

Luncheon panel: deep insight leadless pacing

LEADLESS ATRIAL PACING: FROM CLINICAL EVALUATION TO THERAPEUTIC DECISION

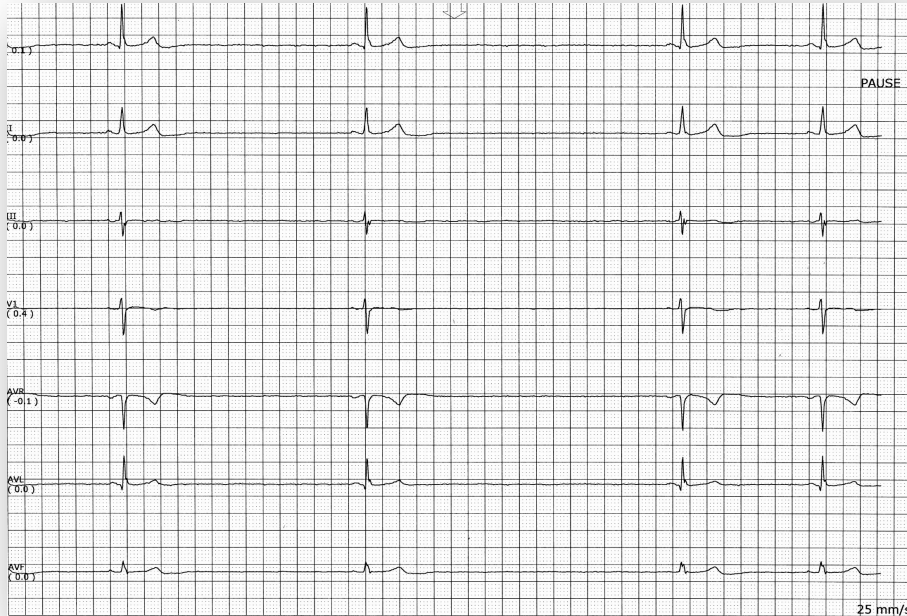
Dr. Danilo Ricciardi

**Fondazione Policlinico Campus Bio-Medico di
Roma**



CLINICAL CASE 1

Male, 78 yo, paroxysmal AF, sinus bradycardia and syncope



Bullous pemphigoid

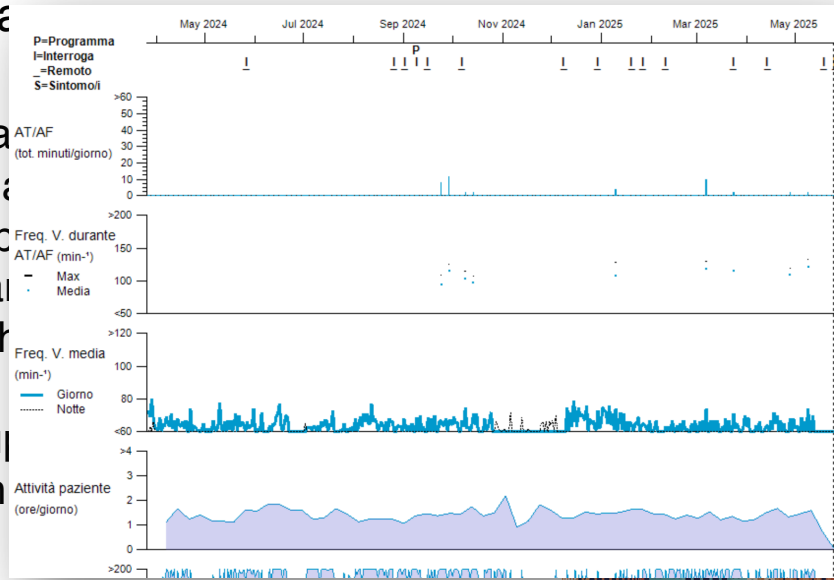


CLINICAL CASE 2

62 YO Female, HBP, Dyslip, previous ILR implant because of bradycardia and syncope (2019-2022)

Symptomatic for asthenia, presyncope and syncopal episodes with trauma, no pauses on loop recorder, only bradycardia

