

Leadless Pacing

Pacing leadless nelle cardiopatie congenite:

una soluzione semplice per casi complessi

Berardo Sarubbi

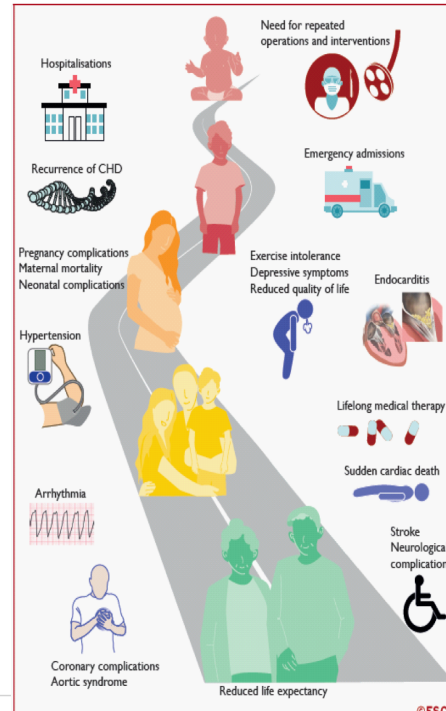
*UOC Cardiopatie Congenite dell'Adulto ed
Aritmie Congenite e Familiari*

A.O.R.N. dei Colli – Ospedale Monaldi – Napoli

www.berardosarubbi.it



- Congenital heart disease (CHD) refers to structural abnormalities of the heart present at birth, affecting **approximately 1%** of live births.
- Advances in surgical techniques have dramatically increased survival into adulthood.
- **Long-term complications:** frequent arrhythmias (e.g., bradycardia)
- Symptomatic bradycardia often requires permanent pacemaker implantation to maintain an adequate heart rate.



Congenital heart disease A lifelong chronic condition

Risk estimates for arrhythmic events and bradycardias in ACHD (1)

	Supraventricular arrhythmias			Ventricular arrhythmias and SCD		Bradycardia			
Type of CHD	AVRT	IART/ EAT	AF	Sustained VT	SCD	SND		AV block	
						Congenital	Acquired	Congenital	Acquired
Secundum ASD		++	++			(+)	+		(+)
Superior sinus venous defect		++	+				+		
AVSD/primum ASD		++	++	(+)		(+)		(+)	++
VSD		+	(+)	+	(+) ^a				+
Ebstein anomaly	+++	++	+	(+)	++ ^b		++		
TOF		++	++	++	++		+		+
TGA									
Atrial switch		+++	+	++ ^c	+++ ^b		+++		+
Arterial switch		+		+ ^c	(+)		(+)		
ccTGA	++	+	+	(+)	++ ^b			+	++
(+) = minimal risk + = mild risk ++ = moderate risk +++ = high risk									

^aConsidering the high prevalence of VSD, the overall risk in unselected patients with VSD is considered to be minimal.

^bSCD may be due to supraventricular arrhythmias with rapid AV conduction.

^cVT higher estimated risk in complex dextro-TGA.

Risk estimates for arrhythmic events and bradycardias in ACHD (2)

	Supraventricular arrhythmias			Ventricular arrhythmias and SCD		Bradycardia			
Type of CHD	AVRT	IART/ EAT	AF	Sustained VT	SCD	SND		AV block	
						Congenital	Acquired	Congenital	Acquired
Fontan operation									
Atriopulmonary connection		+++	++		+ ^b		++		
Intracardiac lateral tunnel		++	+		+ ^b		++		
Extracardiac conduit		+	+		+ ^b		+		
Eisenmenger physiology Incompletely palliated CHD		++	++		+++ ^d				

^bSCD may be due to supraventricular arrhythmias with rapid AV conduction.

^cVT higher estimated risk in complex dextro-TGA.

^dNon-arrhythmic.

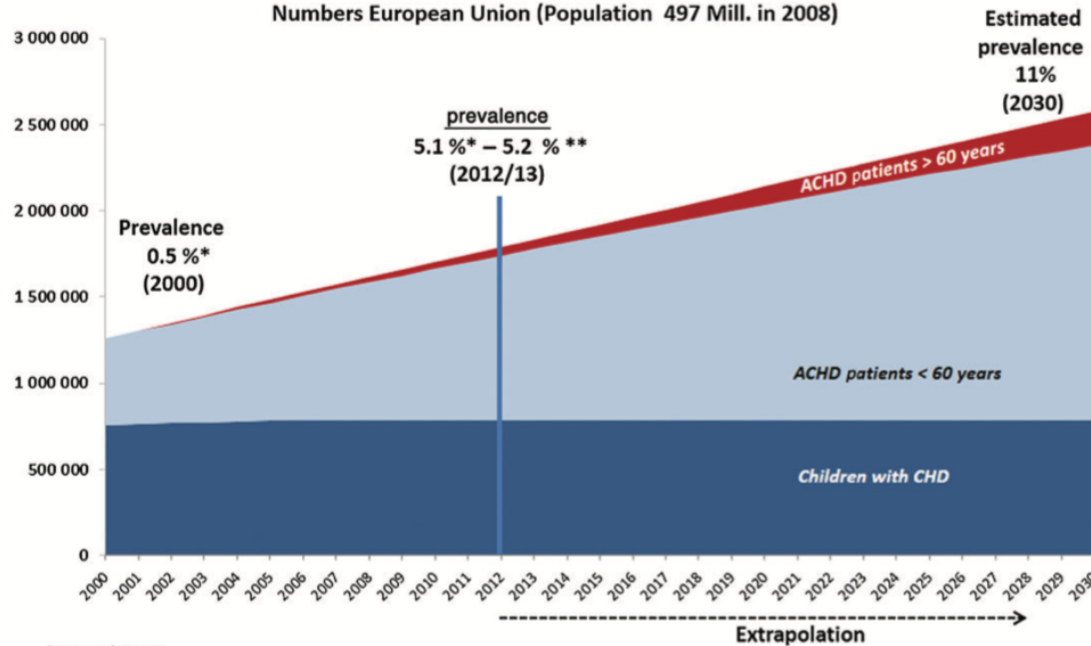
(+)	= minimal risk	+	= mild risk	++	= moderate risk	+++	= high risk
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Expected number of CHD pts (U.S.) with a pacemaker

"At-Risk" Lesion Subtype	ESTIMATED TOTAL NUMBER ANY CRM DEVICE NEED		ESTIMATED NUMBER WITH PACEMAKER NEED		ESTIMATED NUMBER WITH ICD NEED	
	Conservative (15%)	Moderate (32.2%)	Conservative (15%)	Moderate (32.2%)	Conservative (15%)	Moderate (32.2%)
Conotruncal	20,605	44,233	9,510	20,415	9,510	20,415
Systemic RV	26,858	57,655	15,799	33,915	7,899	16,957
Single Ventricle	20,700	44,436	15,923	34,182	3,185	6,836
TOTAL	68,163	146,324	41,232	88,511	20,594	44,209
Percent Total ACH Population	7%	15%	4%	9%	2%	4%

Adapted From "Relative Frequencies of Cardiovascular and Extracardiac Malformations among Studies of CV malformations among Birth Cohorts, in The Science and Practice of Pediatric Cardiology, Second Edition

Changings demographics in CHDs



* Tutarel 2013

Baumgartner H. Eur Heart J 2014;35:683 – 685

- With 84% of the population with CHD now living >40 years, more “*old patients*” will require specific care



Strategies for preventing arrhythmic sudden death in adult congenital heart disease

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Limitations of traditional devices in CHD Patients

Conventional lead-based systems pose significant challenges in patients with surgically altered anatomy.

Anatomical Challenges

- Difficult or absent venous access
- Complex cardiac anatomy (e.g., Fontan circulation)
- Presence of intracardiac shunts
- Previous Surgery
- Right to left emboly
-

Lead-Related Complications

- Lead fracture or dislodgement
- Venous occlusion
- Risk of endocarditis

Pocket-Related Issues

- Generator pocket infections
- Skin erosion
- Aesthetic and psychological impact

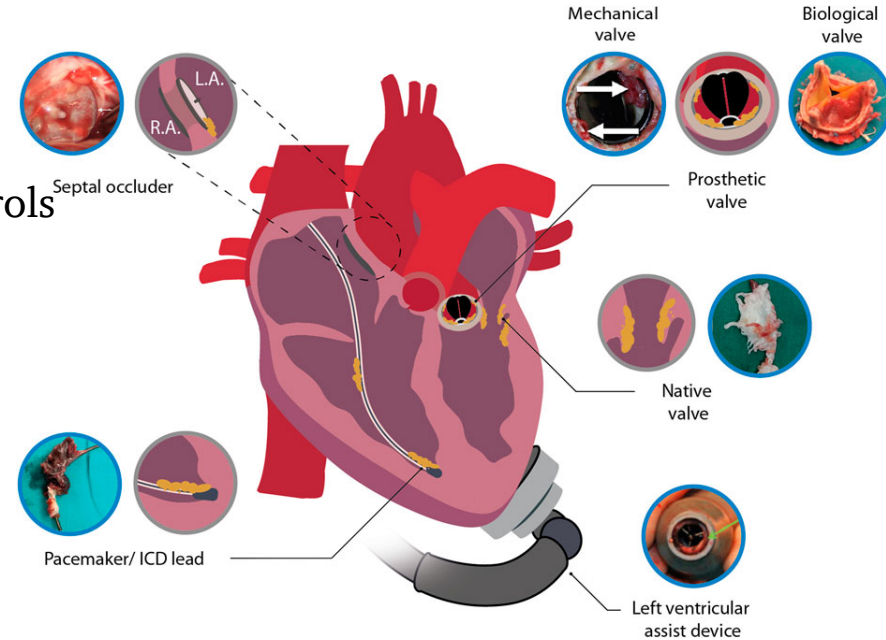
Increased Risk of Infection



Infective endocarditis (IE) in patients with CHD

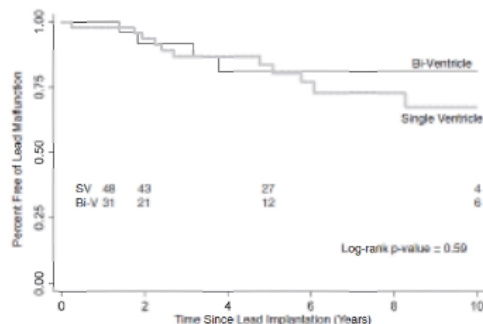
Facts

- Incidence 20-70x higher than general population
- By age of 18 years similar risk to 81-year-old controls
- Higher risk of IE in CHD:
 - Residual shunts
 - Cyanosis
 - **Implanted material**



