

**LEADLESS VS. TRANSVENOUS DUAL-CHAMBER
PACEMAKERS:
REAL-WORLD EVIDENCE FROM
AVEIR™ DR COVERAGE WITH EVIDENCE DEVELOPMENT
(CED) STUDY**

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Disclosures

- Abbott – speaker, consultant
- Philips – speaker, consultant
- Biotronik – speaker
- PaceMate – Medical Advisory Board

Background and Objective

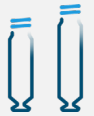
Background

- The U.S. Centers for Medicare & Medicaid Services (CMS) requires a coverage with evidence development (CED) study to provide Medicare insurance coverage for leadless pacemakers
- The purpose of the CED study is to compare complications and outcomes between leadless pacemakers (LP) and transvenous pacemakers (TP)
- Abbott has initiated a real-world AVEIR DR CED (DRIVE) study upon the U.S. Food and Drug Administration (FDA) approval of AVEIR DR

Objective

- To provide early results of the AVEIR DR CED study, which compares real-world 30-day and 6-month patient outcomes between AVEIR DR LP and dual-chamber TP

The World's First Dual Chamber Leadless Pacemaker System



- Two distinct devices



- Sensing and pacing in both the right atrial and right ventricular chambers



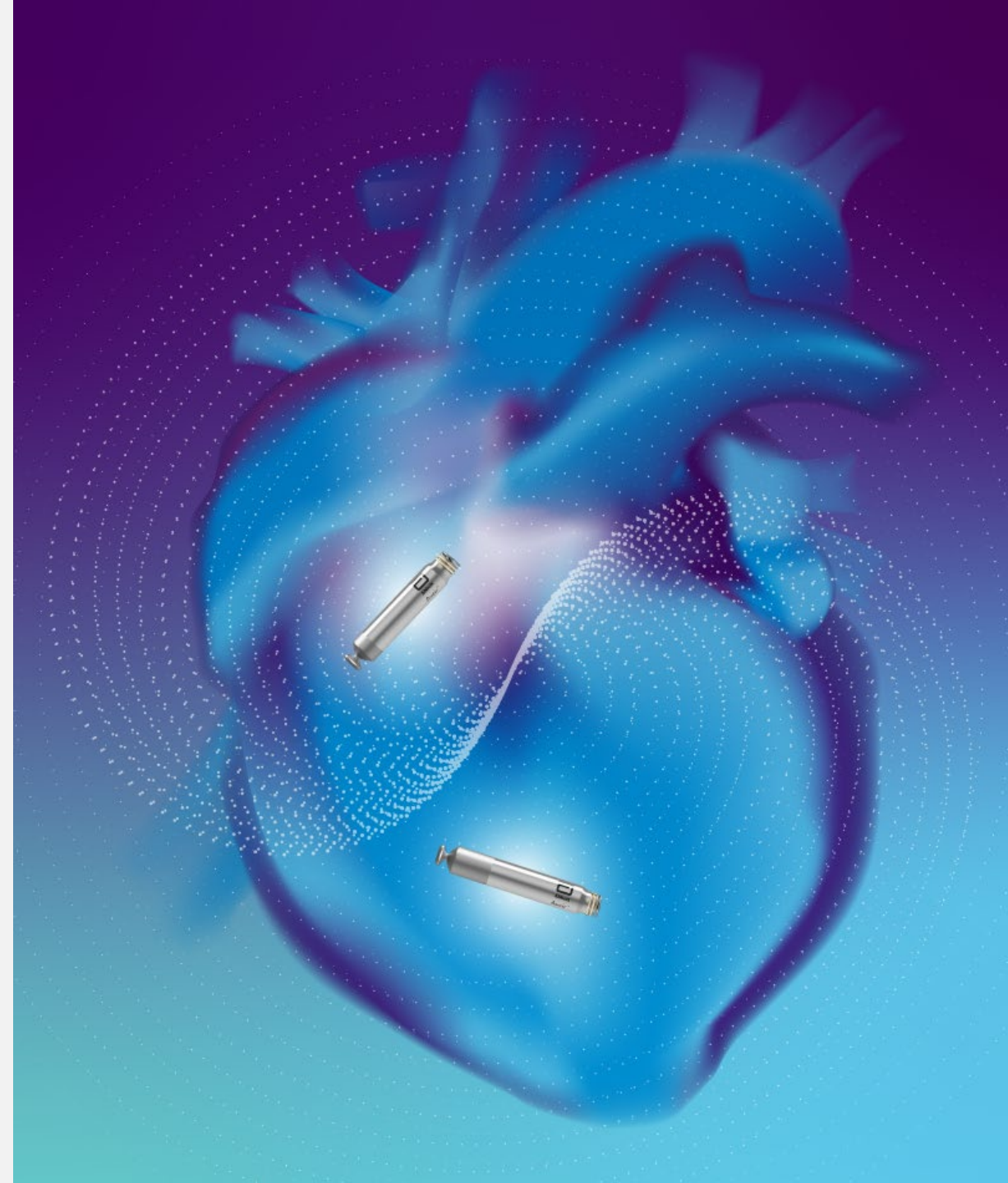
- Atrioventricular synchrony (AVS) made possible through proprietary implant-to-implant (i2i™) communication