Comorbidities: Bilateral mastectomy + right axillary lymph node dissection, currently undergoing oncology follow-up, right mastectomy, oophorectomy in 2015 for fibromatosis, colon polyps, multiple adenomas, nodules on follow up, diverticulosis, spondyloarthritis, grade B esophagitis with hiatal hernia, hemorrhoids, multinodular thyroid disease, osteoporosis, L5/S1 disc herniation, T6, and T7, pulmonary hamartoma on follow-up, bilateral blepharitis; Sleep apnea syndrome on CPAP



CLINICAL CASE 3

- *Male 62 yo, DM, HBP, Dysl, severe CRF in dialysis, Obesity*
- ***May 2024** CRTd implant because of ischemic moderate HF, EF 40%, paroxysmal complete AVB, paroxysmal AF*
- ***Aug 2024** CRTd explant because of pocket infection and Micra AV leadless pacemaker implantation*
- *After few months he returns for a consultation because of **asthenia ad reduced exercise tolerance***



KEY QUESTIONS

DOES THE PATIENT HAVE A REAL INDICATION FOR PACING?

HOW CAN PROCEDURAL AND INFECTION RISK BE MINIMIZED?

WHAT IS THE OPTIMAL STRATEGY?





INDICATIONS

ESC guidelines recommend pacing in the presence of symptoms related to documented bradyarrhythmias and associated syncope.



CHOICE OF PACING MODALITY

The pacing modality should be individualized based on atrial function and **the patient's specific needs**



CLINICAL JUDGMENT

The application of guidelines requires **clinical judgment**, especially in complex patients, to optimize treatment



INNOVATION

Innovative solutions are integrated into clinical practice to improve therapeutic effectiveness.

2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy



RISKS OF TRANSVENOUS LEADS

- **Systemic & Local Infection:** Risk of pocket infections and potentially fatal endocarditis.
- **Vascular Issues:** Venous thrombosis and stenosis (often asymptomatic but complicating future procedures).
- **Mechanical Failures:** Lead insulation breach, conductor fracture, or dislodgement over time.
- **Tricuspid Valve Interference:** Mechanical damage or interference leading to tricuspid regurgitation.
- **Cardiac Injury:** Risk of myocardial perforation or cardiac tamponade during implantation or extraction.

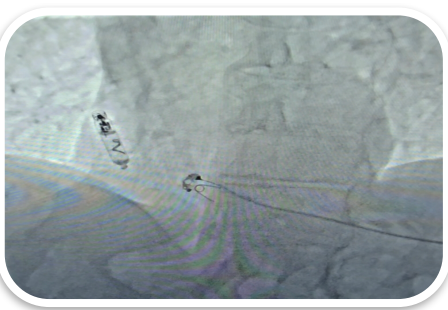


MANAGEMENT OF COMPLICATIONS & COMPLEX PROCEDURES

- For Transvenous Systems:
 - Extraction Complexity: Risks associated with transvenous lead extraction (TLE), especially for old, calcified leads.
 - Lead Revision: Management of redundant/abandoned leads and venous access preservation.
- For Leadless Devices:
 - End-of-Life (EOL) Strategy: Deciding between device abandonment (and "layering" of new devices) vs. percutaneous retrieval.
 - Retrieval Challenges: Increased complexity of retrieval after long-term fibrosis or encapsulation.
 - Procedural Mastery: Managing specialized complications such as femoral access site hematomas or embolization.



HOW MANY OPTIONS DO WE HAVE FOR LEADLESS PACING ?



