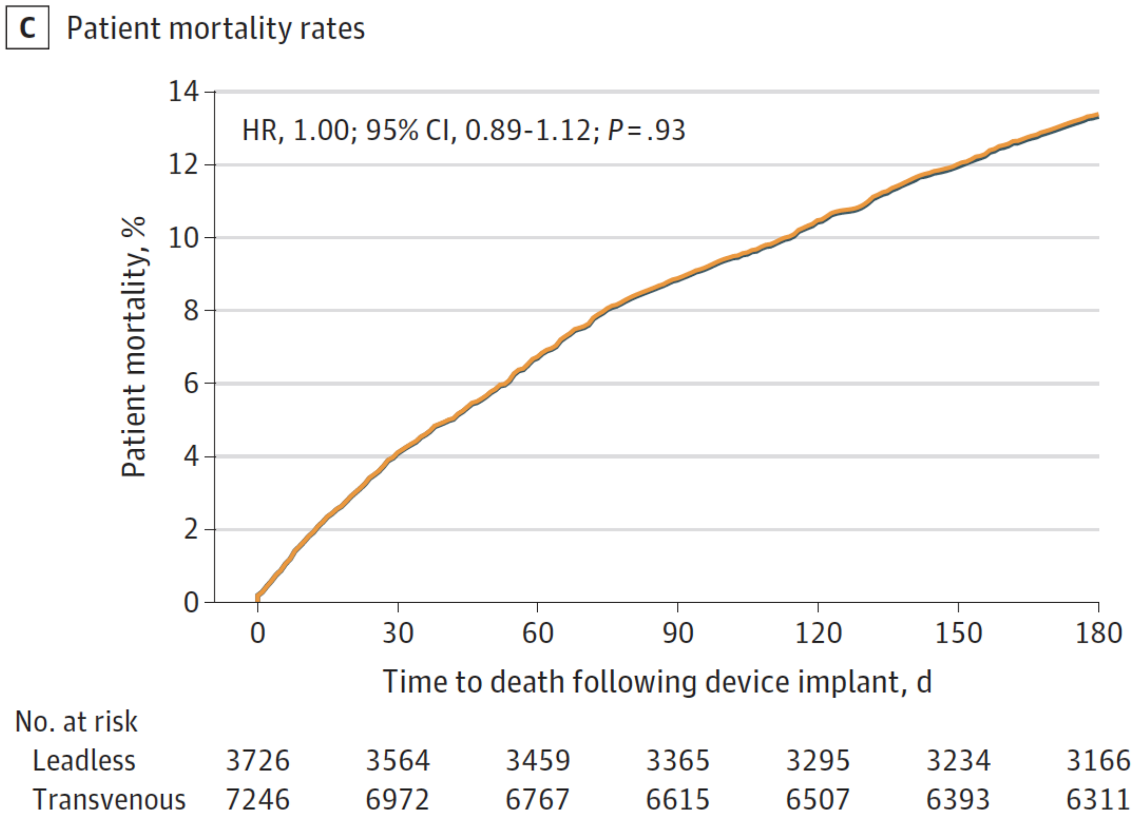


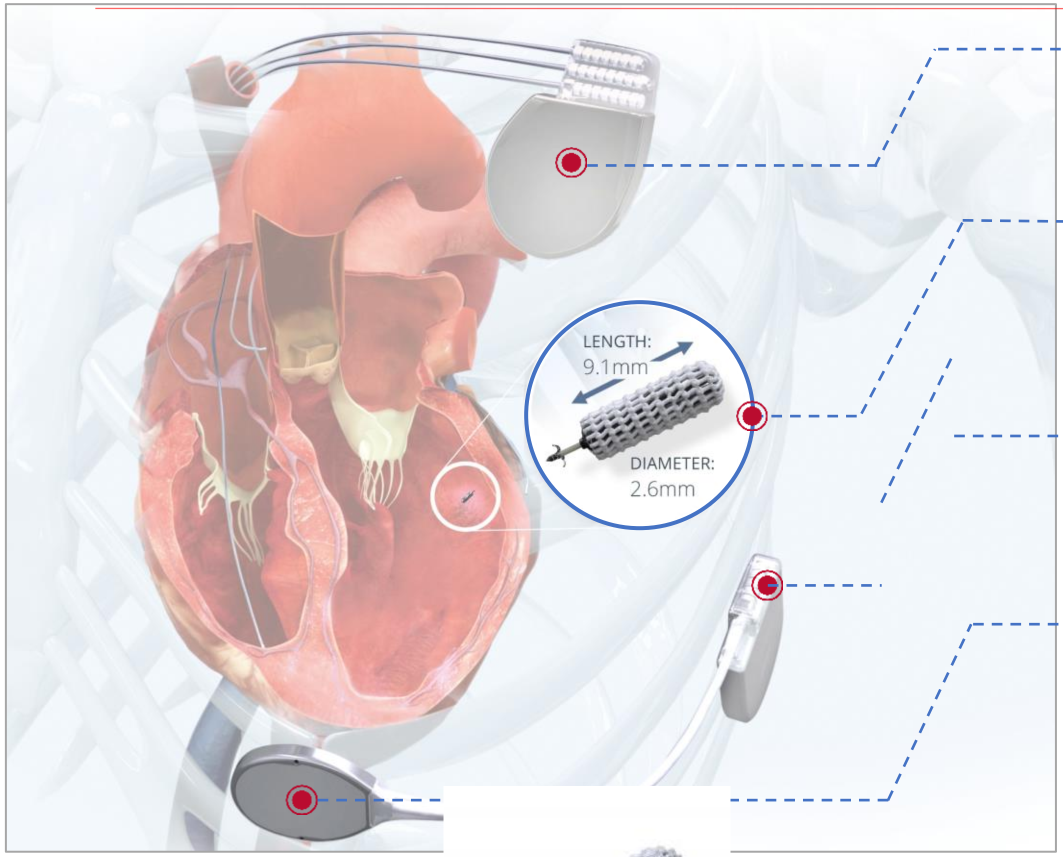


38% lower rate of reinterventions

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

WiSE CRT system

Total :>400 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.

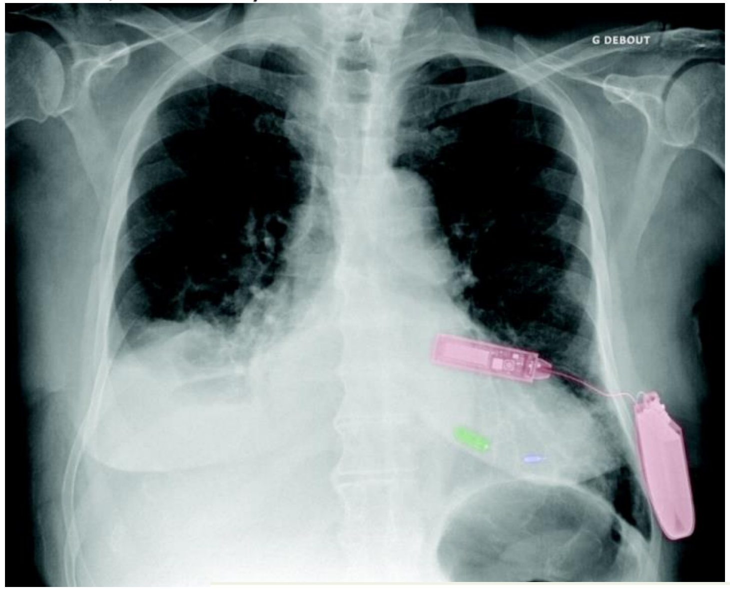
BATTERY
Implanted subcutaneously on the left mid axillary line, powers the transmitter.

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.

