

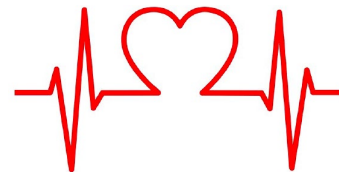
The 18th Asia Pacific Heart Rhythm Society Scientific Session (APHRS 2025)
November 13th, 2025

Dual-chamber leadless pacemaker outcomes in patients < 65 years of age

Rahul Doshi, MD, James Ip, MD, Vivek Reddy, MD, Derek Exner, MD, MPH, Pascal Defaye, MD, Robert Canby, MD, Maria Grazia Bongiorno, MD, Morio Shoda, MD, Gerhard Hindricks, MD, Nicole Harbert, MPH, Anu Bulusu, MS, Reinoud Knops, MD, PhD

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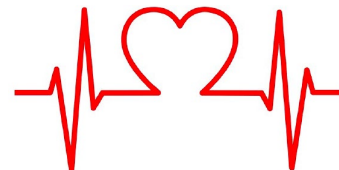
Arrhythmia Service Line



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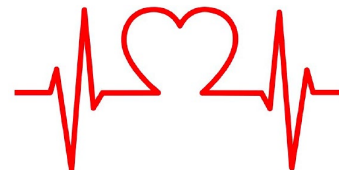
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Presenter Disclosures

- Abbott: consulting fees, steering committee, speaking honoraria
- Boston Scientific: consulting fees, steering committee, speaking honoraria
- Impulse Dynamics: advisory board, speaking honoraria
- Kestra Medical: steering committee
- Medtronic: consulting fees
- Zoll Medical: steering committee

The AVEIR™ DR i2i IDE trial was funded by Abbott



Background

- Safety and performance of the AVEIR™ dual-chamber leadless pacemaker (LP) previously shown in all adult age groups through 12-months.

Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

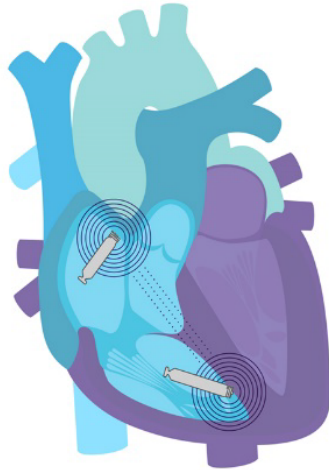


One-Year Safety and Performance of a Dual-Chamber Leadless Pacemaker

Reinoud E. Knops¹, MD, PhD; James E. Ip², MD; Rahul Doshi³, MD; Derek V. Exner⁴, MD, MPH; Pascal Defaye⁵, MD; Robert Canby⁶, MD; Maria Grazia Bongiorno⁷, MD; Morio Shoda⁸, MD; Gerhard Hindricks⁹, MD; Petr Neuzil¹⁰, MD; Mayer Rashtian¹¹, MD; Karel T.N. Breeman¹², MD; Jordan R. Nevo¹³, MS; Leonard Ganz, MD; Chris Hubbard, MBA; Anu Bulusu, MS; Vivek Y. Reddy¹⁴, MD

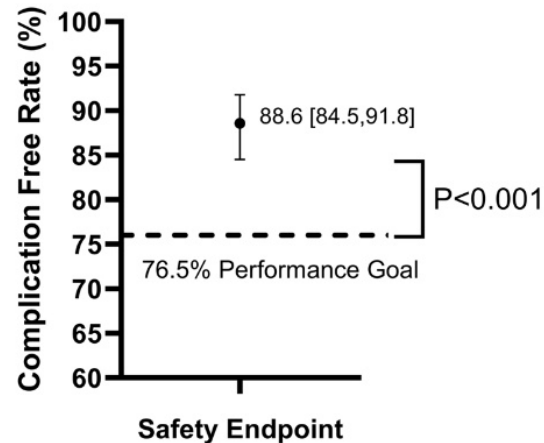
One-Year Safety and Performance of a Dual-Chamber Leadless Pacemaker