- Upgradeable to match patient pacing needs today and over time



- 1.5T and 3T MRI Compatible



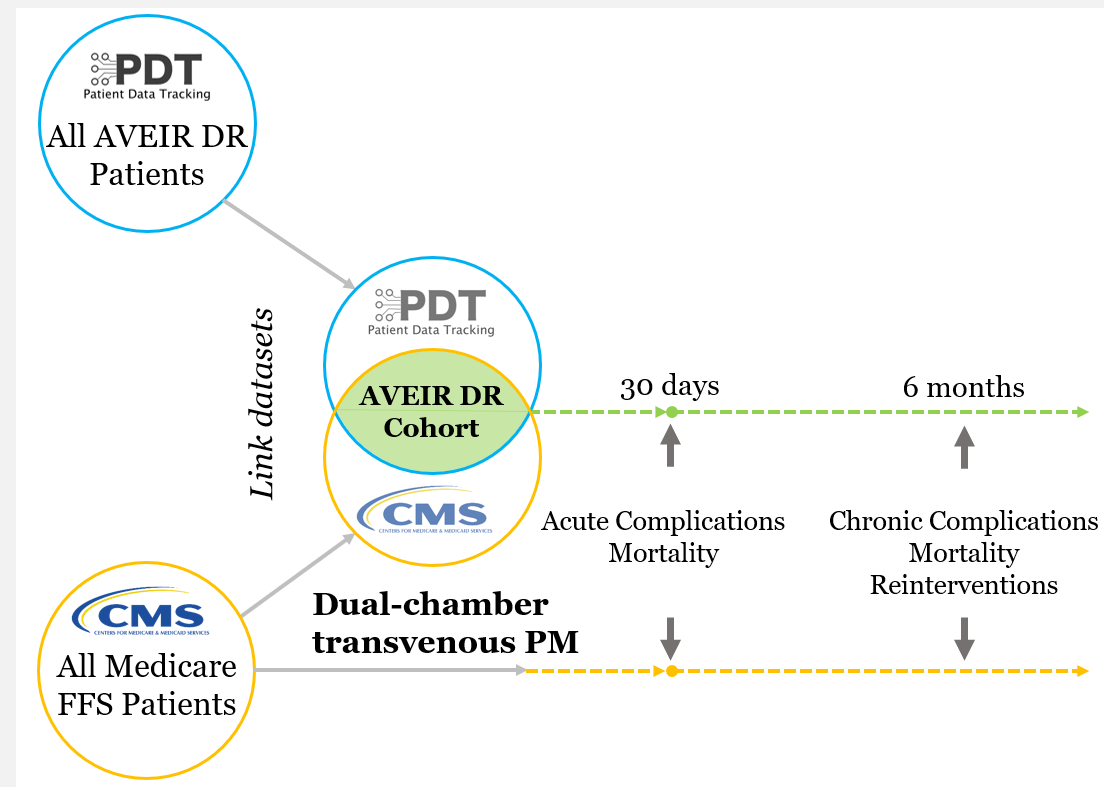
Methods

Study Design & Population

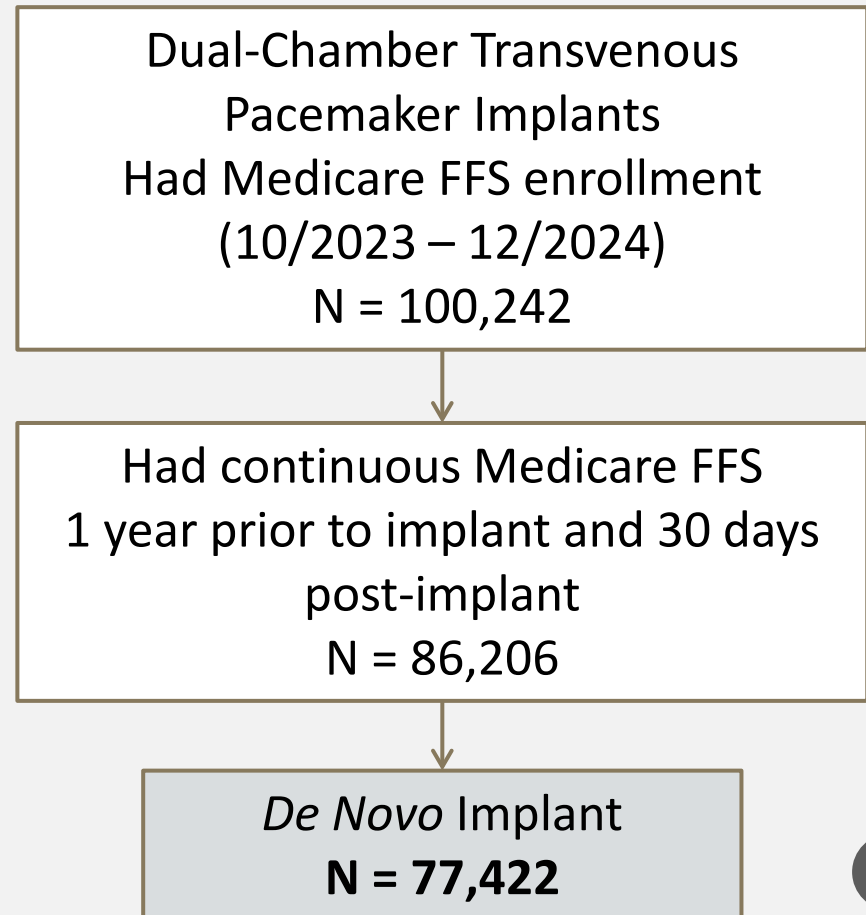
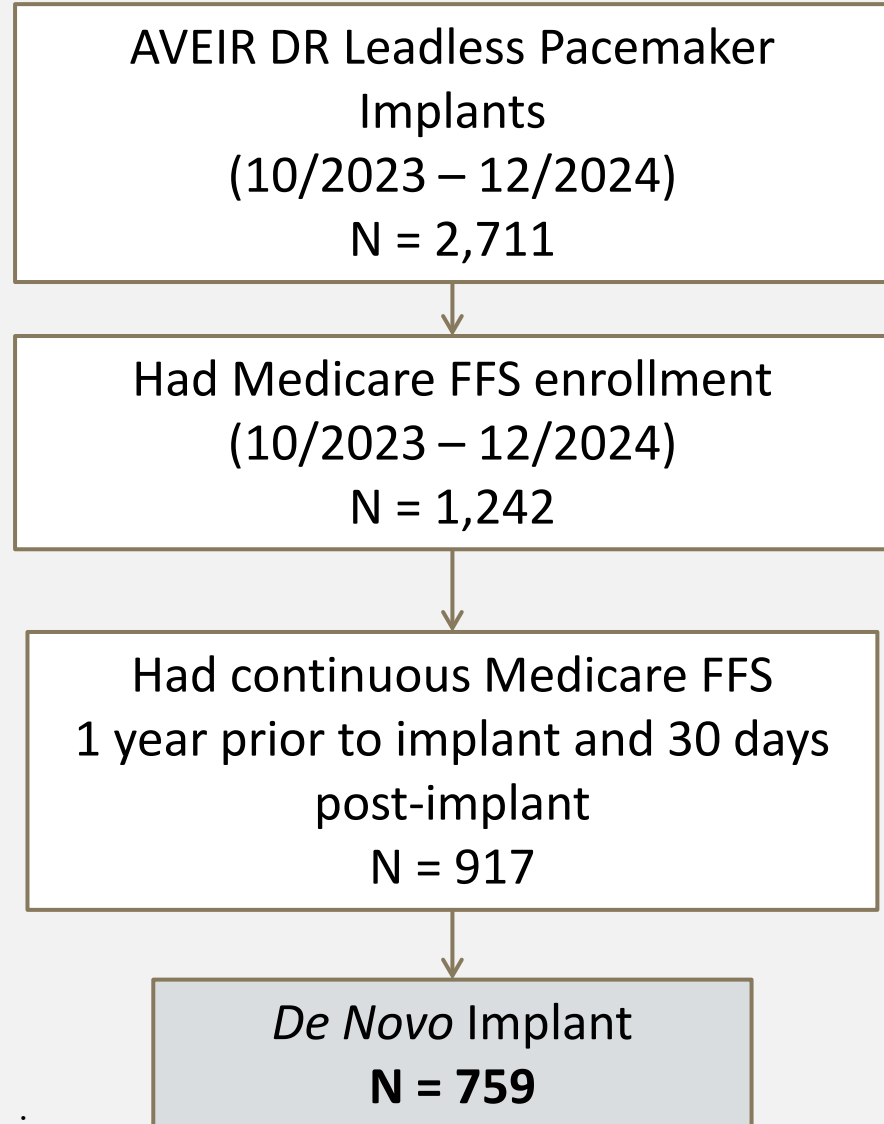
- Comparative observational study using Medicare Fee-for-Service (FFS) and Abbott device registration data
- De novo AVEIR DR LP (implanted 10/2023 –12/2024) or TP (all manufacturers, implanted 10/2023 –12/2024)
- ≥ 1 year FFS coverage pre-implant and coverage 30 days post-implant or until death if within 30 days

Outcomes & Statistical Analyses

- Unadjusted and adjusted comparison between AVEIR DR and TP
 - Acute complication rates at 30 days (Logistic regression)
 - Chronic complication rates at 6 months (Fine-Gray competing risk)
 - Reintervention rates at 6 months (Fine-Gray competing risk)
 - Mortality at 30 days and 6 months (Cox proportional hazard)