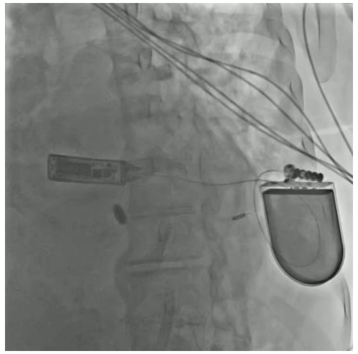
Very Small: 9.1mm x 2.7mm, 0.05cc (Micra .8cc)

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



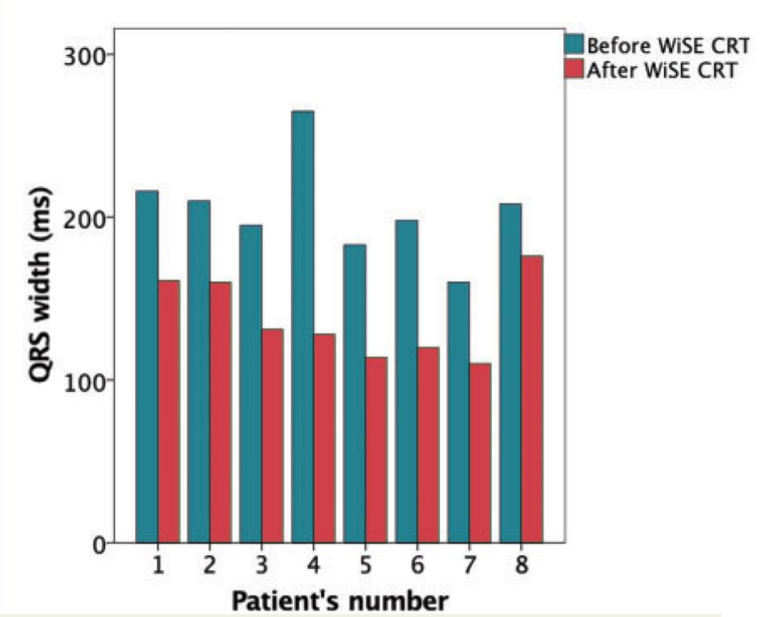
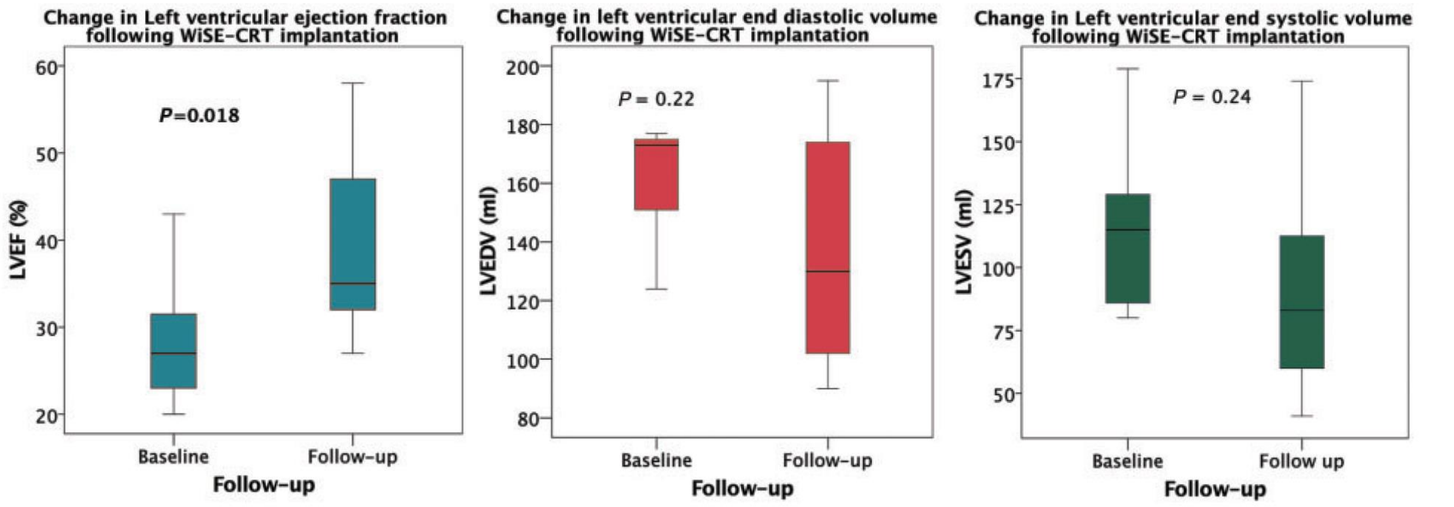
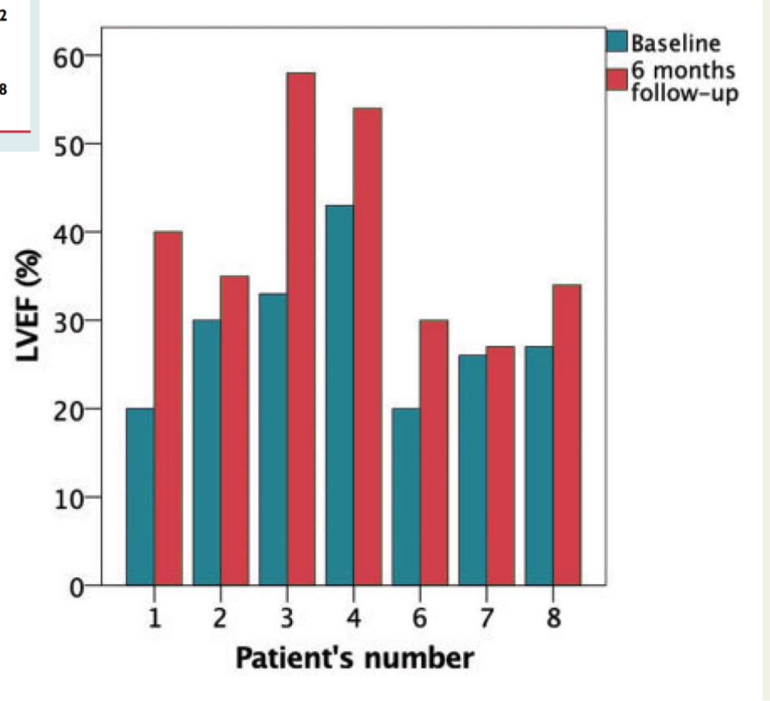


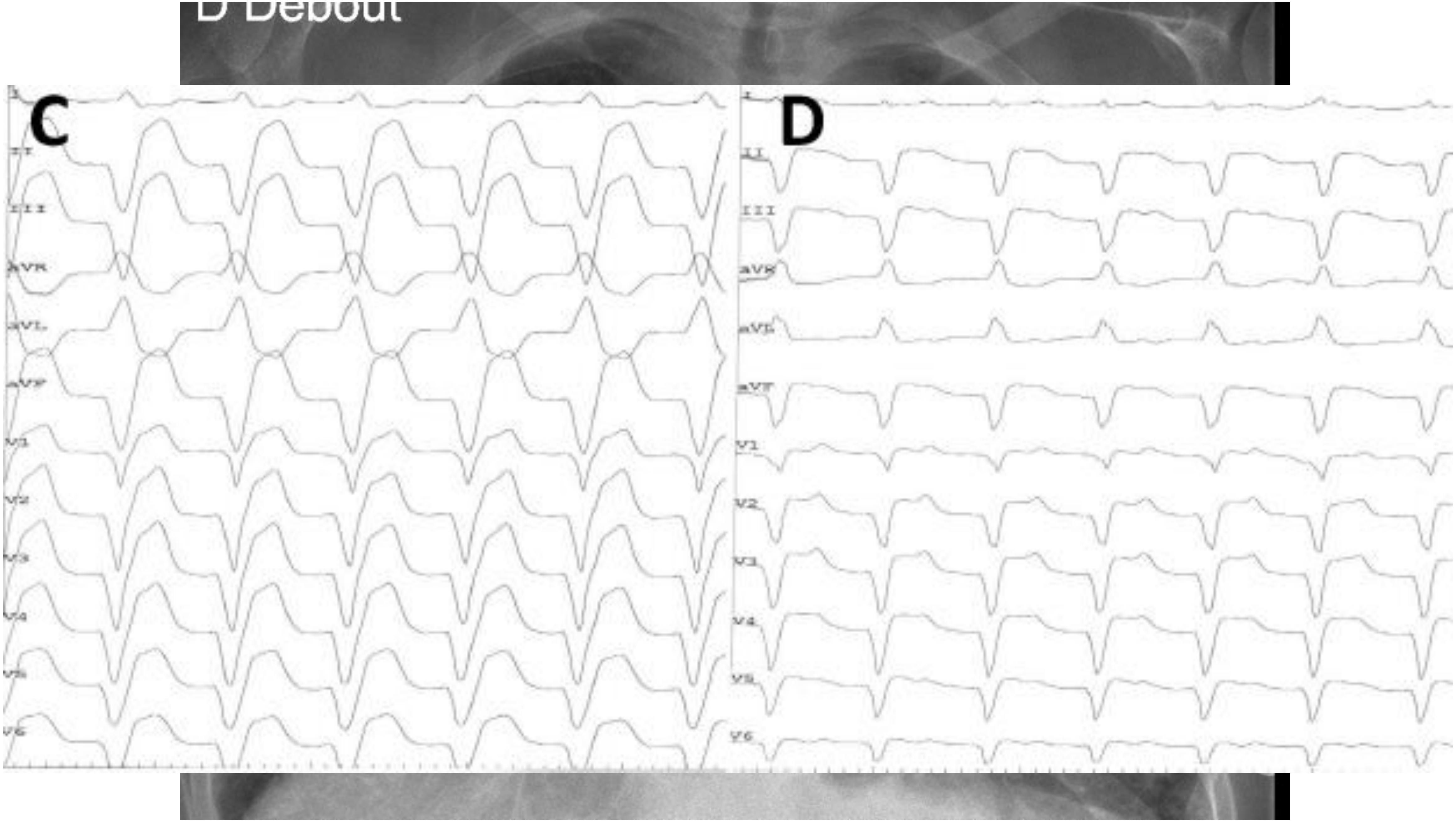
Table 2 Left ventricle function and volumes following WiSE-CRT implantation