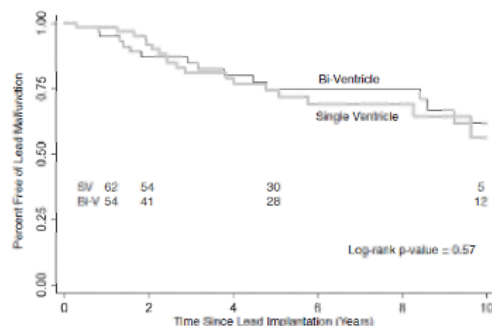
¹ Snygg-Martin U, Clin Infect Dis, 2021 ² Kuijpers JM, Eur Heart J, 2017

A Atrial Epicardial Leads



Atrial lead survival:
67-81%

B Ventricular Epicardial Leads



Ventricular lead survival:
56-62%

Pacing indication

Anatomical diagnosis	Sinus node dysfunction	AV node dysfunction	Other
<i>Single ventricle</i>			
Hypoplastic left ventricle	19 (25.0)	12 (15.8)	2 (2.6)
Hypoplastic right ventricle	24 (31.6)	9 (11.8)	5 (6.6)
"Single ventricle"	4 (5.3)	1 (1.3)	0
<i>Biventricle</i>			
RVOT abnormalities	1 (1.3)	8 (10.1)	0
LVOT abnormalities	1 (1.3)	5 (6.3)	0
Septal defects	2 (2.5)	35 (44.3)	1 (1.3)
Great artery abnormalities	2 (2.5)	17 (21.5)	0
Atrioventricular valve abnormalities	1 (1.3)	2 (2.5)	0
Heart transplant	0	0	0
Pulmonary venous abnormalities	3 (3.7)	1 (1.3)	0

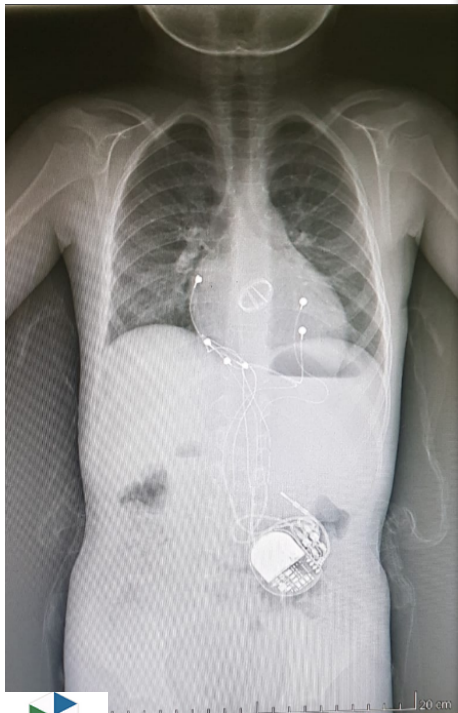
Data are presented as n (%).

AVV = atrioventricular valve; LVOT = left ventricular outflow tract; RVOT = right ventricular outflow tract.

Factor associated with lead malfunction	Atrial	Ventricular
Single ventricle palliation	2.55 (0.63-10.28), $P = .189$	2.61 (1.12-6.07), $P = .026$
Age at first pacer	0.91 (0.81-1.02), $P = .092$	0.90 (0.83-0.98), $P = .019$
Race: black vs white	1.12 (0.12-10.57), $P = .918$	2.18 (0.95-5.01), $P = .066$
Sex: male vs female	3.88 (0.98-15.34), $P = .054$	2.51 (1.20-5.27), $P = .015$
Non-steroid vs steroid eluting	1.02 (0.12-8.47), $P = .984$	0.73 (0.30-1.76), $P = .490$
No. of surgeries	0.68 (0.34-1.34), $P = .265$	0.69 (0.45-1.05), $P = .084$
Era of implantation: 1984-1999 vs 2000-2010	3.18 (0.70-14.43), $P = .134$	3.38 (1.38-8.25), $P = .008$
Thoracotomy vs sternotomy	2.76 (0.71-10.67), $P = .142$	1.77 (0.58-5.36), $P = .310$
Subxiphoid vs sternotomy	1.37 (0.26-7.09), $P = .707$	1.36 (0.64-2.92), $P = .430$

Data are presented as hazard ratio (95% confidence interval), P value.

The Concept of Leadless Pacemaker: A new Era



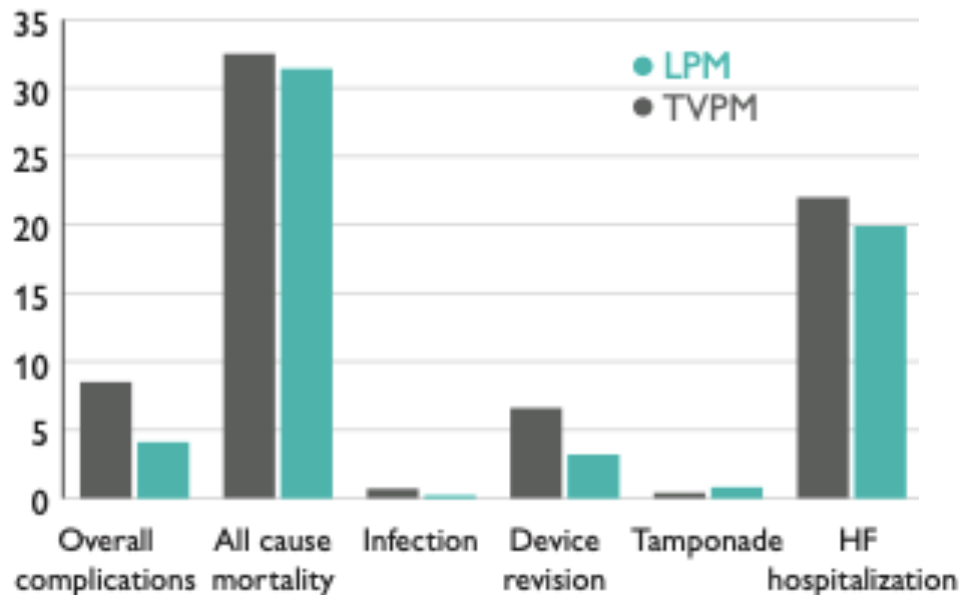
NO LEADS

**NO SURGICAL
POCKET**

**MINIMALLY
INVASIVE
PROCEDURE**



Long-term complications*



1. El-Chami MF, Garweg C, Clementy N, Al-Samadi F, Iacopino S, Martinez-Sande JL, et al. Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry. *Eur Heart J*. 2024;45(14):1241-51.
2. Crossley GH, Piccini JP, Longacre C, Higuera L, Stromberg K, El-Chami MF. Leadless versus transvenous single-chamber ventricular pacemakers: 3-year follow-up of the Micra CED study. *J Cardiovasc Electrophysiol*. 2023;34(4):1015-23.
3. El-Chami MF, Bockstedt L, Longacre C, Higuera L, Stromberg K, Crossley G, et al. Leadless vs. transvenous single-chamber ventricular pacing in the Micra CED study: 2-year follow-up. *Eur Heart J*. 2022;43(12):1207-15.
4. Piccini, Jonathan P, Mikhail El-Chami, Kael Wherry, George H. Crossley, Robert C. Kowal, Kurt Stromberg, Colleen Longacre, Jennifer Hinnenenthal, and Lindsay Bockstedt. 2021. "Contemporaneous Comparison of Outcomes among Patients Implanted with a Leadless vs Transvenous Single-Chamber Ventricular Pacemaker." *JAMA Cardiology* 6 (10): 1187-95.

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.