Cohort Diagram



Demographic and Hospital Encounter Characteristics

	Aveir DR (N = 759)	Transvenous (N = 77,422)	P-value
Demographic Characteristics			
Age, Mean (SD), y	78.5 (7.8)	79.6 (7.5)	<0.01
Female Sex	302 (39.8%)	29,301 (37.8%)	<0.01
Race			<0.01
White	651 (85.8%)	69,742 (90.1%)	
Black	46 (6.1%)	3,183 (4.1%)	
Asian/Hispanic/Native American	18 (2.4%)	1,932 (2.5%)	
Other/Unknown	44 (5.8%)	2,565 (3.3%)	
Dual Eligibility	71 (9.4%)	6,527 (8.4%)	0.36
Hospital Encounter Characteristics			
Inpatient Implant	437 (57.6%)	41,435 (53.5%)	0.03
Admission to Implant, Mean (SD), d	1.8 (4.1)	1.3 (2.6)	<0.01
Weekend Implant	<11	2,522 (3.3%)	<0.01
Admission through Emergency Room	214 (28.2%)	27,687 (35.8%)	<0.01
Temporary pacing during hospitalization	43 (5.7%)	5,246 (6.8%)	0.23

Higher % or
mean
AVEIR DR
Transvenous

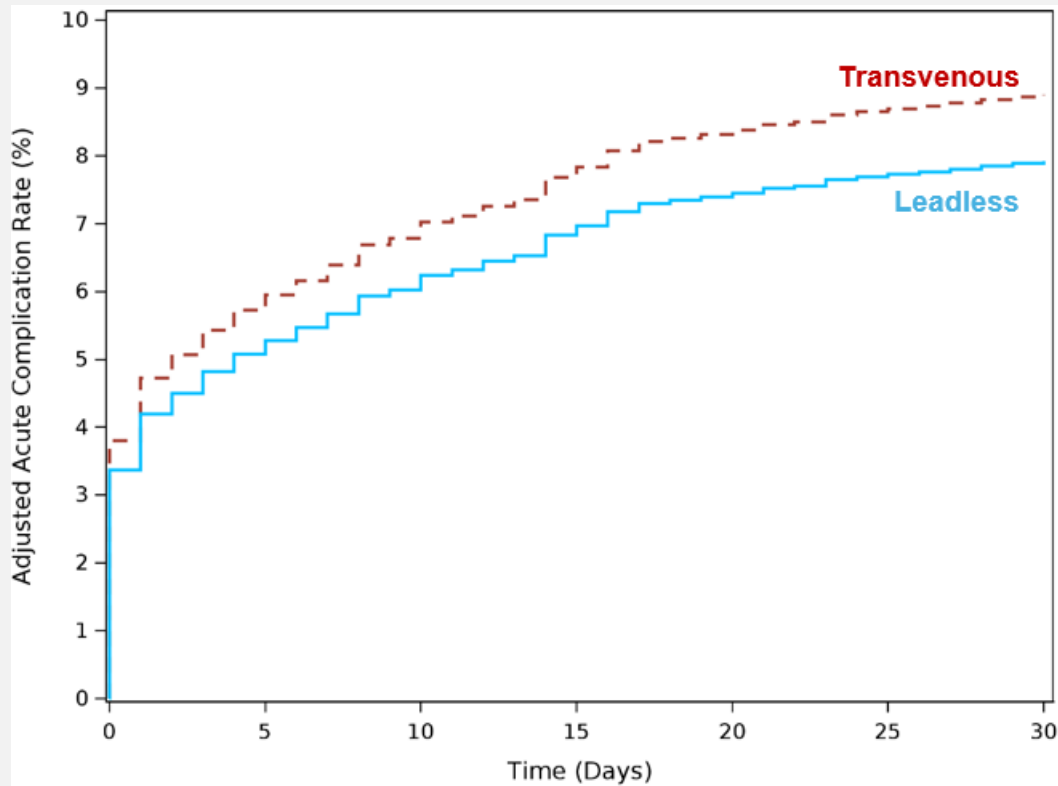
Clinical Characteristics

	Aveir DR (N = 759)	Transvenous (N = 77,422)	P-value
Clinical Characteristics			
Atrial and Ventricular Arrhythmias			
Atrial Fibrillation	440 (58.0%)	41,327 (53.4%)	0.01
Atrial Flutter	153 (20.2%)	14,464 (18.7%)	0.30
Ventricular Arrhythmia	164 (21.6%)	15,053 (19.4%)	0.13
AV block	470 (61.9%)	47,742 (61.7%)	0.88
Sinus node dysfunction	545 (71.8%)	49,352 (63.7%)	<0.01
Charlson Comorbidity Index, Mean(SD)	4.4 (3.2)	4.0 (3.0)	<0.01
Chronic Obstructive Pulmonary Disease	176 (23.2%)	16,583 (21.4%)	0.24
Coronary Artery Disease	451 (59.4%)	42,251 (54.6%)	<0.01
Diabetes	323 (42.6%)	30,619 (39.5%)	0.09
Heart Failure	286 (37.7%)	31,715 (41.0%)	0.07
Hyperlipidemia	663 (87.4%)	66,328 (85.7%)	0.19
Hypertension	713 (93.9%)	72,317 (93.4%)	0.56
Peripheral Vascular Disease	172 (22.7%)	16,017 (20.7%)	0.18
Recent infection due to cardiac implants/prosthetic devices	<11	33 (0.0%)	<0.01
COVID-19 within 30 days before implant	20 (2.6%)	1,336 (1.7%)	0.06
Prior Cardiovascular Events and Procedures			
Prior Coronary Artery Bypass Graft	104 (13.7%)	8,796 (11.4%)	0.04
Prior Acute Myocardial Infarction	135 (17.8%)	13,446 (17.4%)	0.76
Prior Percutaneous Coronary Intervention	135 (17.8%)	12,309 (15.9%)	0.16
Concomitant Atrial Ablation	20 (2.6%)	1,806 (2.3%)	0.58
Concomitant TAVR	12 (1.6%)	2,071 (2.7%)	0.06
Prior TAVR	11 (1.5%)	1544 (2.0%)	0.26
Renal Disease	367 (48.4%)	35,978 (46.5%)	0.30
End Stage Renal Disease	50 (6.6%)	972 (1.3%)	<0.01
Dialysis Dependence	48 (6.3%)	846 (1.1%)	<0.01
Tricuspid Valve Disease	234 (30.8%)	21,733 (28.1%)	0.09
Tricuspid Valve Regurgitation	136 (17.9%)	12,097 (15.6%)	0.08