Wireless
Implant-to-Implant Communication

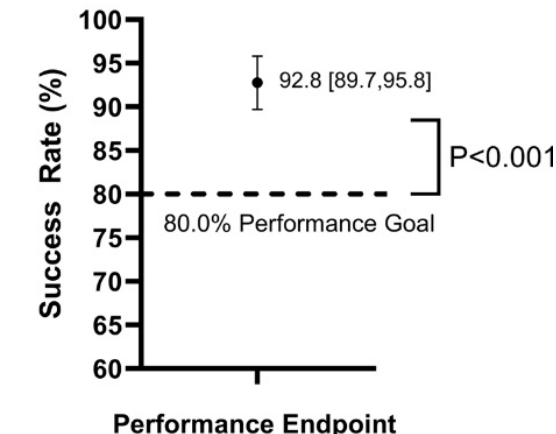


N = 300

12M Safety



12M Performance



(Atrial Capture \leq 3.0V & P-Wave Sensing \geq 1.0mV)

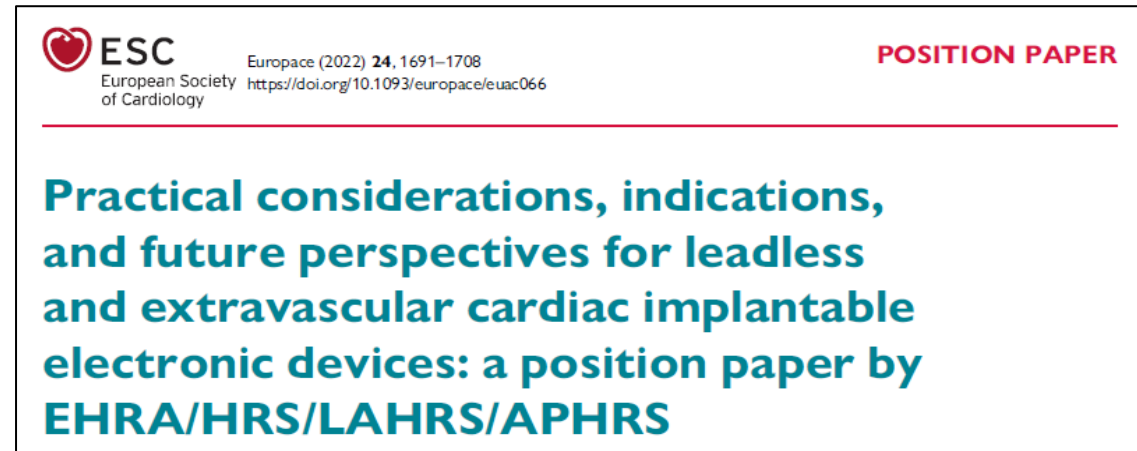
Error Bars represent 95% Confidence Intervals

Background

- **Current Leadless Pacemaker Guideline/Position Paper references:**
 - Focus on ventricular LP use and use in patients ≥ 65 years of age
- **LP's may be more advantageous in younger patients**
 - *Higher activity levels & longer average survival could lead to higher lead related complications with transvenous systems*
- **HRS Consensus Statements for Lead Management/Extraction & Management of Patients with Bradycardia:**
 - *To be updated with leadless pacemaker information in 2026 & 2027*

Goal:

- **Investigate 12-month outcomes of dual-chamber LPs in younger age groups, specifically in patients < 65 yr and ≥ 65 yr.**