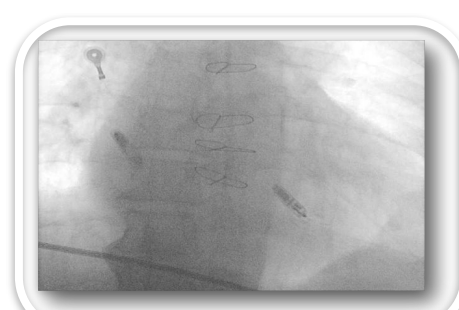
AAI



VVI/VDD



DDD



HYBRID



Dedicated leadless atrial pacing system

AR + VR

Active or passive fixation

Retrievability

VDD Technologies



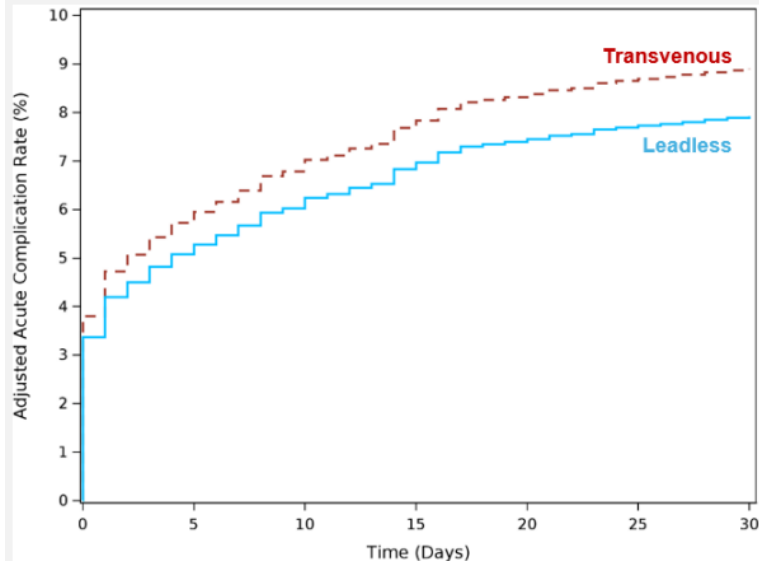
ORIGINAL ARTICLE **OPEN ACCESS**

Leadless Versus Transvenous Dual-Chamber Pacemakers: Real-World Evidence From AVEIR DR Coverage With Evidence Development Study

Monica Lo¹ | Anish K. Amin²  | Marcin Kowalski^{3,4} | Anne Kroman⁵ | Dilip Mathew⁶ | Valay Parikh^{3,4} | Stanislav Weiner⁷ | Jennifer M. Joseph⁸ | Leonard Ganz⁹ | Mohammed Mortada^{10,11} | AVEIR DR Study Group/Consortium



LEADLESS VS TRANSVENOUS DUAL-CHAMBER PACEMAKERS: REAL-WORLD EVIDENCE*



	Aveir DR (N = 759)	Transvenous (N = 77,422)	Odds Ratio (95% CI)	P-value
30-day Unadjusted	8.0%	8.3%	0.91 (0.63,1.32)	0.62
30-day Adjusted	7.9%	9.2%	0.85 (0.60, 1.20)	0.36

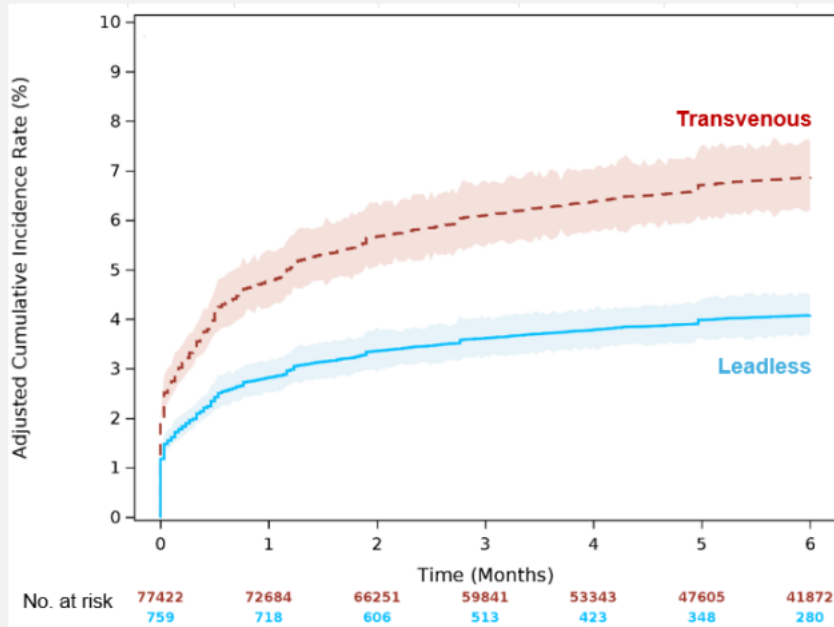
No significant difference in overall acute complications between AVEIR DR and Transvenous pacemakers.