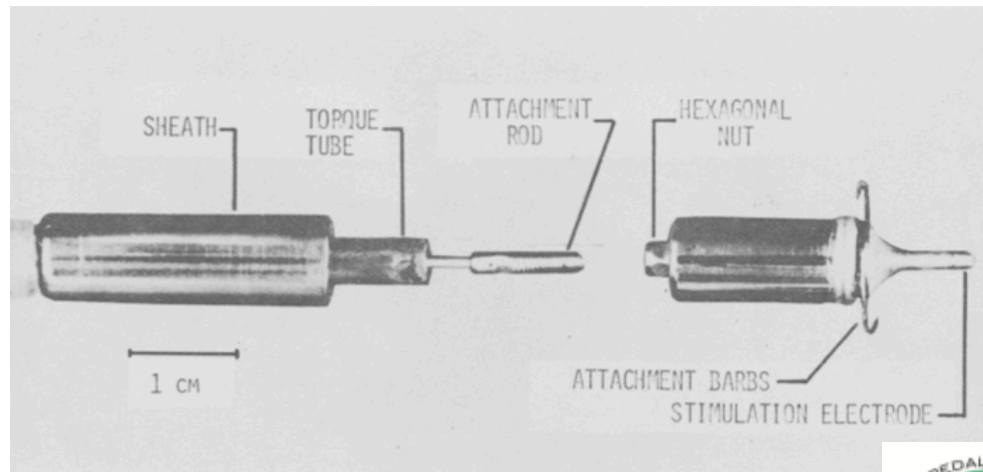
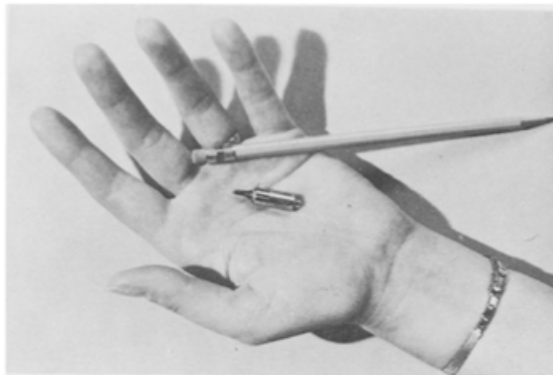


Fig. 8. Nuclear-powered intracardiac pacemaker.

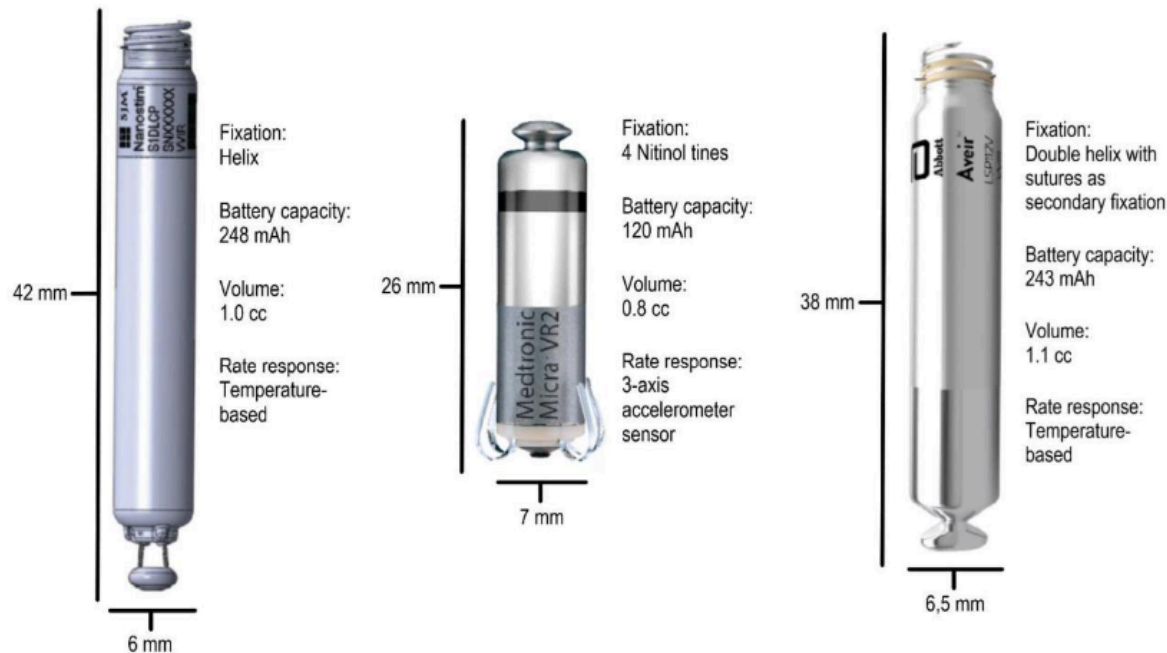


Figure 1 Comparison of the size and volume of the different leadless pacemakers. The Nanostim leadless pacemaker, the Micra leadless pacemaker, and the AVEIR leadless pacemaker with device characteristics

Leadless Pacemakers Comparison

Feature	Nanostim™ (St. Jude / Abbott)	Micra™ (Medtronic)	Aveir™ (Abbott)
First human implants	2012 (Europe)	2013 (Europe)	2020 (clinical trial)
Key initial study	LEADLESS (2014, 33 pts)	Micra TPS (2015, 725 pts)	Aveir VR i2i (2020+)
Fixation method	Helical screw	4 nitinol tines	Helical screw (repositionable & retrievable)
Size	~42 mm x 5.9 mm	~25.9 mm x 6.7 mm	~32 mm x 6 mm
Battery life (estimated)	8–13 yrs (premature depletion)	10–12 yrs (confirmed)	~15–20 yrs (longer life)
CE Mark	2016	2015	EU trials
FDA approval	Never (halted)	2016 (VR), 2020 (AV)	2022 (VR), 2023 (DR dual-ch)
Complications	Perforation, delivery failure, early battery depletion	Low major complications (<2%), rare perforation/infection	High success, retrievable, dual-chamber capability
Current status	Suspended since 2017	Widely used, standard of care	Active clinical use (VR & DR)
Unique features	First-ever leadless pacemaker	First successful commercial system	Retrievable, modular, first dual-chamber

Feasibility of Leadless Pacemakers in CHD



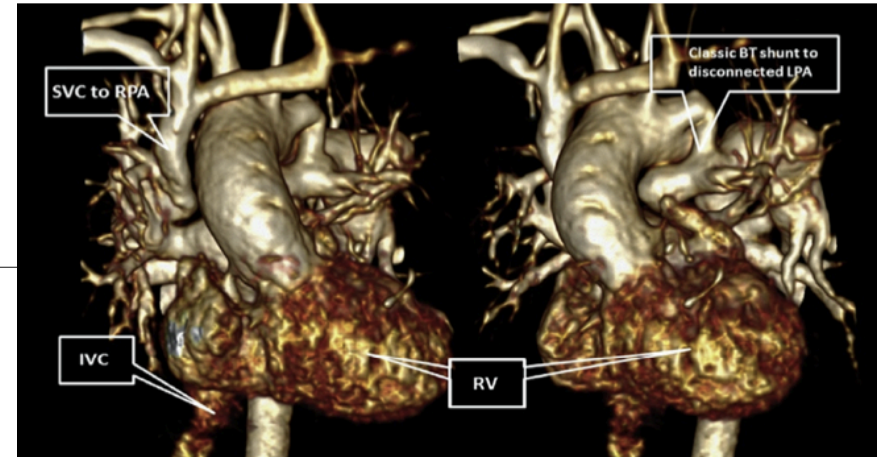


Leadless pacemaker implantation in a patient with complex congenital heart disease and limited vascular access

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ESC

European Society
of Cardiology

European Heart Journal - Case Reports (2024) 8, ytae506
<https://doi.org/10.1093/ehjcr/ytae506>

CASE REPORT

Electrophysiology

Indian Pacing and Electrophysiology Journal 25 (2025) 28–31

Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Indian Pacing and Electrophysiology Journal



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¹Department of Card
of Cardiac Electrophys

Received 5 April 2024,

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European Heart Journal - Case Reports (2025) 9, ytaf146
<https://doi.org/10.1093/ehjcr/ytaf146>

CASE SERIES

Adult congenital heart disease

Received: 29 September 2023 | Revised: 7 December 2023 | Accepted: 19 December 2023

DOI: 10.1111/jce.16173

ORIGINAL ARTICLE

WILEY

Guo et al. *BMC Cardiovascular Disorders* (2025) 25:63
<https://doi.org/10.1186/s12872-025-04511-3>

BMC Cardiovascular Disorders

Case report for leadless ventricle he

Patrick Hayle *, Fa

Department of Cardiology, Liverpool Heart an

Received 30 May 2024; revised 20 November 20

Different leadless p
the atrium/Micra A
dextrocardia and dc
infected device exti

Carter English MD | Dali F

CASE REPORT

Open Access

Leadless pacemaker implantation in a patient with congenital azygos continuation of the inferior vena cava

Lanyan Guo¹, Minxia Zhang¹, Ying Zhao¹, Qun Yan¹, Xuyang Feng¹ and Ling Tao^{1*}



Adult Congenital
Heart Disease Unit



Aveir retrievable, 38-mm length, leadless pacemaker implantation in a 23-kg pediatric patient with congenital heart disease

Jacob Rodriguez ^{1,2} | Daniel Cortez MD, PhD¹

Dual Chamber Aveir Retrievable Leadless Pacemaker Implant via the Right Internal Jugular Vein in a 12-Year-Old With Congenital Conduction System Disease

European Heart Journal Supplements (2025) 27 (Supplement 2), ii14-ii20
The Heart of the Matter
<https://doi.org/10.1093/eurheartjsupp/suae090>

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Received: 21 October 2024 | **Accepted:** 3 December 2024

Keywords: dual chamber | leadless pacemaker | pediatri



Leadless pacing in young patients

Paul Richard Roberts ^{1*} and Saverio Iacopino²

¹Faculty of Medicine, University of Southampton, University Road, Southampton SO17 1BJ, UK; and ²GVM Care & Research, Maria Cecilia Hospital, Cotignola, RA, Italy