Higher % or mean
AVEIR DR
Transvenous

Acute Complication Rate

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



	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

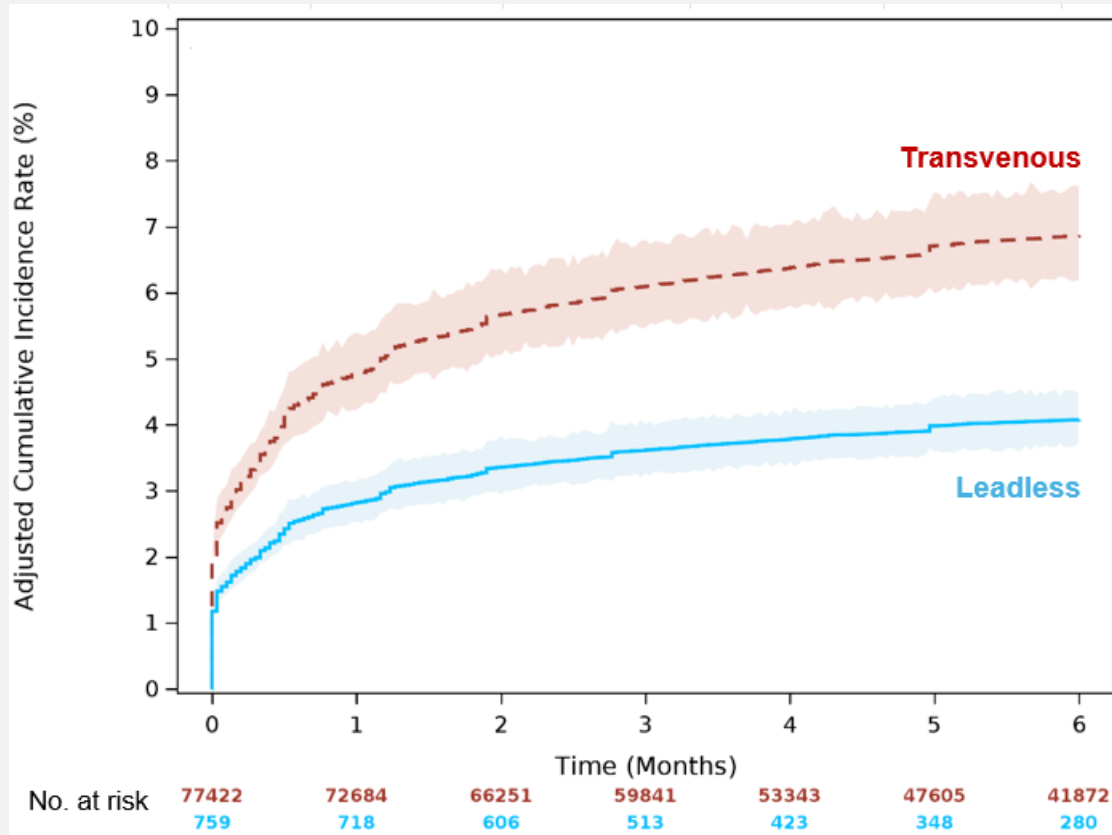
Acute Individual Complications

Individual Complication	Unadjusted			Adjusted		
	Aveir DR (N =759) n (%)	Transvenous (N = 77,422) n (%)	P-value	Aveir DR (N = 759) %	Transvenous (N = 77,422) %	P-value
Embolism and Thrombosis	18 (2.4)	1778 (2.3)	0.89	2.3	2.5	0.77
Deep vein thrombosis	11 (1.5)	859 (1.1)	0.37	1.4	1.2	0.75
Pulmonary embolism	<11	990 (1.3)	0.82	1.2	1.3	0.76
Thrombosis due to cardiac device	0	39 (0.05)	N/A	0	0.04	N/A
Embolism due to cardiac device	<11	<11	<0.01	0.1	0	N/A
Events at puncture site	<11	169 (0.2)	<0.01	1.0	0.5	0.07
Cardiac Effusion/Perforation	<11	419 (0.5)	0.02	1.2	0.6	0.047
Device-related complication	15 (2.0)	2890 (3.7)	0.01	2.0	3.9	<0.01
Device dislodgement	<11	1316 (1.7)	0.17	1.0	1.7	0.15