Monica Lo and AVEIR DR Study Group/Consortium JCE 2026;



LEADLESS VS TRANSVENOUS DUAL-CHAMBER PACEMAKERS: REAL-WORLD EVIDENCE*

41% lower risk of overall chronic complications for AVEIR DR compared to Transvenous pacemakers at 6 months.



	Aveir DR (N = 759)	Transvenous (N = 77,422)	Hazard Ratio (95% CI)	P-value
6-month Unadjusted	4.2%	6.6%	0.63 (0.43, 0.92)	0.02
6-month Adjusted	4.1%	6.9%	0.59 (0.40, 0.86)	<0.01

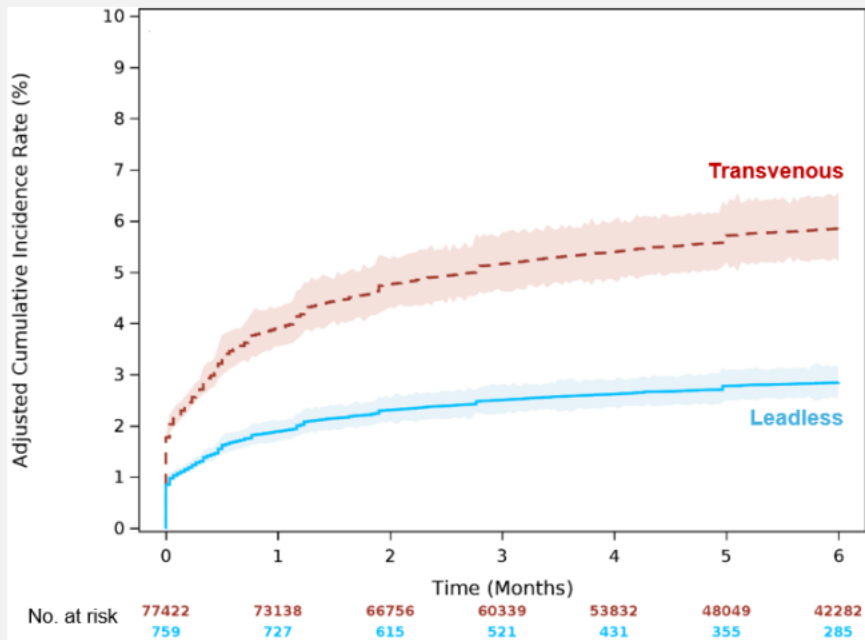
- Includes only a subset of the complications evaluated for the acute endpoint
- Rate includes the first 30 days

Monica Lo and AVEIR DR Study Group/Consortium JCE 2026;



LEADLESS VS TRANSVENOUS DUAL-CHAMBER PACEMAKERS: REAL-WORLD EVIDENCE*

52% lower risk of device-related complications for AVEIR DR compared to Transvenous pacemakers at 6 months.