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



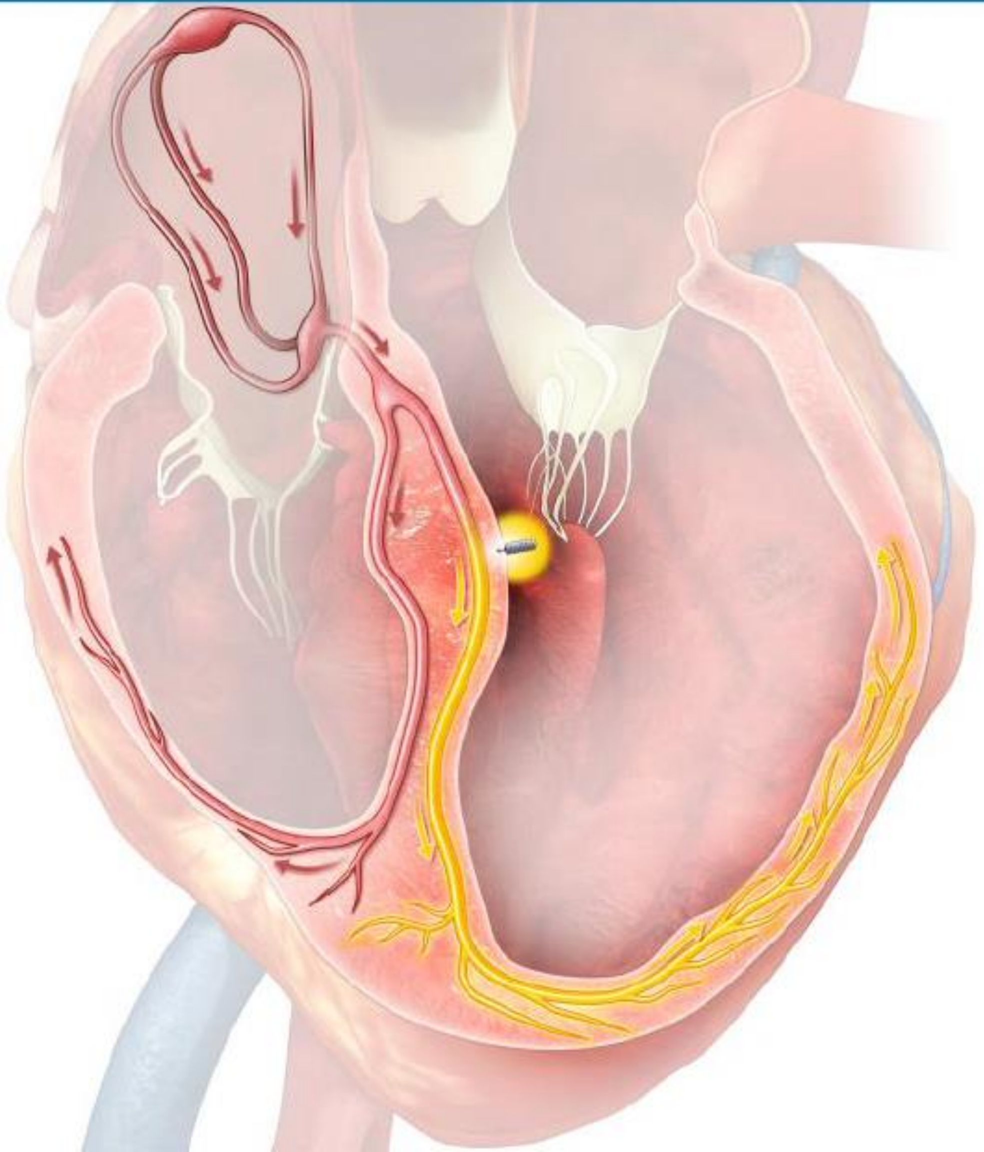


Europace 2021; 21;740-747



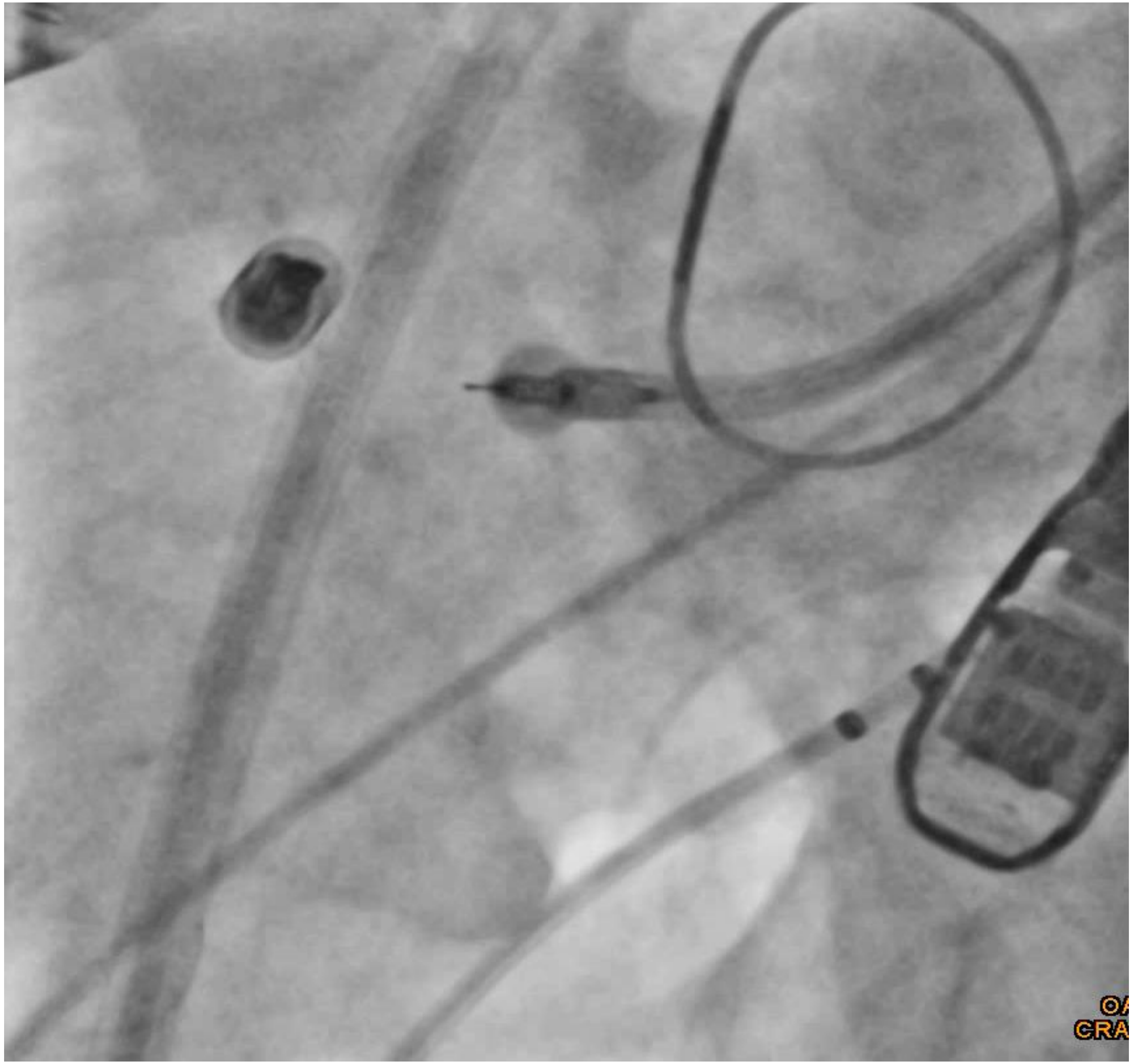
“Leadless CRT”