Aveir VR/AR/DR - Key Innovations

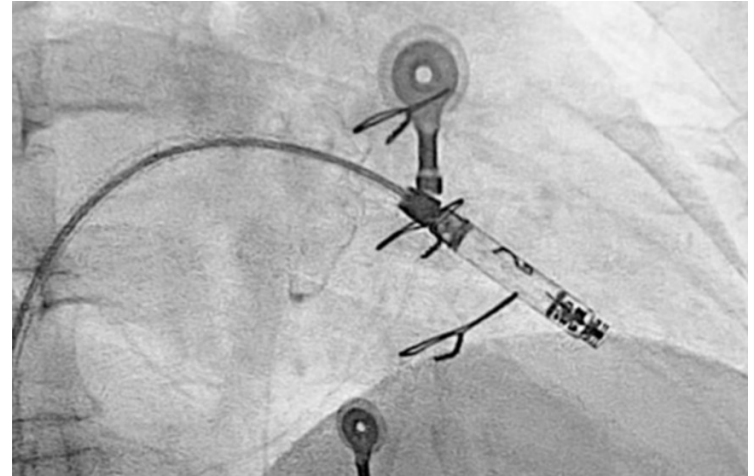
Retrievability: Designed for safe retrieval if necessary, via a dedicated fixation mechanism

Extended Battery Longevity: Provides prolonged device lifespan

Active Screw Fixation: Ensures precise and stable placement

Pre-Implant Mapping: Allows assessment of optimal site prior to final deployment

Dual-Chamber Capability (DR): Enables wireless communication between atrial and ventricular devices for physiological pacing



Young Patients – What about end-of-life management?

❖ Longevity?



❖ Retrievability?



❖ Upgradability?



European Heart Journal Supplements (2025) 27 (Supplement 2), iii4-iii20
The Heart of the Matter
<https://doi.org/10.1093/eurheartj/suap/uaa090>



Leadless pacing in young patients

Paul Richard Roberts ^{1*} and Saverio Iacopino ²

¹Faculty of Medicine, University of Southampton, University Road, Southampton SO17 1BJ, UK; and ²GVM Care & Research, Maria Cecilia Hospital, Cotignola, RA, Italy

AVEIR VR LP

LONGEVITY (YRS)

Pacing Rate	Pace Amplitude	% Pacing	Impedance	
			500 Ω	600 Ω
50 bpm	1.25 V	100%	18.4	19.4
		50%	21.8	22.6
		0%	26.9	27.1
50 bpm	2.5 V	100%	10.4	11.5
		50%	15.0	16.1
		0%	26.9	27.1
60 bpm	1.25 V	100%	16.1	17.1
		2.5 V 100%	8.9	9.9
		5.0 V 100%	2.7	3.2



Mean ventricular device impedance at 3-month IDE follow-up²

AVEIR AR LP

LONGEVITY (YRS)

Pacing Rate	Pace Amplitude	% Pacing	Impedance	
			300 Ω	400 Ω
50 bpm	1.25 V	100%	10.7	11.9
		50%	13.5	14.5
		0%	18.3	18.7
50 bpm	2.5 V	100%	5.3	6.3
		50%	8.3	9.5
		0%	18.3	18.7
60 bpm	1.25 V	100%	9.3	10.4
		2.5 V 100%	4.5	5.4
		5.0 V 100%	1.2	1.5



Mean atrial device impedance at 3-month IDE follow-up²

¹ AVEIR Leadless Pacemakers and Delivery Catheter IFU. ARTEN600307044.

² A Dual-Chamber Leadless Pacemaker. New England Journal of Medicine (Supplementary Appendix) (2023). DOI: 10.1056/NEJMoa2300080

Single Chamber Longevities^{1,2}

Retrieval and replacement of a helix-fixation leadless pacemaker at 9 years post-implant



Petr Neužil, MD, PhD,* Jan Petrů, MD,* Milan Chovanec, MD, PhD,*
Pavel Hála, MD, PhD,* Lucie Šedivá, MD, PhD,* Vivek Y. Reddy, MD*†

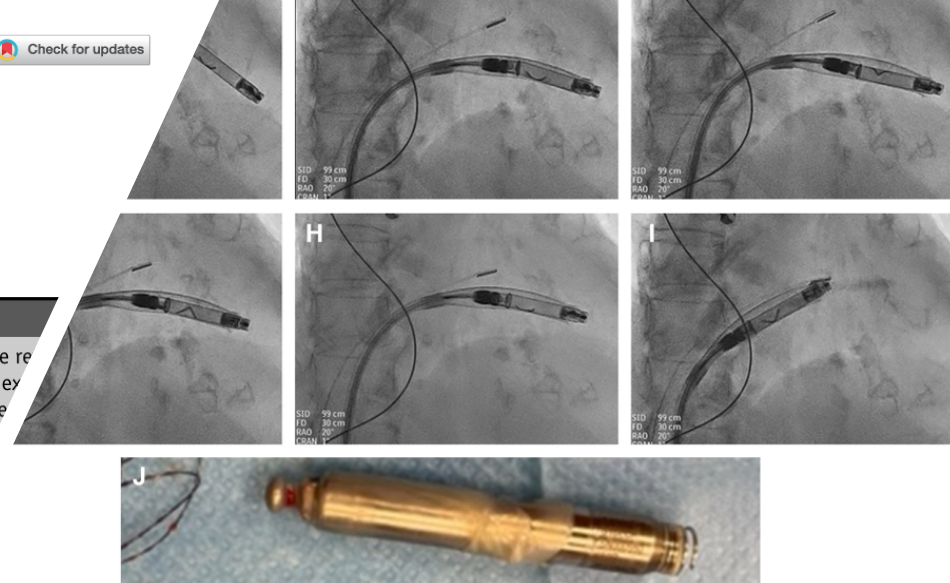
From the *Na Homolce Hospital, Prague, Czech Republic, and †Icahn School of Medicine at Mount Sinai Hospital, New York, New York.

Introduction

Leadless pacemakers (LP) are now established as a safe and effective alternative to traditional, transvenous pacemakers for single-chamber ventricular pacing.^{1,2} Although eliminating the transvenous pacing lead and pulse generator pocket may streamline LP delivery, long-term patient management may ultimately necessitate LP retrieval for device

KEY TEACHING POINTS

- There is limited experience with the retrieval of leadless pacemakers (LPs) after an extended implant duration. This case study describes the successful retrieval of an existing LP after 9 years post-implant, with



Neužil et al Chronic Replacement of Helix Fixation Leadless Pacemaker

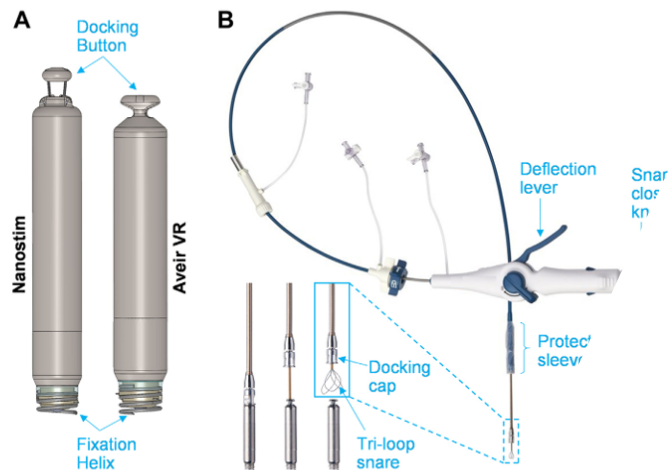


Figure 1 Schematics illustrating the Nanostim and replacement Aveir VR leadless pacemakers, also Aveir VR leadless pacemakers, both equipped with fixation helices and docking buttons. **B:** Aveir VR leadless pacemaker and docking mechanism.





Impact of LPM vs TVPM in ACHD patients

*Data from “Monaldi Care Registry”
“ACHD population subset”*

March 2025-April 2026

- 12 Aveir LPM Implant in ACHD
- 5F/7M
- Aged 53.6-12.5 years old

No significant differences in terms of:

- Hospital care
- Time for procedure
- Acute complications
- Pacing/sensing thresholds
- Lesser Early/Late complications
- No residual TR....

Unpublished data

Giulia I.