Infection	0	310 (0.4)	N/A	0	0.4	N/A
Hemorrhage	0	250 (0.3)	N/A	0	0.4	N/A
Device malfunction	<11	1076 (1.4)	0.28	0.9	1.3	0.36
Pain	0	137 (0.2)	N/A	0	0.2	N/A
Stenosis	<11	92 (0.12)	0.26	0.3	0.2	0.44
Pocket complications	N/A	434 (0.6)	N/A	N/A	N/A	N/A
Other complications						
Postprocedural hematoma	<11	166 (0.2)	<0.01	0.7	0.2	<0.01
Postprocedural hemorrhage	<11	69 (0.1)	<0.01	0.8	0.1	<0.01
Pericarditis	<11	564 (0.7)	0.15	1.2	0.8	0.24
Acute myocardial infarction	<11	88 (0.1)	0.03	0.4	0.2	0.33
Intraoperative cardiac arrest	<11	101 (0.1)	0.99	0.1	0.1	0.96
Bleeding or failure of vascular closure device requiring intervention	<11	92 (0.1)	<0.01	0.8	0.2	<0.01
Hemothorax	0	<11	N/A	0	0	N/A
Pneumothorax	N/A	905 (1.2)	N/A	N/A	N/A	N/A

Higher %
AVEIR DR
Transvenous

Chronic Complication Rate At 6 Months

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

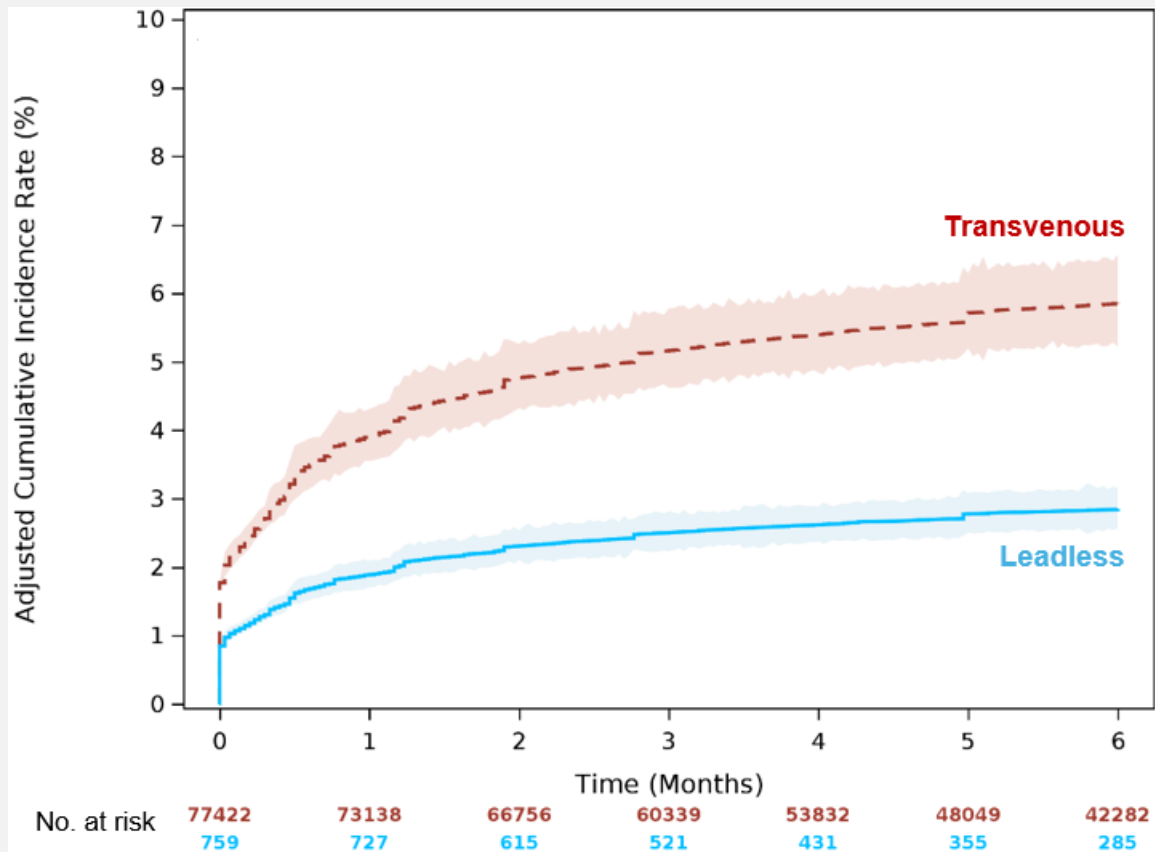
Chronic Individual Complications At 6 Months