Leadless left bundle branch pacing

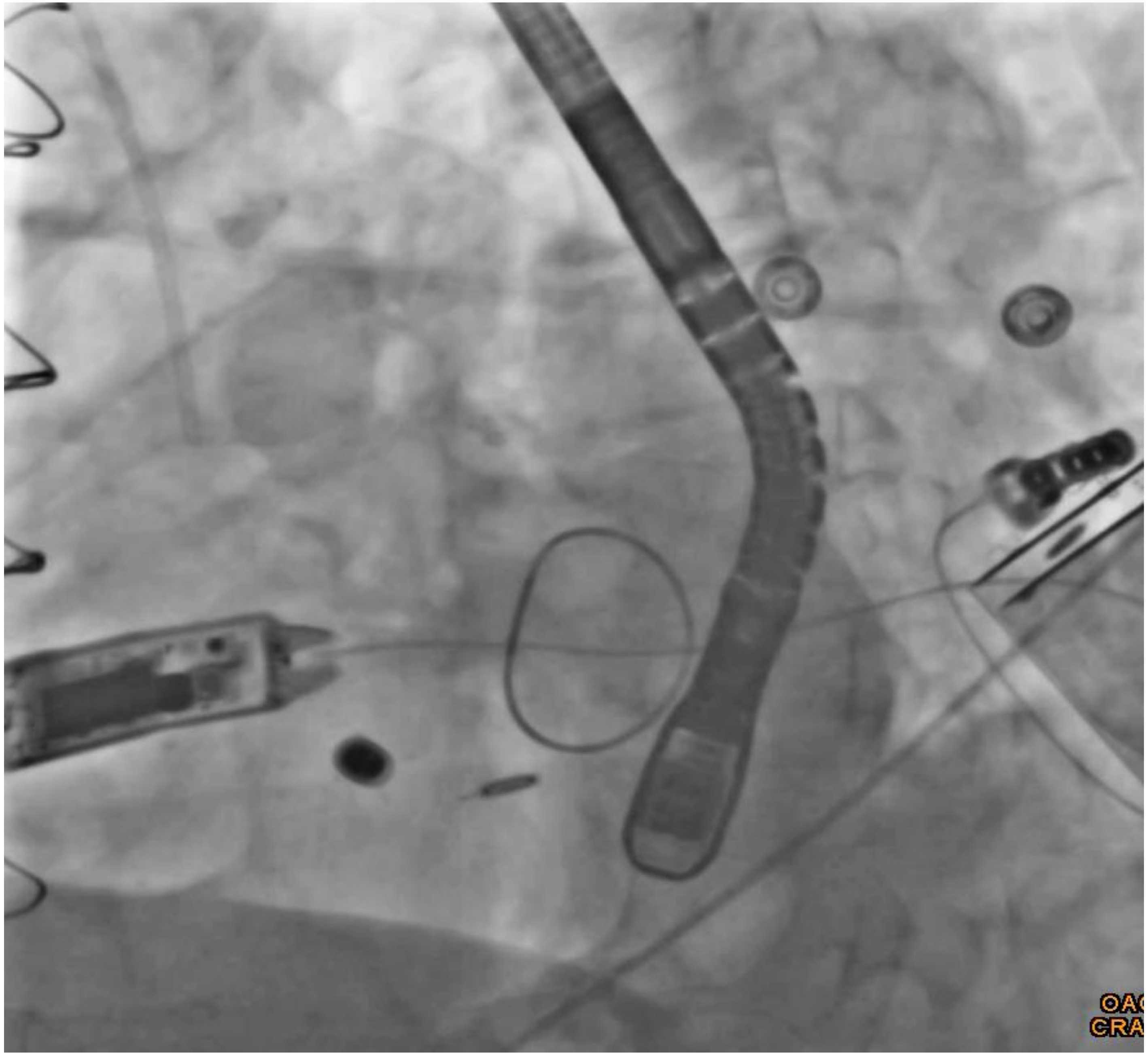


Potential advantages:

- 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



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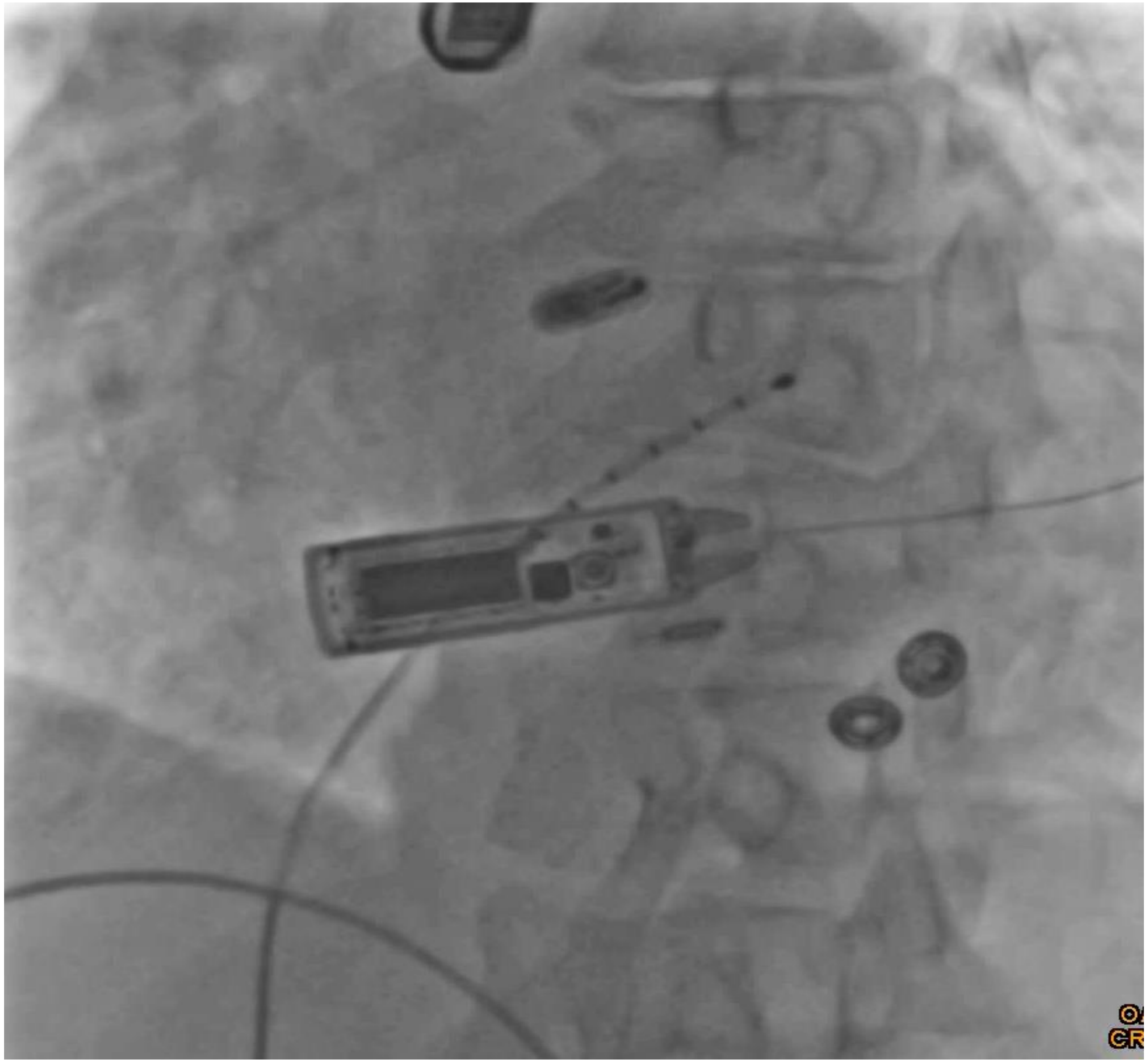


12/04/2022

Dual chamber leadless pacemaker

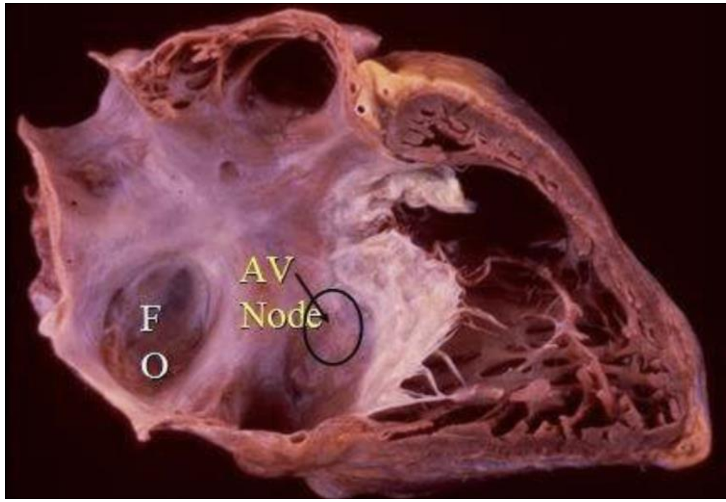
Abbott Aveir

Requirements :