- D.O.B. 12.02.76
- TOF
- 3 years old – Surgical correction
- 29 years old – Contegra 22 RVOT conduit
- 40 years old – Endocarditiis (Streptococcus Gordonii)

Severe RVOT obstruction

Homograft 24 implant

- 45 years old - Paroxysmal A fib – AA drugs required
- 2024/2025 - I° AV block, RBBB, Left axis deviation
- 2025: pre-Syncope, ECG Holter 2:1 AV block

Im: 1/180
Se:3

GIULIA
33362
12/12/1976 M
Azienda Ospedaliera dei Colli
1
FL Card



WL: 112 WW: 106 [D]
RAO: 27

13/03/2025 16:36:25

Im: 1/281
Se:7

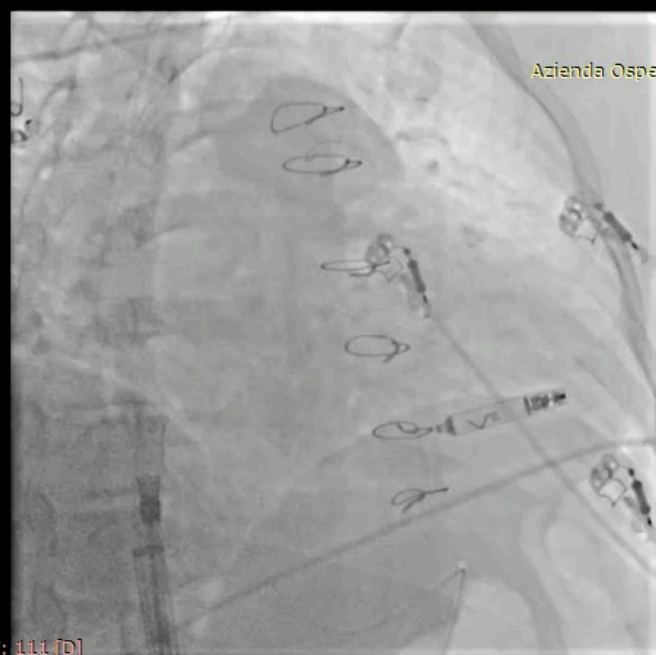


O GIULIA
33362
12/12/1976 M
Azienda Ospedaliera dei Colli
1
FL Card

WL: 112 WW: 116 [D]
RAO: 27

13/03/2025 16:43:36

Im: 1/115
Se:10



GIULIA
33362
12/12/1976 M
Azienda Ospedaliera dei Colli
1
FL Card

WL: 112 WW: 111 [D]
RAO: 32

13/03/2025 16:47:56

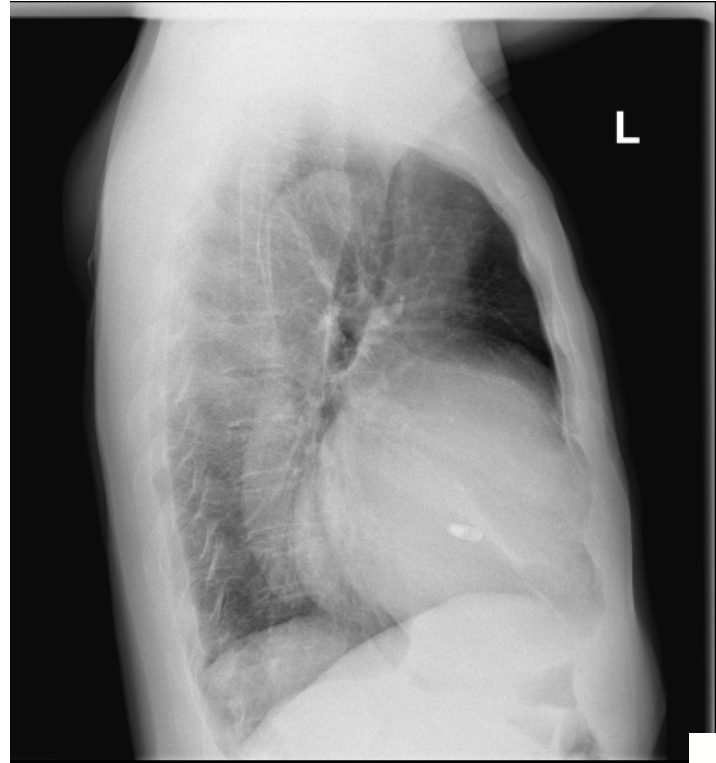
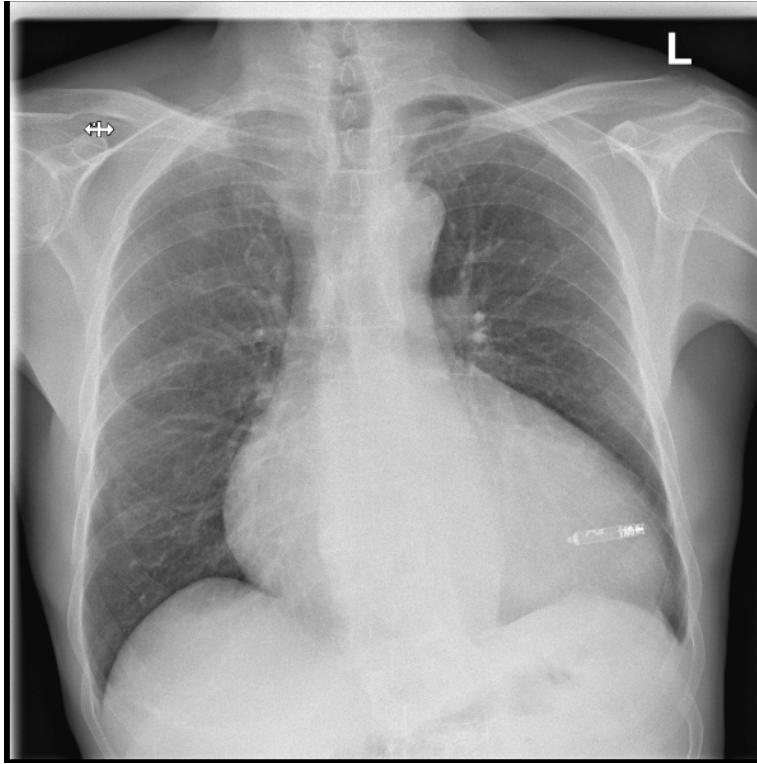
Giovanni C.

- D.O.B. 12.07.58
- Car mechanic

2025 - Peripheral hospital

- Pre-op ophthalmology (cataract)
- A fib with low ventricular response
- Suspected tricuspid valve abnormality....





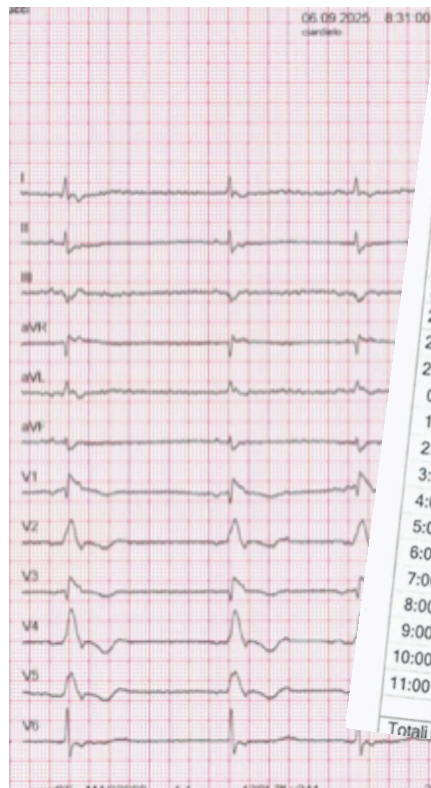
Arturo N.

- D.O.B. 27.01.84
- Truncus Arteriosus Type 1
- 4 months - Surgical correction – Pulmonary homograft n°12
- 6 years and 9 years old – Homograft replacement
- 17 years old (2001)– Edwards 22 porcine valved conduit
- 23 years old (2007) – Bilateral pulmonary arteries stenting
- 37 years old (2021)– Reduced LV EF: 35%, nsVT – S-ICD implant
- 39 years old (2023) – repeated IART, unresponsive to Amio, b-block

Drugs: Amio, b-block, Apixaban, Furosemide, Ramipril







Ora	Totale Battiti	Med FC	Min FC	Max FC	SDNN	Spettrale Potenza	Assoluto ST CH 1	Assoluto ST CH 2	Assoluto ST CH 3	VE coppiaun	SVE	sircoppiaun	Pausa > 2.5 sec	Bic
11:30	1165	42	39	46	47	960.3	0	-2.2	0	+2.4	0	-2.3	0 0 0	2 2 0 0
12:00	2412	43	38	67	151	2926.5	0	-2.0	0	+2.4	0	-2.4	0 0 0	11 9 1 0
13:00	2865	48	40	65	101	410.2	0	-1.8	0	+0.8	0	-2.0	0 0 0	12 12 0 0
14:00	2539	44	41	46	40	894.6	0	-2.3	0	+2.6	0	-2.4	0 0 0	16 10 3 0
15:00	2616	45	40	49	44	611.3	0	-2.2	0	+2.5	0	-2.3	0 0 0	36 26 5 0
16:00	3273	54	39	63	43	465.7	0	-2.1	0	+2.3	0	-2.2	0 0 0	31 19 6 0
17:00	3290	55	38	63	42	1105.0	0	-2.2	0	+2.2	0	-2.1	0 0 0	19 11 4 0
18:00	2446	40	38	43	60	130.5	0	-2.3	0	+2.6	0	-2.7	0 0 0	4 2 1 0
19:00	2684	45	40	64	122	3003.0	0	-2.2	0	+2.5	0	-2.4	0 0 0	25 13 6 0
20:00	2861	47	38	64	78	466.4	0	-2.4	0	+2.8	0	-2.6	0 0 0	14 8 3 0
21:00	2489	42	34	65	151	5075.0	0	-2.5	0	+2.5	0	-2.5	0 0 0	54 34 10 0
22:00	3020	50	33	67	75	2416.3	0	-2.4	0	+2.5	0	-2.2	0 0 0	18 16 1 0
23:00	2495	41	38	48	90	1750.1	0	-1.8	0	+1.1	0	-2.2	0 0 0	7 3 2 0
0:00	2429	40	34	44	50	1105.8	0	-2.3	0	+2.3	0	-2.0	0 0 0	0 0 0 0
1:00	2995	49	37	58	45	1151.7	0	-1.9	0	+1.0	0	-1.1	0 0 0	0 0 0 0
2:00	2973	49	33	54	29	874.6	0	-1.8	0	+0.8	0	-0.8	0 0 0	4 4 0 0
3:00	2984	49	45	54	32	597.4	0	-1.7	0	+1.0	0	-1.6	0 0 0	0 0 0 0
4:00	2650	43	24	53	41	985.4	0	-2.1	0	+1.2	0	-1.8	0 0 0	2 2 0 0
5:00	2243	36	33	37	25	319.6	0	-2.1	0	+2.5	0	-2.1	0 0 0	0 0 0 0
6:00	2207	37	31	52	72	1165.2	0	-2.1	0	+2.3	0	-2.1	0 0 0	0 0 0 0
7:00	2180	38	31	43	0	1812.6	0	-2.2	0	+2.6	0	-1.6	0 0 0	46 42 2 0
8:00	2425	44	32	65	48	3049.3	0	-2.2	0	+2.4	0	-1.5	0 0 0	73 59 7 0
9:00	2722	48	30	61	123	7753.5	0	-2.2	0	+2.4	0	-1.8	0 0 0	49 39 5 0
10:00	1221	53	51	56	23	123.4	0	0.0	0	0.0	0	0.0	0 0 0	114 59 20 5
11:00	0	N/A	N/A	N/A	0	N/A	0	0.0	0	0.0	0	0.0	0 0 0	0 0 0 0
Totale	61184	45	24	67	116	1707.1	0	-2.5	0	+2.8	0	-2.7	0 0 0	537 370 76 5