Individual Complication	Unadjusted			Adjusted		
	Aveir DR (N = 759) n (%)	Transvenous (N = 77,422) n (%)	P-value	Aveir DR (N = 759) %	Transvenous (N = 77,422) %	P-value
Embolism and Thrombosis						
Thrombosis due to cardiac device	0.0	0.9	N/A	0.0	0.1	N/A
Embolism due to cardiac device	0.2	0.01	<0.01	0.1	0.0	N/A
Device-related complication	2.9	5.7	<0.01	2.8	5.9	<0.01
Device malfunction	1.5	2.2	0.18	1.4	2.2	0.20
Device dislodgement	1.3	2.3	0.08	1.2	2.3	0.06
Infection/inflammatory reaction	0.1	1.0	0.06	0.2	1.1	0.06
Hemorrhage due to cardiac device	0.0	0.4	N/A	0.0	0.4	N/A
Pain due to cardiac device	0.0	0.3	N/A	0.0	0.3	N/A
Stenosis due to cardiac device	0.5	0.2	0.25	0.5	0.3	0.32
Pocket complication	N/A	0.9	N/A	N/A	0.9	N/A
Other complications						
Pericarditis	1.3	1.2	0.71	1.2	1.2	0.94
Hemothorax	0.0	0.01	N/A	0.0	0.01	N/A

Higher %
AVEIR DR
Transvenous

Device-Related Complication Rate at 6 Months

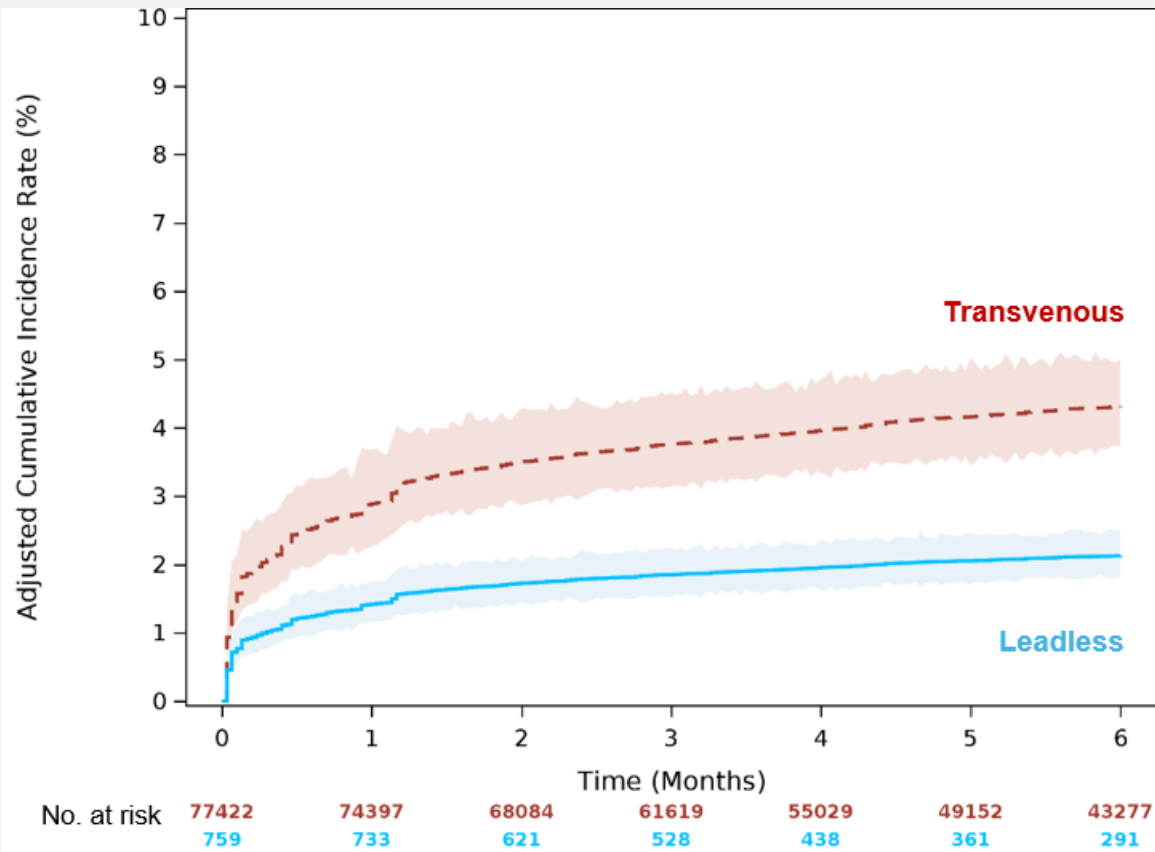
52% lower risk of device-related complications for AVEIR DR compared to Transvenous pacemakers at 6 months.