AVEIR™ Dual-Chamber Leadless Pacemaker System

AVEIR™ DR Dual Chamber Leadless Pacemaker System

Loadable, Active Fixation Device Design



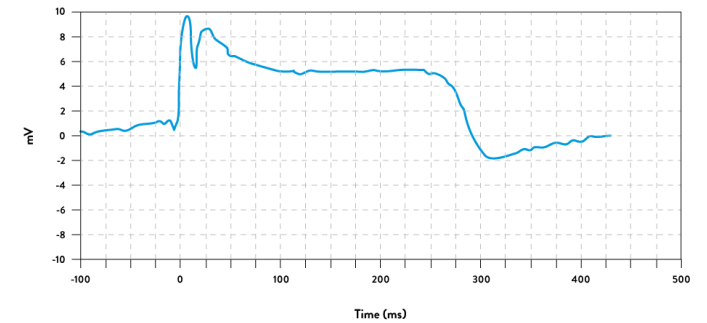
AVEIR™ Delivery and Retrieval Catheters

Designed For Ergonomic, Single Operator Use



AVEIR™ Link Module and Merlin™ Patient Care System (PCS)

No Additional Cost, Fits Current Programmer



Methods

– AVEIR™ DR i2i™ IDE study:

- Prospective, multi-center, global, non-randomized, single-arm study
 - Enrolled up to 550 patients at up to 85 centers worldwide
 - Data collection: Implant, pre-discharge, 1, 3, 6, and 12-months follow-up
 - Patients with dual-chamber pacing indications received de novo AVEIR DR leadless pacemaker
 - Split the cohort into two age groups
 - **<65 yr vs. ≥65 yr**
- Evaluated the following in each group:
 - Complication free rate, composite success rate of acceptable atrial pacing/sensing thresholds and mean i2i throughput at 12-mo post implant
 - Complications defined as device or procedure-related serious events & adjudicated by independent CEC
 - Acceptable atrial pacing/sensing thresholds defined as ≤ 3.0 V at 0.4 msec and P wave of ≥ 1.0 mV
 - Atrioventricular synchrony (AVS) success at 3-mo post implant
 - Defined as a paced or sensed ventricular beat ≤ 300 msec of atrial paced or sensed beat in $\geq 70\%$ of evaluable cardiac cycles during a 5-minute seated recording
 - Battery longevity assessed at 12-mo post implant

Results – Baseline Characteristics & Medical History

Baseline Characteristics & Medical History	All Subjects (N=452)		
	<65 yrs (n=121) Mean ± SD or %, n	≥65 yrs (n= 331) Mean ± SD or %, n	P-value
Age (years)	52.4±11.7	76.1±6.3	<0.0001
Gender, Female	48.7% (59/121)	34.7% (115/331)	0.0067
Primary Pacing Indication			
Sinus Node Dysfunction	67.8% (82/121)	65.0% (215/331)	NS
AV Block	28.1% (34/121)	31.4% (104/331)	NS
3 rd degree	55.9% (19/34)	35.6% (37/104)	0.0363
Atrial Fibrillation	21.5% (26/121)	42.6% (141/331)	<0.0001
Atrial Flutter	4.96% (6/121)	12.08% (40/331)	0.0336
Hypertension	43.0% (52/121)	74.9% (248/331)	<0.0001
Diabetes	16.5% (20/121)	27.8% (92/331)	0.0140
Hyperlipidemia	37.2% (45/121)	68.0% (225/331)	<0.0001
Coronary heart disease	19.0% (23/121)	39.9% (132/331)	<0.0001
Myocardial infarction	5.8% (7/121)	12.4% (41/331)	0.0437
Tricuspid Valve Disease	13.2% (16/121)	24.2% (80/331)	0.0118
Prior transvenous lead extraction	15.7% (19/121)	4.5% (15/331)	<0.0001

¹ From t-test. ² From Chi-square test. All p-values are two-tailed and not from pre-specified hypothesis testing.