Im: 1/300
Se:13



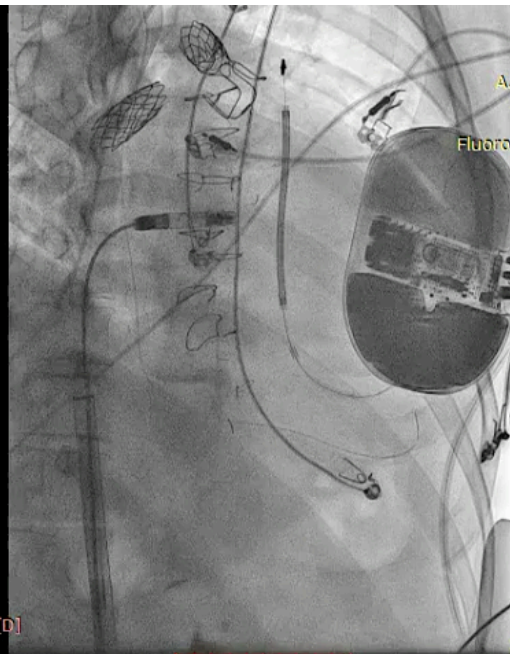
NARDUCCI ARTURO
34587
27/01/1984 M
A.O. DEI COLLI NAPOLI
2025091609181467

Fluoroscopiaata

WL: 128 WW: 256 [D]
RAO: 34

16/09/2025 12:49:28

Im: 1/139
Se:19

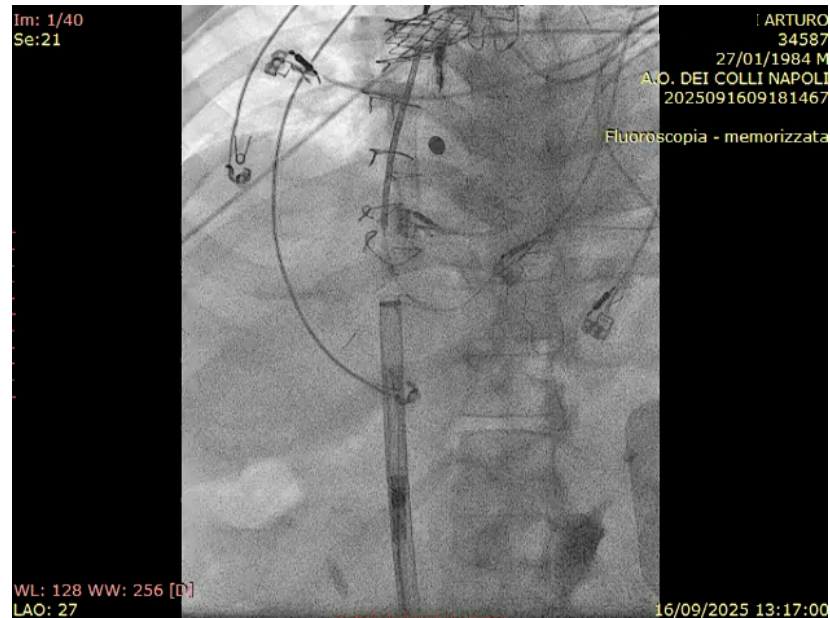
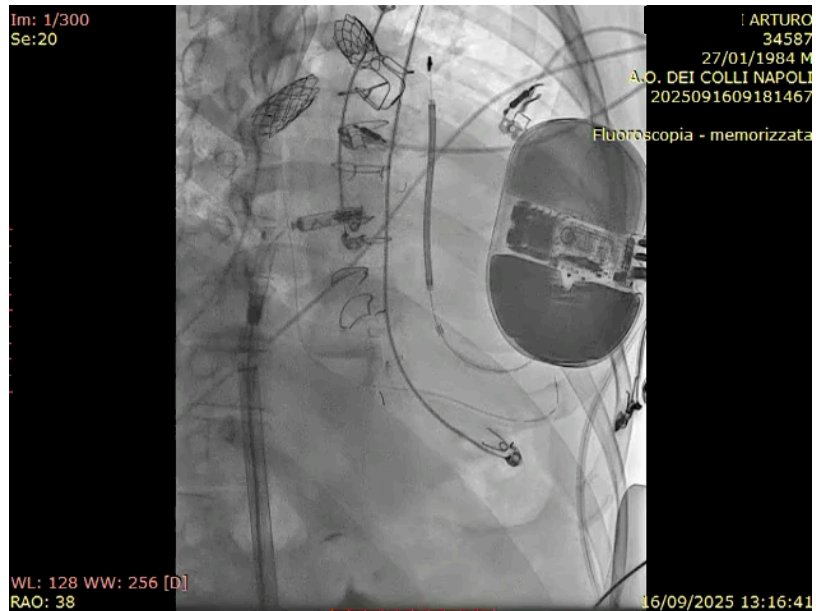


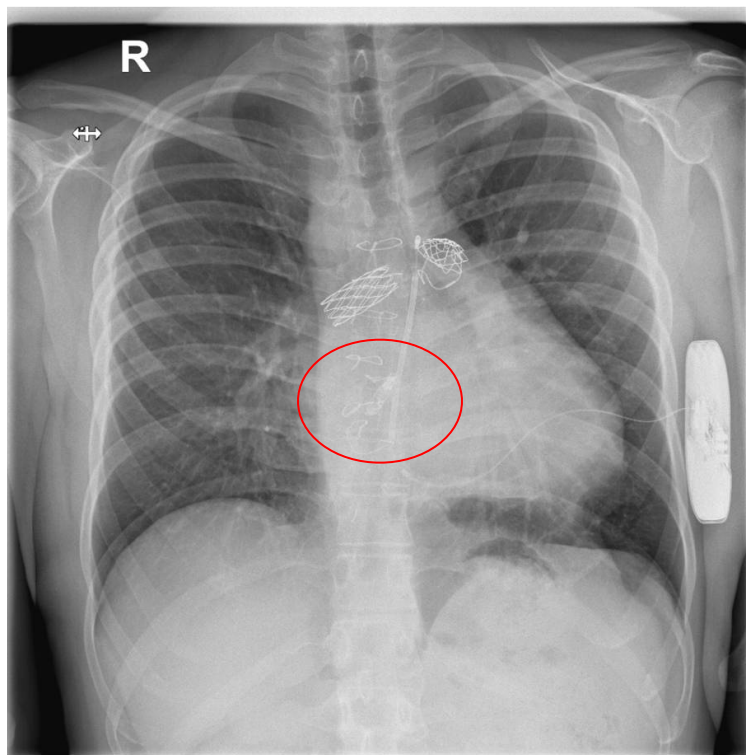
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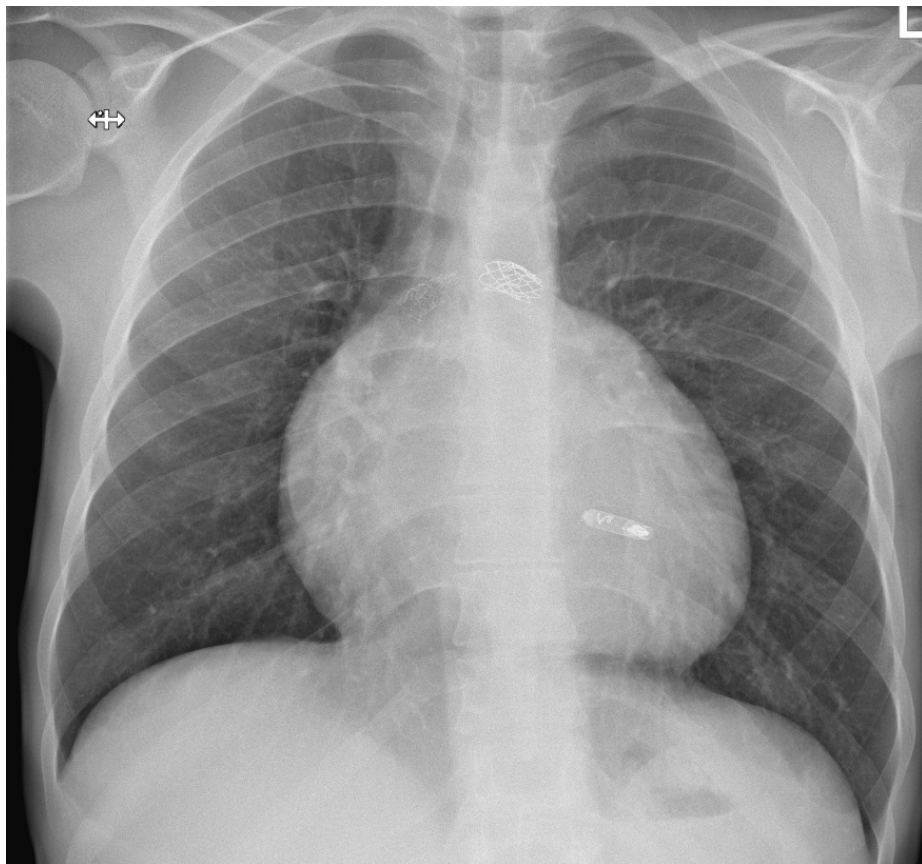
Fluoroscopiaata