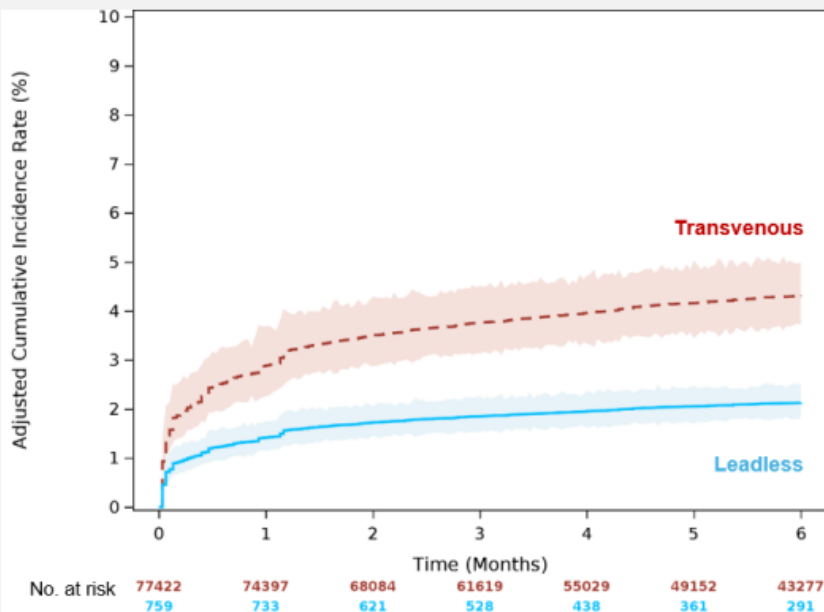
	Aveir DR (N = 475)	Transvenous (N = 59,565)	Hazard Ratio (95% CI)	P-value
Unadjusted	2.9%	5.7%	0.50 (0.32, 0.79)	<0.01
Adjusted	2.8%	5.9%	0.48 (0.30, 0.75)	<0.01

Monica Lo and AVEIR DR Study Group/Consortium JCE 2026;



LEADLESS VS TRANSVENOUS DUAL-CHAMBER PACEMAKERS: REAL-WORLD EVIDENCE*

51% lower risk of overall device reinterventions for AVEIR DR compared to Transvenous pacemakers at 6 months.



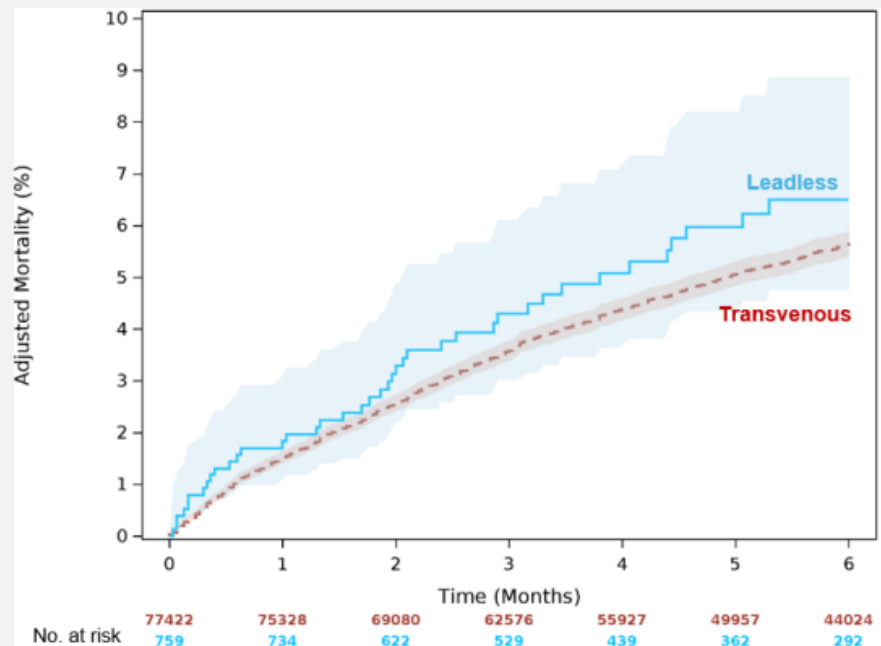
	Aveir DR (N = 759)	Transvenous (N = 77,422)	Hazard Ratio (95% CI)	P-value
Unadjusted	2.2%	4.2%	0.51 (0.31, 0.83)	<0.01
Adjusted	2.1%	4.3%	0.49 (0.30, 0.80)	<0.01

- Device reintervention includes revisions, replacements, removals, lead-related reinterventions, and upgrades to CRT or ICD.
- The most common reason for reintervention in the transvenous group was lead-related reinterventions (2.4%).