Results – Procedural Characteristics & Implant Success Rate

Procedural Characteristics	All Subjects (N=452)		
	<65 yrs (n=121) Mean ± SD	≥65 yrs (n= 331) Mean ± SD	P-value ¹
Total Procedure Time - min.			
Ventricular	25.8 ± 15.2	26.0 ± 18.0	0.4912
Atrial	37.9 ± 21.9	43.7 ± 24.5	0.0043
Total	70.1 ± 31.9	76.3 ± 32.1	0.0194

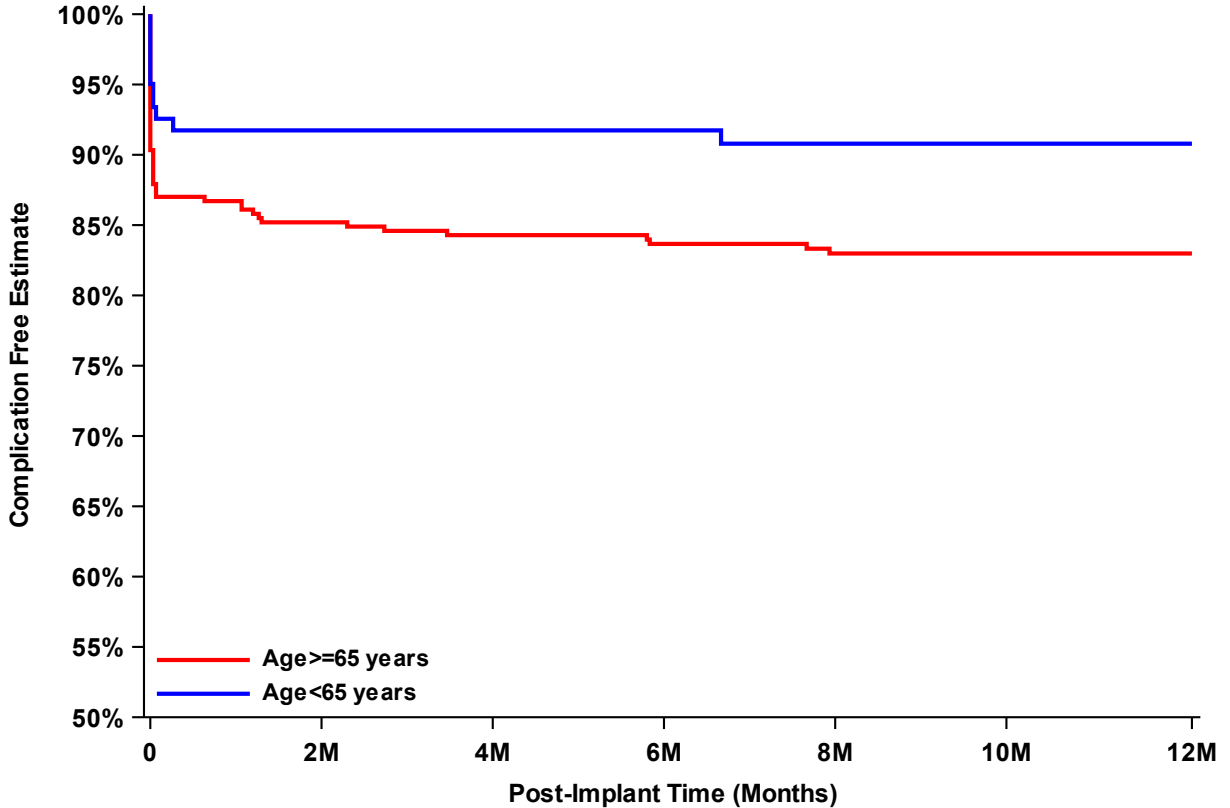
¹ From Chi-square test. All p-values are two-tailed and not from pre-specified hypothesis testing.

Implant Success = Both leadless pacemakers implanted with established i2i communication

Implant success rate: < 65 yr = 99.2% & ≥ 65 yr = 97.3%

- < 65 yr age group displayed shorter atrial implant and total implant procedure time.
- Both age groups displayed similar implant success rates (p-value = NS diff)

Results – Higher 12-month Complication Free Rate in < 65 yr group



- Within the first-year post implant, 88.6% of all complications from both age groups occurred within 90 days of implant.