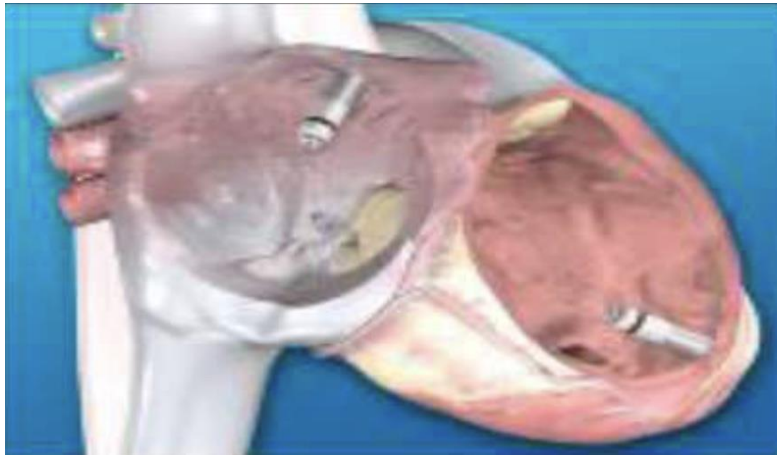
- **Safe atrial implant**
  - **Wall thickness vs fixation mechanism**
  - **Angle of implant/retrieval**
  - **>18 F catheter femoral**