Monica Lo and AVEIR DR Study Group/Consortium JCE 2026;



LEADLESS VS TRANSVENOUS DUAL-CHAMBER PACEMAKERS: REAL-WORLD EVIDENCE*



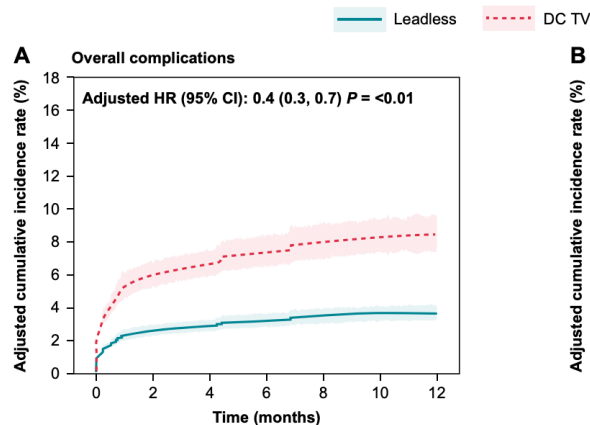
	Aveir DR (N = 759)	Transvenous (N = 77,422)	Hazard Ratio (95% CI)	P-value
30-Day Mortality				
Unadjusted	1.9%	1.3%	1.42 (0.86, 2.35)	0.18
Adjusted	1.8%	1.5%	1.21 (0.72, 2.02)	0.47
6-Month Mortality				
Unadjusted	6.8%	4.8%	1.41 (0.95, 2.10)	0.09
Adjusted	6.6%	5.6%	1.18 (0.79, 1.76)	0.43

Monica Lo and AVEIR DR Study Group/Consortium JCE 2026;

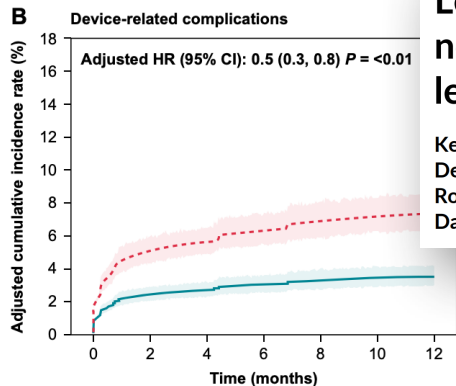


Leadless atrial versus transvenous pacing for sinus node dysfunction: 1-year outcomes from the leadless ARRIVE real-world study

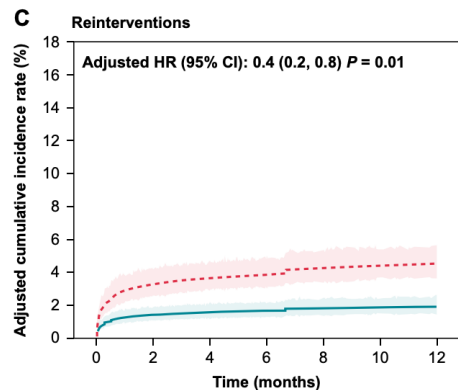
Kent R. Nilsson Jr ¹, Ulrika Birgersdotter-Green², Shmaila Saleem-Talib ³, Deepti Bettampadi ⁴, Zeyuan Yang⁴, Jorge O. Diaz ⁵, James K. Gabriels ⁶, Robert D. Schaller ⁷, Himanshu H. Shukla ⁸, Michael Kühne ⁹, Mauro Biffi ¹⁰, Daniel Hofer ¹¹, John Paisley¹², Yelena Nabutovsky ¹³, and Christophe Garweg ^{13*}