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RAO: 38

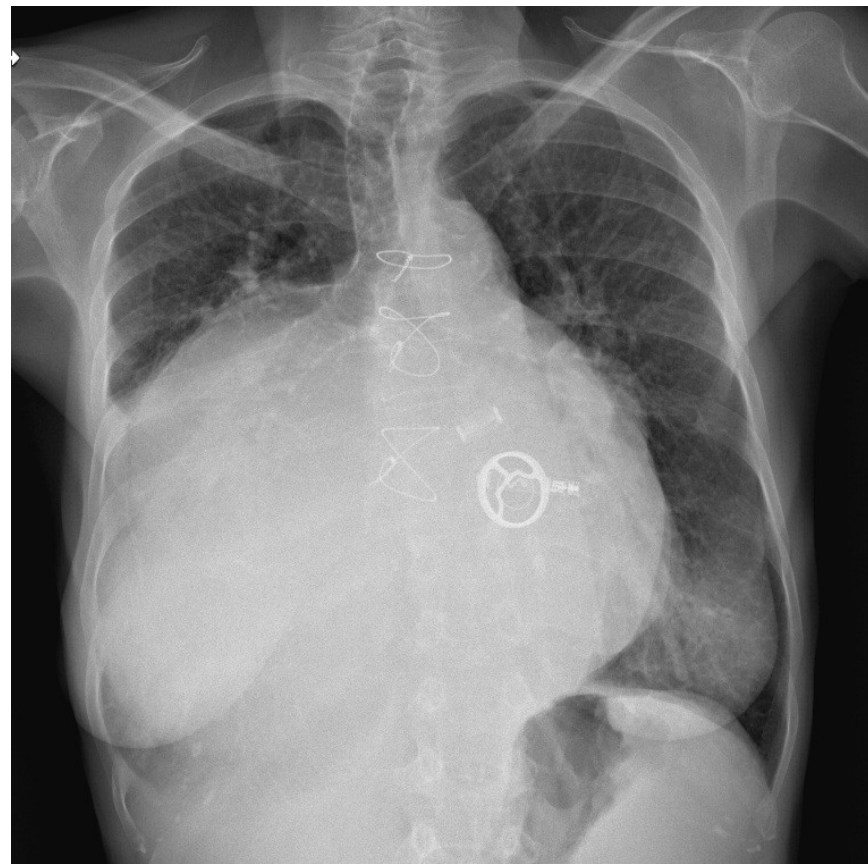
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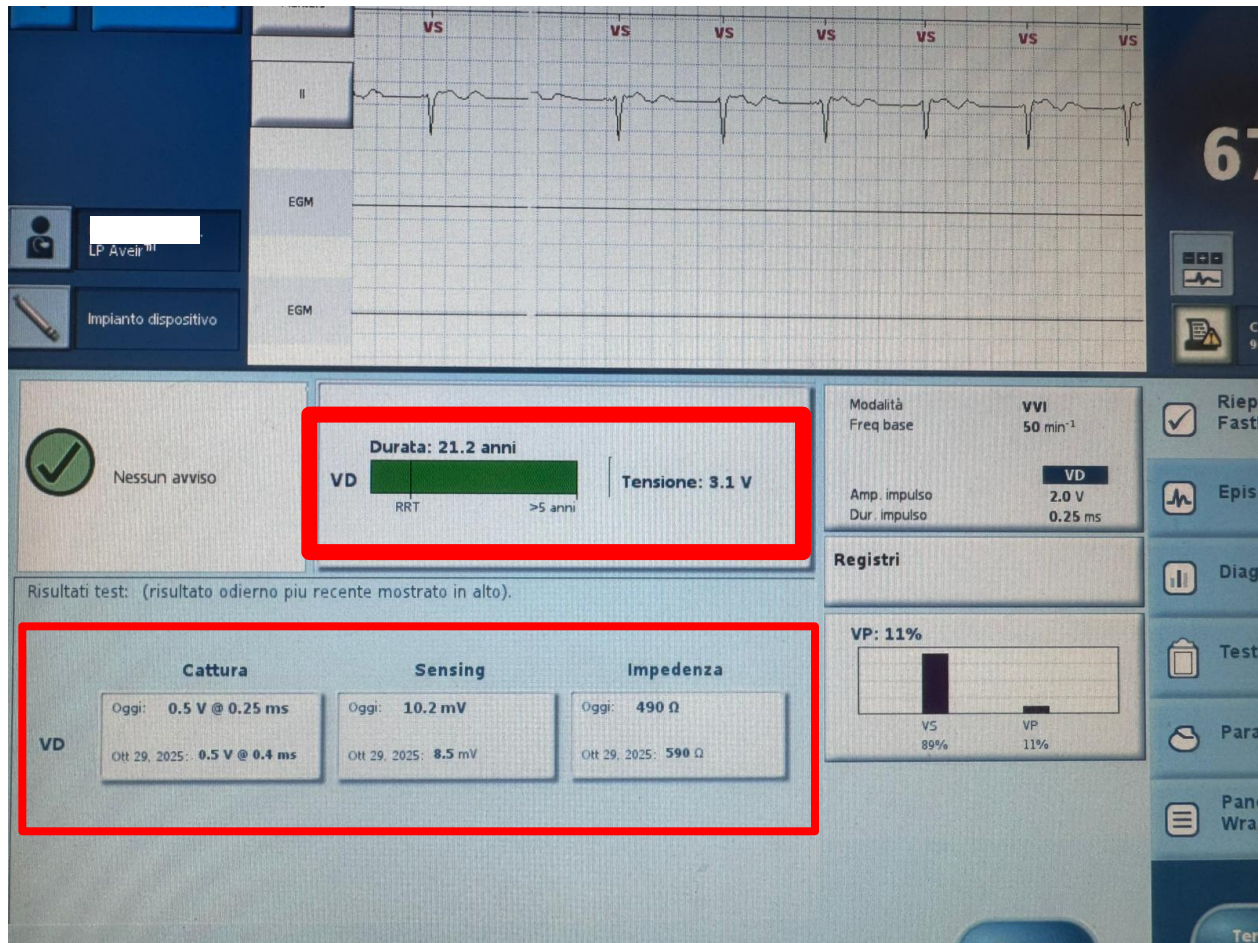




TGA with residual intracardiac shunt due to Gerbode VSD.



Congenital mitral and aortic stenosis s/p mechanical mitral and aortic valve repl. Severe R heart dilation.