	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

Device Reintervention Rate at 6 Months

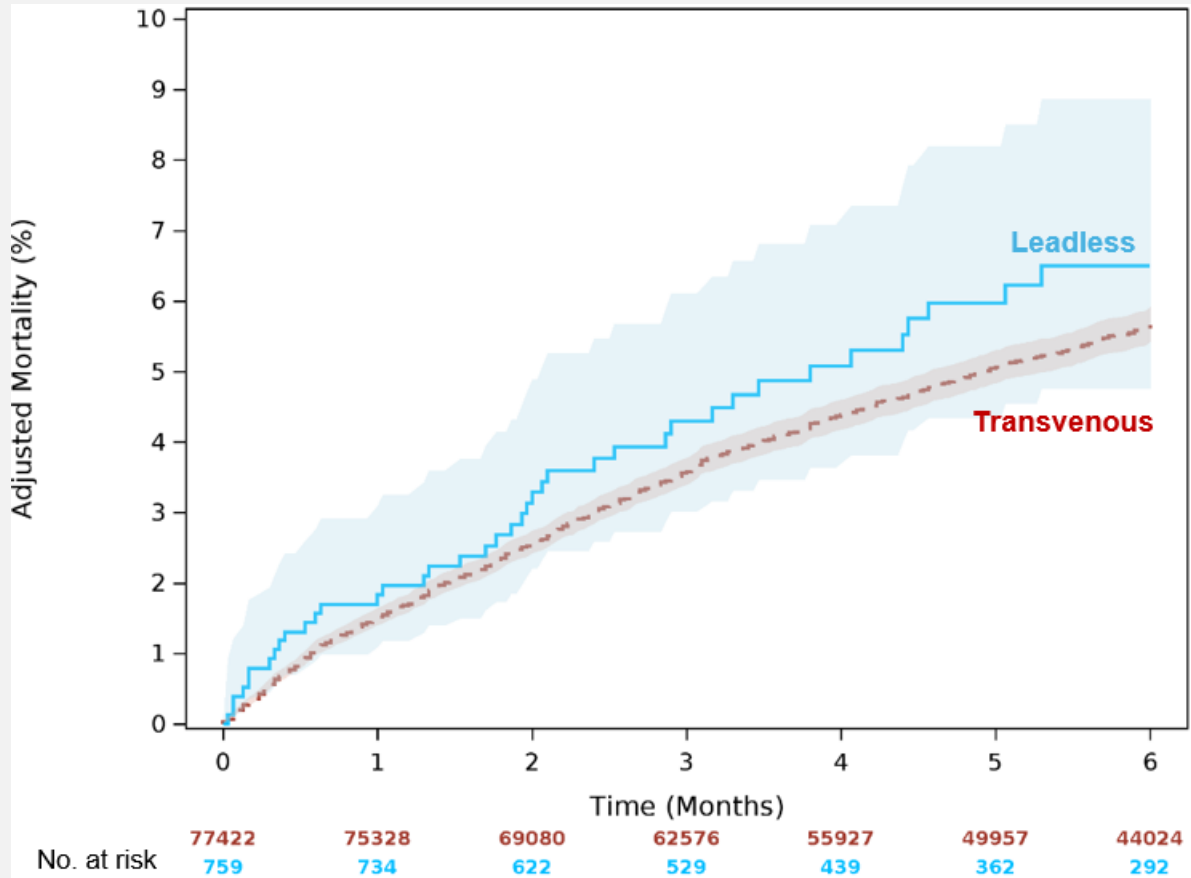
51% lower risk of overall device reinterventions for AVEIR DR compared to Transvenous pacemakers at 6 months.



	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%).

All-cause Mortality



	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

Conclusion

Compared to patients implanted with dual-chamber transvenous pacemakers, patients implanted with AVEIR DR leadless pacemakers had a higher comorbidity burden, yet **significantly fewer**:

- 30-day and 6-month device-related complications
- Overall complications at 6 months
- Device reinterventions at 6 months

There were **no significant differences** in:

- Overall complications at 30 days
- 30-day and 6-month mortality

These findings support the expanding role of leadless pacing in routine clinical practice.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Important Safety Information (USA):

Indications for Use: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following chronic clinical presentations: syncope, pre-syncope, fatigue, disorientation, and one or more of the indications which follow. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for patients exhibiting one or more of the following conditions: sick sinus syndrome; chronic, symptomatic second- and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with: sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of AV block or sinus arrest, chronic atrial fibrillation. MR Conditional: The AVEIR Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The AVEIR™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and the right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy.

The AVEIR™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the AVEIR™ Leadless Pacemaker is contraindicated in these cases:

Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.

Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.

Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor driven rates.

Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.

Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in the Product Materials section of the IFU) contained in the device and a thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the AVEIR™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: cardiac perforation; cardiac tamponade; pericardial effusion; pericarditis; endocarditis; thrombus formation; thromboembolism; valve damage or regurgitation; heart failure; pneumothorax/hemothorax; cardiac arrhythmias; diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation; palpitations; hypotension; syncope; cerebrovascular accident; infection; hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function; pacemaker syndrome; inability to interrogate or program the LP due to programmer or LP malfunction; intermittent or complete loss of capture, pacing or sensing (non-battery related); oversensing; increased capture threshold; inappropriate sensor response; corrupted, intermittent, or loss of i2i communications; interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic; battery malfunction/ premature battery depletion; device-related complications (premature deployment, device dislodgement/embolization of foreign material, inability to release/re-dock of the LP from catheter, helix distortion); additional surgery or intervention; death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: vascular access complications, such as perforation, dissection, puncture, groin pain; bleeding or hematoma; thrombus formation; thromboembolism; air embolism; local and systemic infection; peripheral nerve damage; general surgery risks and complications from comorbidities; such as dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and adverse events.

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