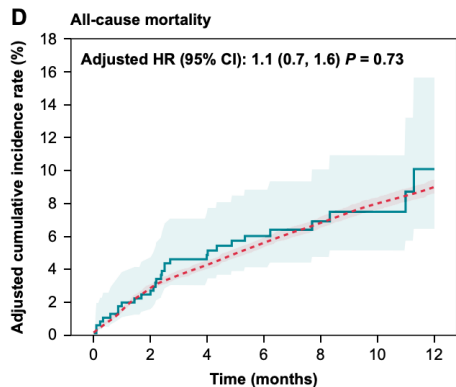
	428	396	340	241	162	105	49
Leadless	428	396	340	241	162	105	49
Dual-transvenous	39 881	36 899	33 664	28 457	23 422	18 055	12 758



	428	397	341	242	163	106	50
Leadless	428	397	341	242	163	106	50
Dual-transvenous	39 881	37 184	33 977	28 748	23 693	18 273	12 905



	428	401	344	246	164	106	50
Leadless	428	401	344	246	164	106	50
Dual-transvenous	39 881	37 932	34 717	29 394	24 259	18 734	13 241



	428	401	344	246	164	106	50
Leadless	428	401	344	246	164	106	50
Dual-transvenous	39 881	38 477	35 285	29 887	24 682	19 053	13 477

Comparison of :

- 1-year complications (A)
- device-related complications (B)
- reinterventions (C)
- all-cause mortality (D)





AVEIR™ AR

(*N* = 428)

VS.



Transvenous

(*N* = 39 881 dual-chamber, *N* = 389 right atrial)

30%



Lower 30-day complications with AVEIR™ AR

DCTV: OR 0.7 (0.5, 0.98), *P* = 0.04 RATV: OR 1.0 (0.6, 1.8), *P* = 0.94

60%



Lower 1-year complications with AVEIR™ AR

DCTV: HR 0.4 (0.3, 0.7), *P* < 0.01 RATV: HR 0.4 (0.2, 0.9), *P* = 0.02

60%



Lower 1-year reinterventions with AVEIR™ AR

DCTV: HR 0.4 (0.2, 0.8), *P* = 0.01 RATV: HR 0.3 (0.1, 0.8), *P* = 0.02



Similar all-cause mortality

DCTV: HR 1.1 (0.7, 1.6), *P* = 0.73 RATV: HR 0.7 (0.4, 1.2), *P* = 0.20

DCTV: dual-chamber transvenous

RATV: right atrial transvenous

Leadless atrial versus transvenous pacing for sinus node dysfunction: 1-year outcomes from the leadless ARRIVE real-world study

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Dual-chamber leadless systems: Twice the technology, double the long-term management challenges

**WHY NOT OPT FOR AN ATRIAL
LEADLESS DEVICE?**

**WHY NOT START WITH ATRIAL
PACING AND THEN CONSIDER DDD
PACING IF NEEDED?**



Successful implantation

Consistent electrical performance

Infections observed

Proven clinical benefit

Time for DDD upgrading





CONCLUSIONS



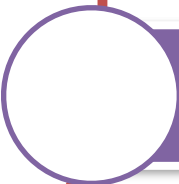
LEADLESS ATRIAL PACING

- Leadless atrial pacing is a new frontier with significant potential for complex patients



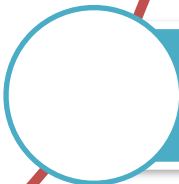
PERSONALIZED ASSESSMENT

- Thorough assessment and a personalized approach guide the choice of the most appropriate technology



THERAPEUTIC INNOVATION

- Leadless pacing expands therapeutic options, overcoming the limitations of traditional pacing



REAL CLINICAL BENEFIT

- Right patient, right technology, conscious decision