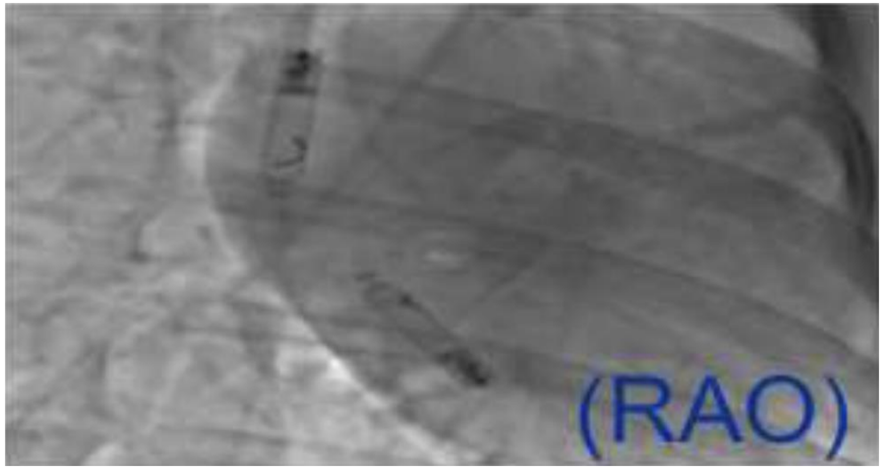
- **Sufficient longevity**

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

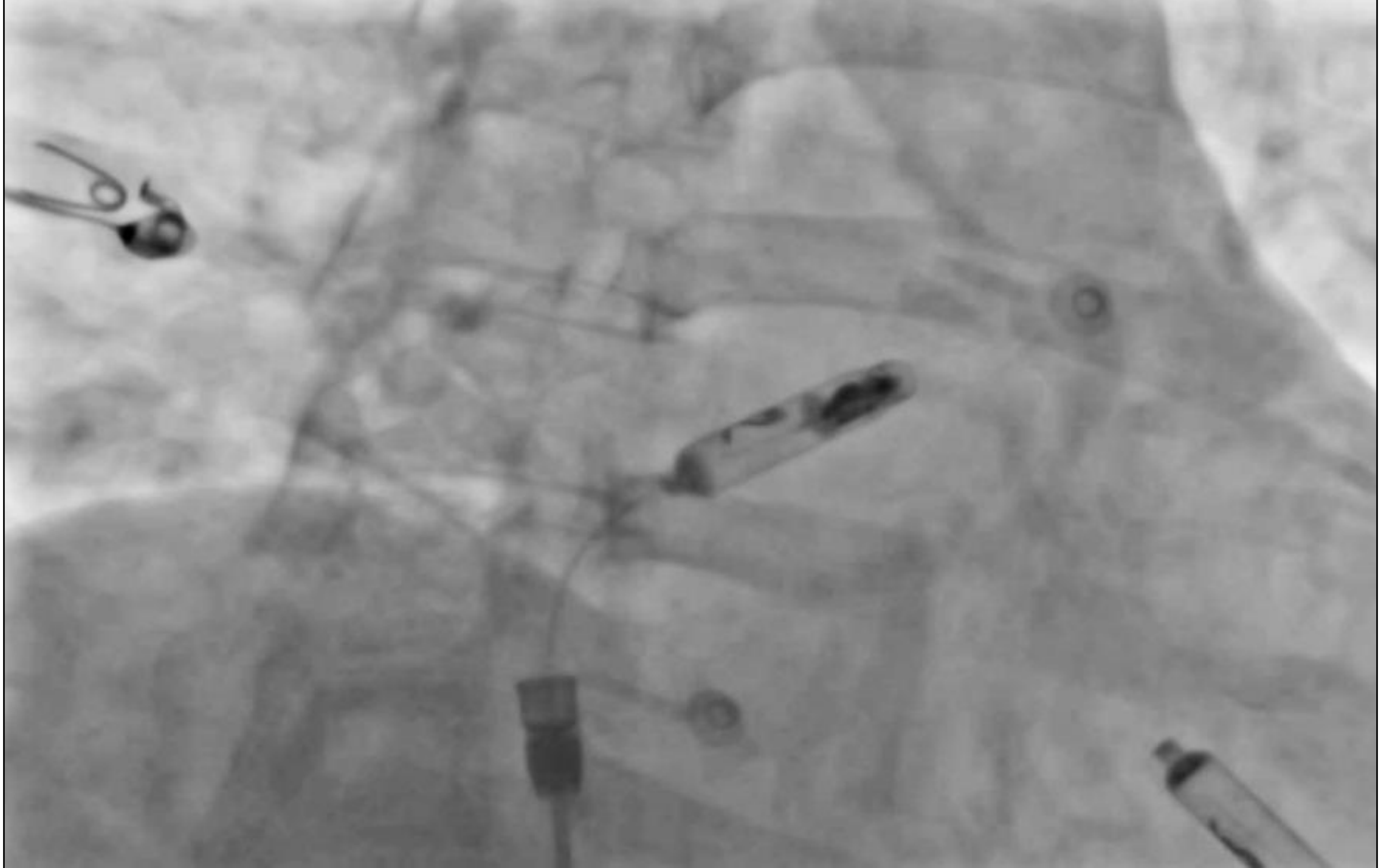


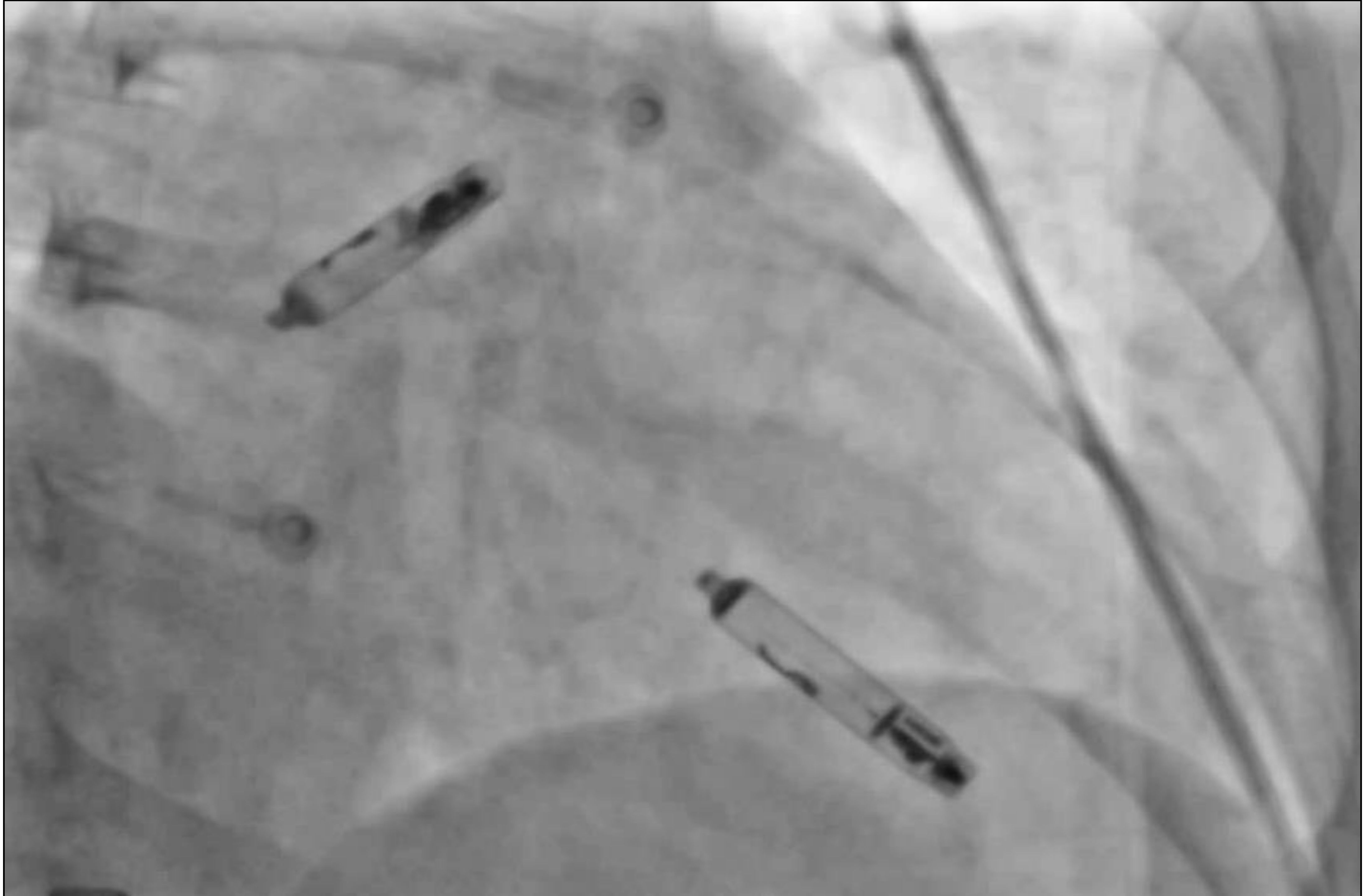
IMM Montsouris/2015





Clinical study 2022

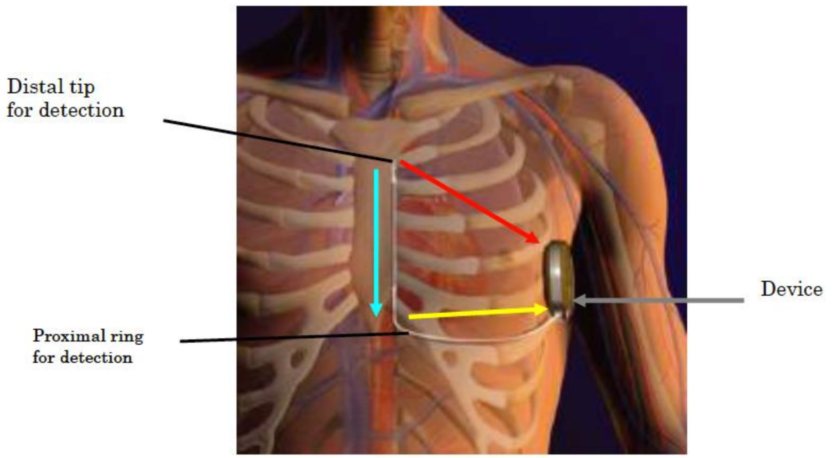




ORIGINAL RESEARCH ARTICLE

Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial

Michael R. Gold, MD, PhD
Pier D. Lambiase, PhD
Mikhael F. El-Chami, MD
Reinoud E. Knops, MD,



- **Primary prevention patients with LVEF≤35% and no pacing indications were included**

- **Programmation : rate-based therapy delivery for rates ≥250 bpm and morphology discrimination for rates ≥200 and <250 bpm**

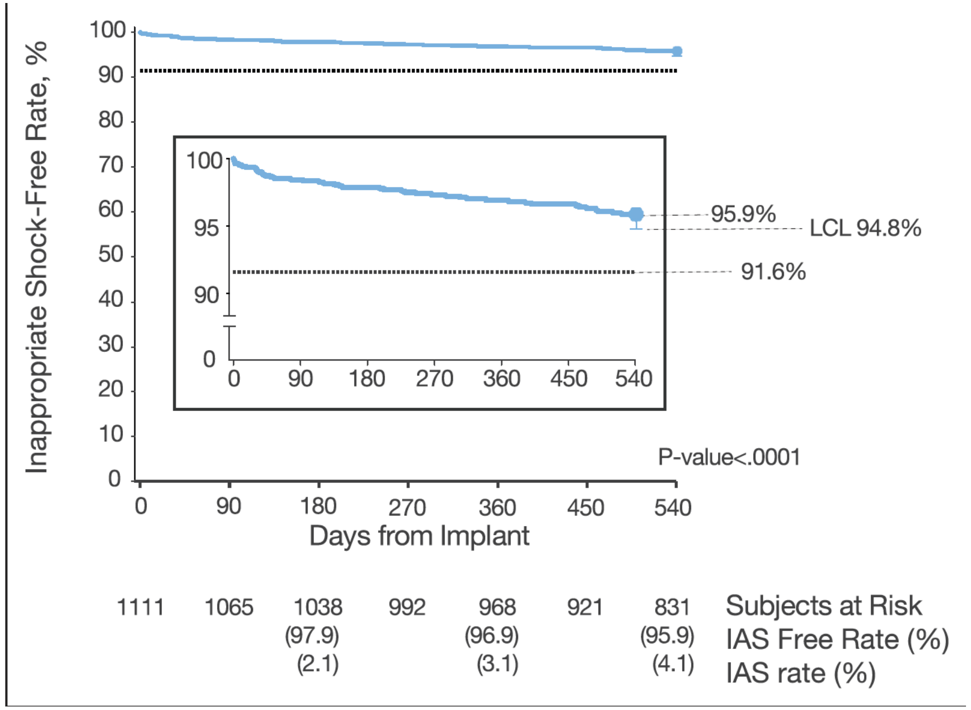


Table 3. Cause of Inappropriate Shock

IAS category	Total: Episodes	Total: Subjects n (% of 1111)
Cardiac	70	30 (2.7)
T-wave oversensing	35	18 (1.6)
Other cardiac oversensing	14	10 (0.9)
Oversensing of VT/VF below rate zone	21	4 (0.4)
Noncardiac	17	16 (1.4)
Myopotential	3	2 (0.2)
Other noncardiac oversensing	14	14 (1.3)
SVT	0	0 (0)
Discrimination error	0	0 (0)
SVT above discrimination zone	0	0 (0)
Other	1	1 (0.1)
Total	88	45 (4.1)

Circulation. 2021;143:7–17

The ATLAS trial: Avoid Transvenous Leads in Appropriate Subjects/Jeff HEALEY et Blandine MONDESERT

Etude canadienne multicentrique

- **Objectif I: comparaison complications liées à la sonde à 6 mois /T-DAI.**
- **Objectif II : chocs inappropriés, risque de réintervention sur la sonde**
- **>18 ans + au moins une des pathologies suivantes : CMD, CMH, DVDA, Brugada, LQTS ou ERS + hémodialysés, BPCO, après dispositif infecté ou une chirurgie valvulaire.**
- **246 S-ICD et 243 T-ICD.**
- **Age moyen: 49 ans, hommes (72 à 76%).**
- **Prévention II : 31% des patients.**
- **38% coronariens/ 21% CMD/ 18% CMH.**

HRS 2022

The ATLAS trial: Avoid Transvenous Leads in Appropriate Subjects/Jeff HEALEY et Blandine MONDESERT

Résultats

- **Objectif I: réduction de 92% à 6 mois complications liées à la sonde :**

  0,4% groupe S-ICD vs 4,8% pour le T-DAI (p 0,003).

- **Composite : infections graves, hématomes, IdM, d'AVC, décès : idem : S-ICD 4,4%, T-DAI 5,6%**

- **Objectif II: pas de différence à 6 mois du nombre de chocs inappropriés :**

  - 2,7%/an : groupe S-ICD

  - 1,2%/an : groupe T-DAI.