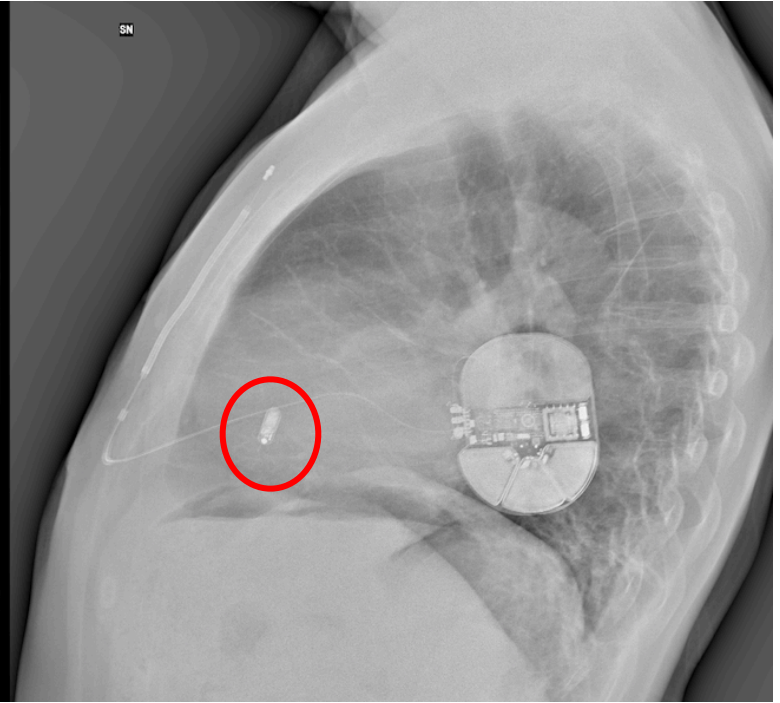
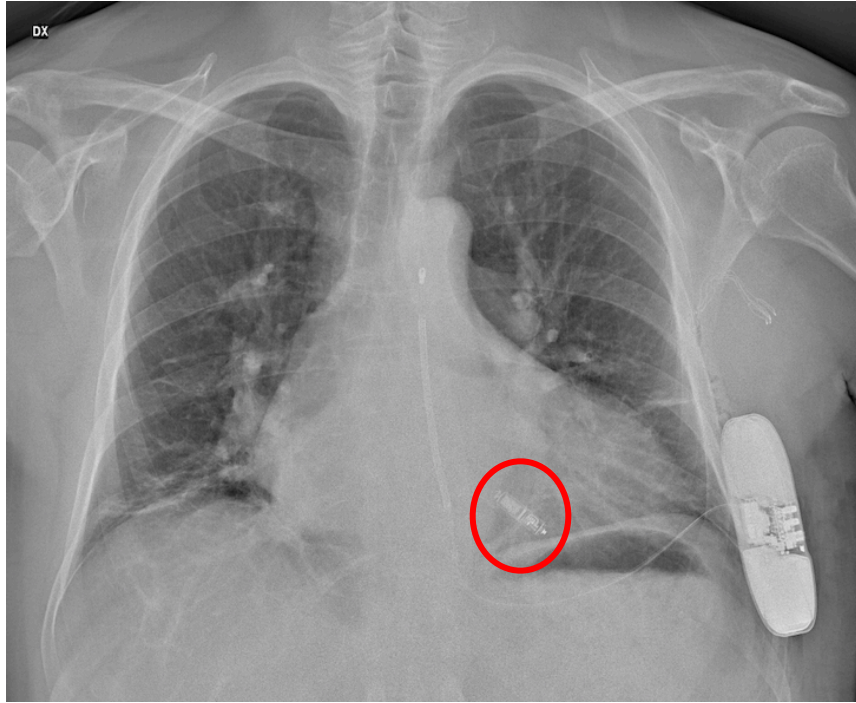




Combined subcutaneous implantable cardioverter defibrillator and pacemaker devices in complex congenital heart disease: a single-center experienced based study

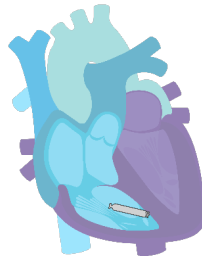
Berardo Sarubbi¹  · Giovanni Domenico Ciriello¹ · Giovanni Papaccioli¹ · Anna Correra¹ · Emanuele Romeo¹ · Nicola Grimaldi¹ · Diego Colonna¹ · Michela Palma¹

Patient	Year of implant + PMK type	PM dependency	Ventricle lead position	Year of implant + S-ICD type	Sensing vectors	Incision technique	S-ICD lead position	S-ICD can position	Conditional shock zone/ shock zone	Prætorian score	Arrhythmias during F-U	AS	IAS	F-U (months)	Outcome
No. 1	2013 (endo) DDDPMK	No	RV septum	2015 Emblem A209	3	Three-incision technique	Left	Left/IM	200/250 bpm	No	No	No	No	85	HTX
No. 2	2001 (endo) VVIPMK	No	RV septum	2020 Emblem A219	2	Two-incision technique	Left	Left/IM	200/250 bpm	60	AF	No	No	33	Good
No. 3	2010 (epi) VVIPMK 2014 (endo) VVIPMK	Yes	RV Apex	2020 Emblem A219	3	Two-incision technique	Left	Left/IM	220/250 bpm	30	AT	No	No	32	Good
No. 4	2005 (epi) VVIPMK 2007 (endo) VDD PMK	Yes	LV Free wall (subpulm)	2021 Emblem A219	2	Two-incision technique	Right	Left/IM	200/250 bpm	60	nsVT	No	No	14	Good
No. 5	2021 (epi) DDD PMK	Yes	Single V Free wall (epi)	2021 Emblem A219	1	Two-incision technique	Left	Left/IM	180/230 bpm (reprogrammed to 200/230 bpm)	60	nsVT	No	Yes double counting on T waves	19	Good
No. 6	2013 (endo) DDD PMK	Yes	LV Septum (subpulm)	2021 Emblem A219	2	Two-incision technique	Left	Left/IM	220/250 bpm	60	nsVT	No	No	20	Good
No. 7	2009 (epi) VVIPMK 2016 (endo) VVIPMK	No	RV Apex	2020 Emblem A219	3	Two-incision technique	Right	Left/IM	220/250 bpm	30	No	No	No	32	Good
No. 8	2010 DDD PMK (epi)	No	RV Free wall (epi)	2021 Emblem A219	2	Two-incision technique	Left	Left/IM	200/250 bpm	60	AF	No	No	21	Good
No. 9	1994(endo) VDD PMK	Yes	LV Infer-wall (subpulm)	2021 Emblem A219	2	Two-incision technique	Left	Left/IM	200/250 bpm	60	No	No	No	13	Good
No. 10	2004 (endo) VVIPMK 2018 (endo) CRT-D 2022 (epi)	No	RV Free wall (epi)	2021 Emblem A219	2	Two-incision technique	Left	Left/IM	200/250 bpm	30	AF	No	No	8	Good
No. 11	2022 (endo) Leadless PMK	No	RV Apex	2022 Emblem A219	2	Two-incision technique	Left	Left/IM	200/250 bpm	30	No	No	No	4	Good



Potential Advantages of Leadless Pacemakers in CHD

- Overcoming anatomical barriers:** Transfemoral approach bypasses thoracic venous obstructions and adapts to complex anatomies
- Drastic reduction of infection risk:** Absence of pocket and leads eliminates major infection sites
- Improved quality of life:** No visible chest scar, no arm movement restrictions, better psychological acceptance
- Greater freedom for future options:** Preserves venous system for potential future cardiac interventions



Single-chamber retrievable leadless pacemaker in adult congenital heart disease: a single-center experience

Giovanni Domenico Ciriello, Diego Colonna, Anna Correra, Giovanni Papaccioli, Emanuele Romeo, Berardo Sarubbi

Key findings

- ✓ Single-chamber retrievable leadless pacemaker implantation (Aveir VR and AR) is feasible and safe in ACHD patients, with excellent short-term outcomes.
- ✓ The retrievable design, active fixation and mapping-guided implantation may be particularly advantageous in complex congenital anatomies.
- ✓ Leadless pacing expands therapeutic options for ACHD patients at high infective, thromboembolic, or surgical risk.
- ✓ Aveir AR may broaden leadless pacing options by enabling AAI atrial-only pacing in selected ACHD patients with isolated sinus node dysfunction.

Heart Rhythm 2026, in press

Azienda Ospedaliera dei Colli
Ospedale Monaldi

UOC CARDIOPATIE CONGENITE DELL' ADULTO (GUCH)
ARITMIE CONGENITE E FAMILIARI

Direttore: Dott. Berardo Sarubbi

GUCH@ospedalideicolli.it



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Multicenter Prospective Registry on Active-Fixation Leadless Pacemaker Implantation in Patients with Congenital Heart Disease

ACHIEVE Registry
(Aveir in Congenital Heart Disease EValuation)

Study Promoter

Dr. Berardo Sarubbi - *Adult Congenital Heart Disease Unit, Monaldi Hospital, Naples -Italy.*

Participating Centers

International multicenter registry involving tertiary referral centers for congenital heart disease and electrophysiology.

Proposed Investigators:

Dr. Oscar Cano - *Hospital Universitari I Politècnic La Fe and Centro de Investigaciones Biomédicas en RED en Enfermedades Cardiovasculares (CIBERCV), Valencia, Spain*

Dr. Victor Waldmann - *Unité Médico-Chirurgicale de Cardiologie Congénitale Adulte, Hôpital Européen Georges Pompidou, Paris, France*

Dr. Tom Wong - *Heart Rhythm Centre, Royal Brompton and Harefield Hospitals, Guy's and St. Thomas' NHS Foundation Trust, London, UK.*



Adult Congenital
Heart Disease Unit



The first rule of any technology used in a business is that automation applied to an efficient operation will magnify the efficiency.

The second is that automation applied to an inefficient operation will magnify the inefficiency....



Bill Gates

JOINT INTERNATIONAL CONGRESS IN ADULT CONGENITAL HEART DISEASE



Save the date!

NAPLES
2-3
OCTOBER
2026

See you soon in Naples

Scientific directors:

Margarita **Brida**
Michael A. **Gatzoulis**
Berardo **Sarubbi**
Giancarlo **Scognamiglio**

MAIN TOPICS

- Arrhythmia
- Advanced heart failure
- Challenges in percutaneous treatment
- Advanced imaging
- Role of AI
- Ageing and acquired heart disease
- Surgery for complex patients

Information and registration:

<https://www.defla.it/evento/joint-international-congress-in-adult-congenital-heart-disease/>



Organizing secretariat:

www.defla.it - - congressi@defla.it



Figure 5 Double inlet left ventricle transposition of great arteries, hypoplastic aortic arch after multiple surgeries, including the Glenn shunt (1-year-old). A transvenous dual-chamber pacemaker, atrial lead at the superior vena cava stump, ventricular lead punctured the Glenn shunt (14-year-old). A S-ICD for secondary prevention of SCD (24-year-old). Dual-chamber leadless pacemaker (26-year-old).⁴⁷