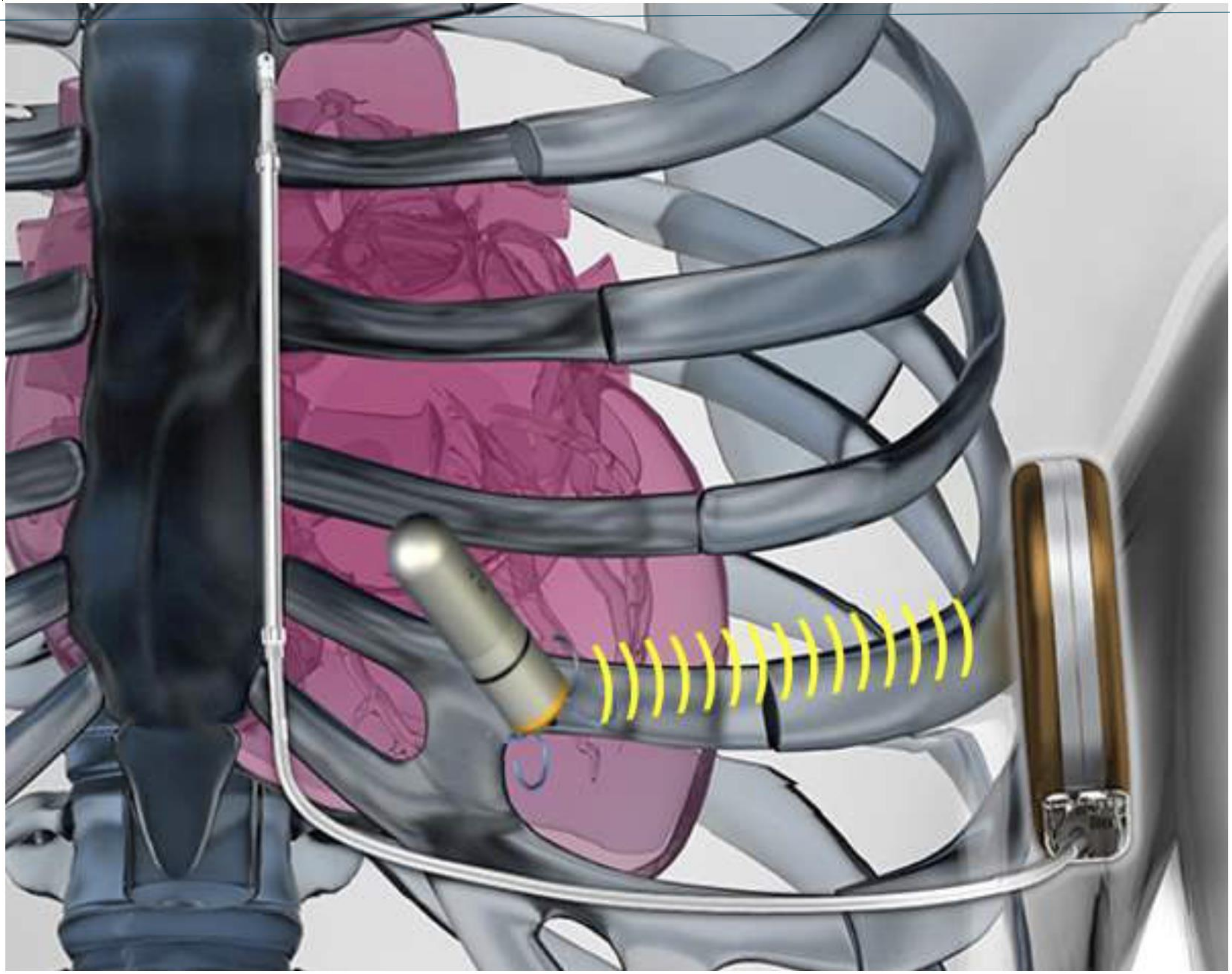
HRS 2022

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)



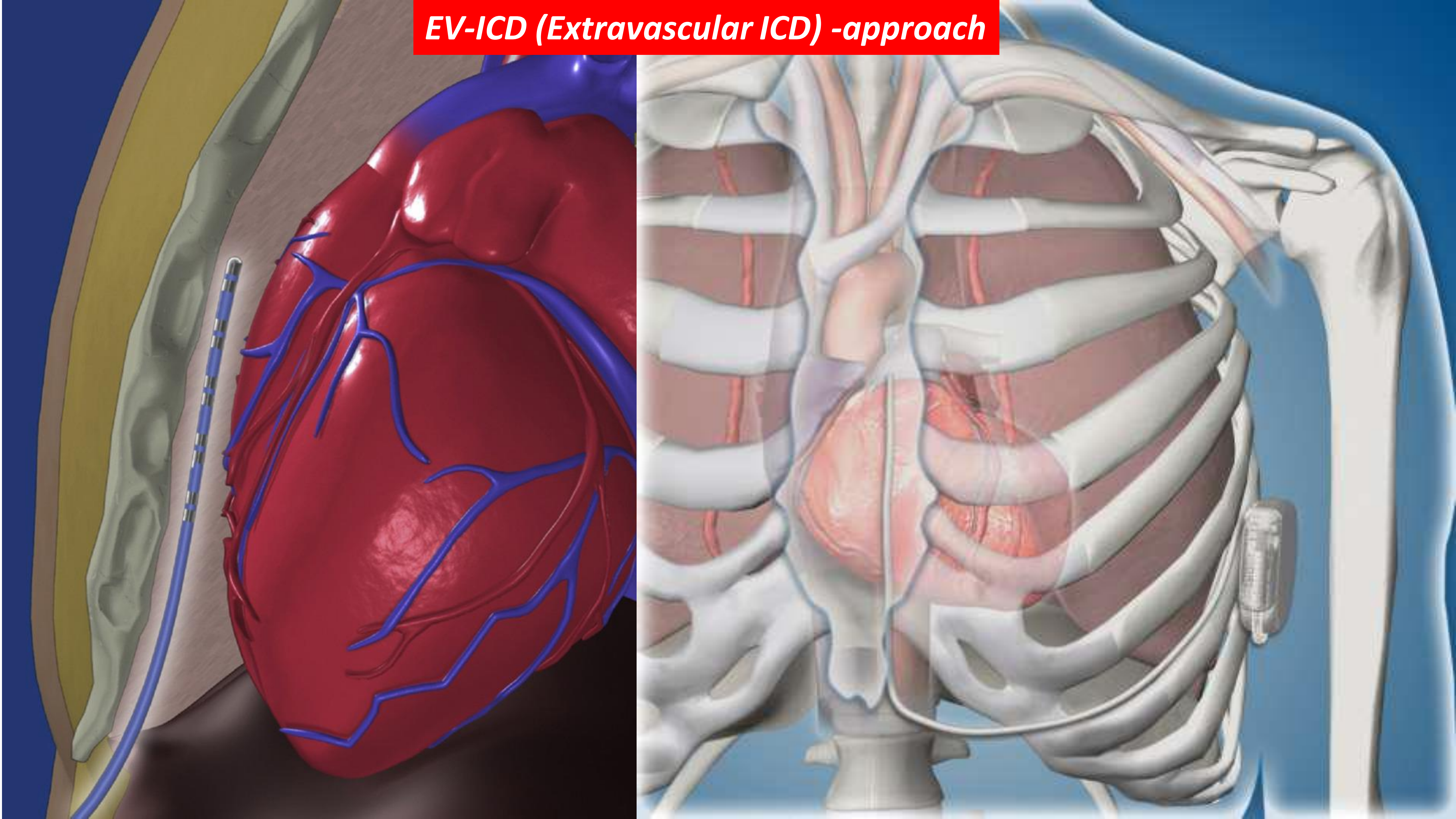
- December 2021 : first implantation in the *MODULAR ATP clinical trial*
- *Beginning of the France implantations : Lille, Grenoble, Nantes*

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©

EV-ICD (Extravascular ICD) -approach

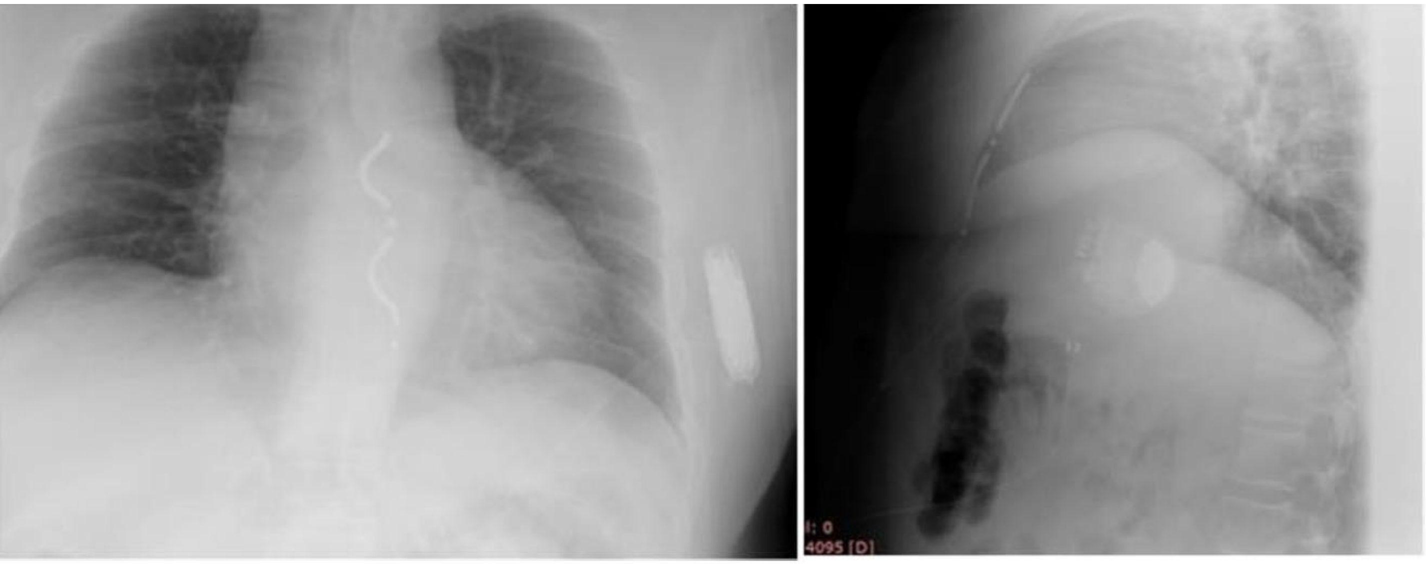


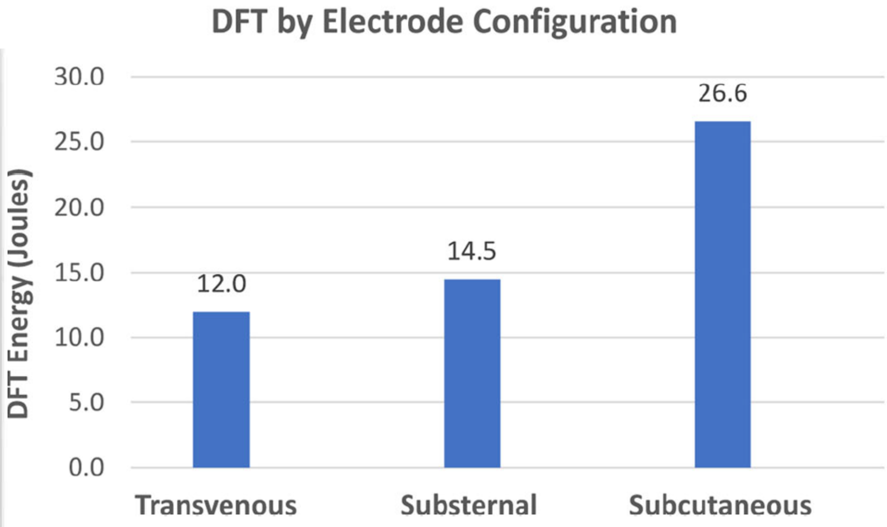
REVIEW

The development of the extravascular defibrillator with substernal lead placement: A new Frontier for device-based treatment of sudden cardiac arrest

Amy E. Thompson MS, MBA[1] | Brett Atwater MD[2] | Lucas Boersma MD, PhD[3] | Ian Crozier MD, CHB[4] | Gregory Engel MD[5] | Paul Friedman MD, FHRS[6] | J. Rod Gimbel MD[7] | Bradley P. Knight MD[8] | Jaimie Manlucu MD[9] | Francis Murgatroyd FRCP[10] | David O'Donnell MBBS[11] | Juergen Kuschyk MD[12] | Paul DeGroot MS[13]

	Transvenous ICD[a]	Subcutaneous ICD[b]	Extravascular ICD[c]
Lead location	Endovascular/endocardial	Parasternal (subcutaneous)	Anterior mediastinum (substernal)
Potential for cardiac injury/perforation	Present	Absent	Present
ICD generator location	Pectoral	Left midaxillary region	Left midaxillary region
Maximum delivered energy	40 J	80 J	40 J
ATP	Available	Not available	Available
Chronic pacing therapy	Available as chronic pacing therapy	Not available	Available as short-duration pause prevention pacing
Postshock pacing	Available	Available	Available
Generator volume	33 cc	60 cc	33 cc
Generator mass	79 g	130 g	77 g





J Cardiovasc Electrophysiol. 2022;1–11.

WILEY

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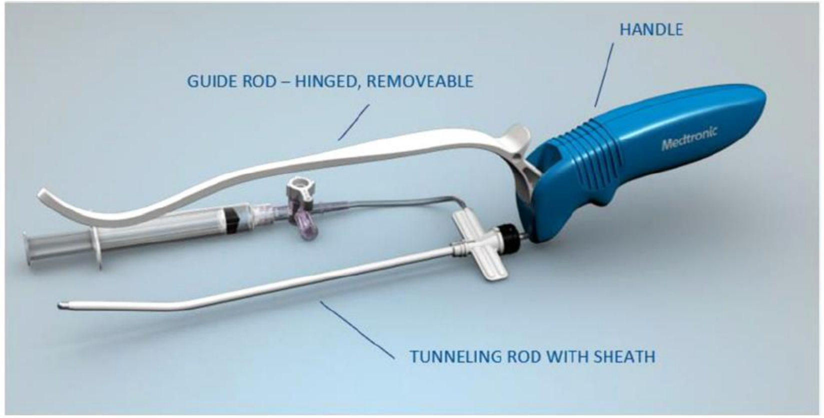
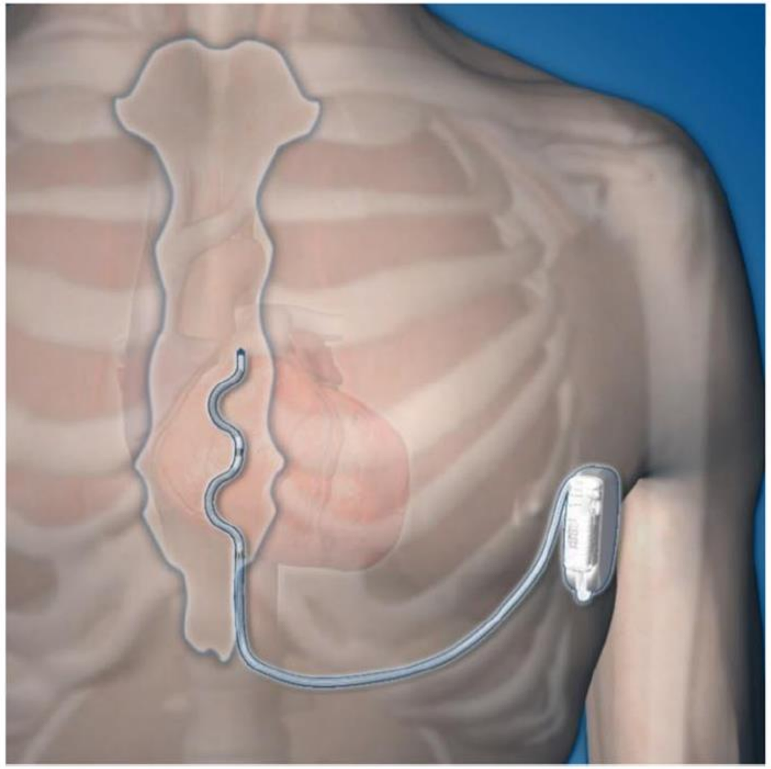
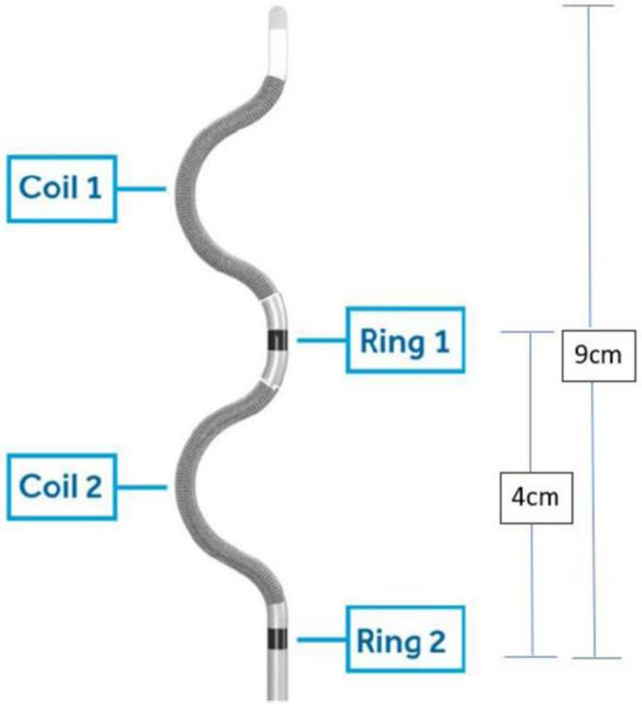


FIGURE 5 Sternal tunneling tool. A 9-French introducer sheath is backloaded onto the malleable tunneling rod and introduced into the anterior mediastinum. Subsequently, the sternal tunneling tool is removed, and the lead is inserted through the retained introducer sheath.





Pivotal study ongoing : 400 pts/ follow-up : 3,5 years

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Conclusion : l'essentiel de l'année en rythmologie : Devices

- ***Recommandations 2021 CRT et stimulation physiologique :***
  Classe I : ≥150 ms/ IIa : ≥130 ms si BBG
  Avancée vitesse V stimulation Branche G

- ***APAF-CRT : renouveau ablation NAV + CRT***

- ***Développement du leadless pacing***
  - ***Simple chambre ++++ Micra***
  - ***Double chambre Micra AV / Aveir DDD***
  - ***Resynchronisation »all leadless » EBR Wise CRT et stimulation br. G***

- ***S-ICD : confirmation***
- ***EV-ICD : étude clinique en cours***