	Age < 65 yrs % (n/N) 95% CI	Age ≥ 65 yrs % (n/N) 95% CI	P-value*
12-month complication free rate	90.9% (110/121) [84.3%, 95.4%]	83.1% (275/331) [78.6%, 87%]	0.0374

* p-value calculated with Fisher Exact test, are two tailed and not from pre-specified hypothesis testing

Results – Complication type and timeframe for < 65 yr group

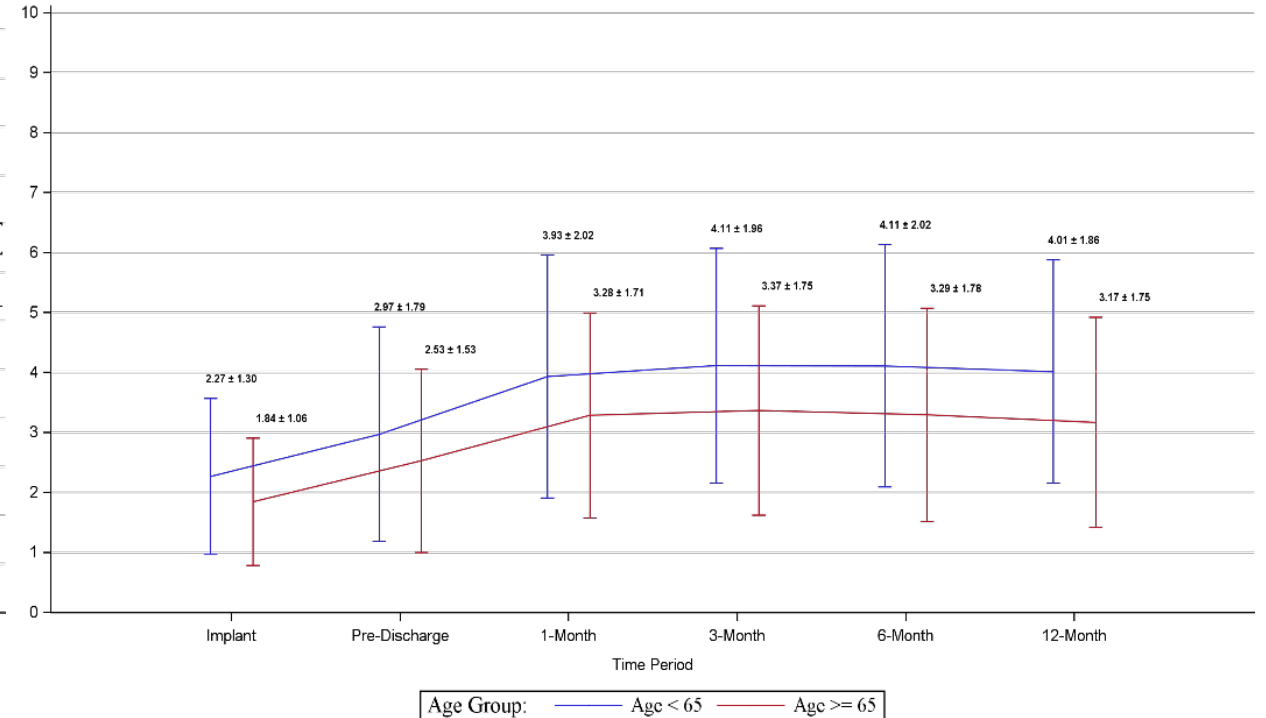
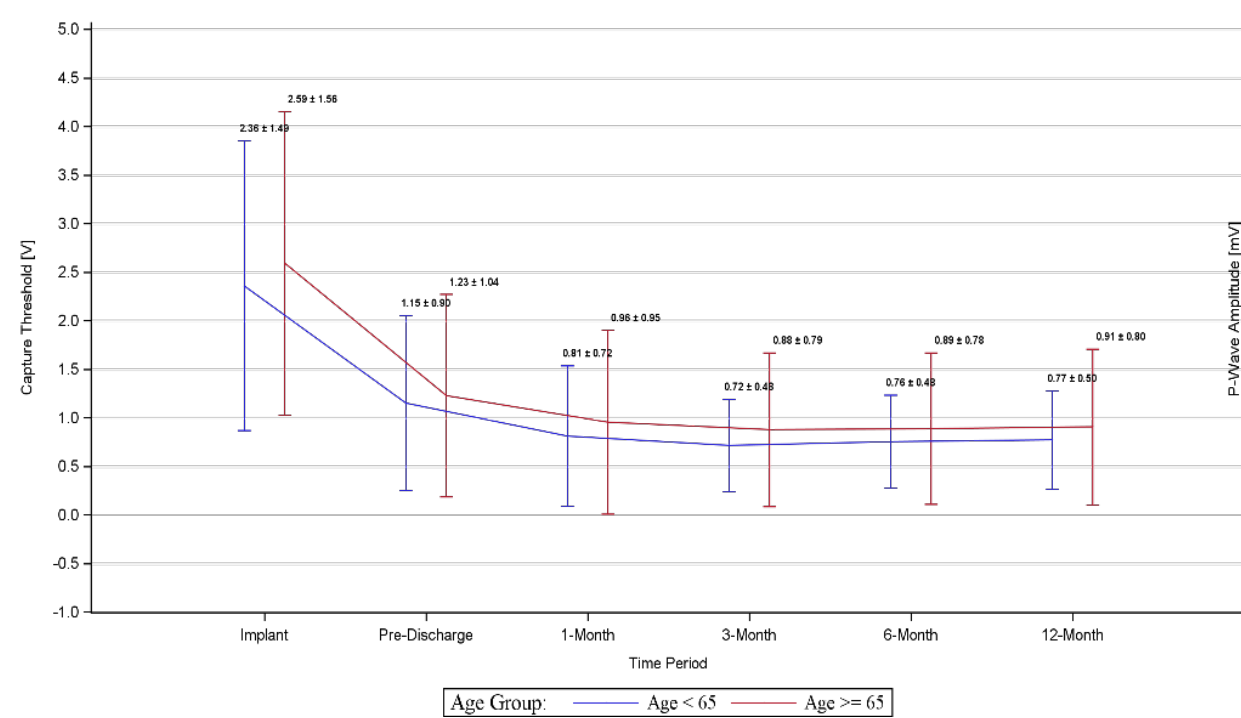
Event	Complications* (n=121) Event count (N,%)			
	# of Events	Within 2 days of implant	Within 3-90 days post implant	> 90 days post implant (91-365 days)
Access Site Oozing	1 (1, 0.8%)	1 (1, 0.8%)		
Cardiac Arrhythmia - Atrial Fibrillation	2 (2, 1.7%)	2 (2, 1.7%)		
Device Dislodgement (Intraprocedural & Postprocedural)	3 (3, 2.5%)	2 (2, 1.7%)	1 (1, 0.8%)	
Heart Failure	1 (1, 0.8%)			1 (1, 0.8%)
Inadequate Fixation During Implant with LP Migration	1 (1, 0.8%)	1 (1, 0.8%)		
Oral Pain	1 (1, 0.8%)	1 (1, 0.8%)		
Pacemaker Syndrome	1 (1, 0.8%)		1 (1, 0.8%)	
Total	10 (9, 7.4%)	7 (6, 5.0%)	2 (2, 1.7%)	1 (1, 0.8%)



Results – Complication type and timeframe for ≥ 65 yr group

Event	Complications (n=331), Event count (N,%)			
	# of Events	Within 2 days of implant	Within 3-90 days of implant	Within 91-365 days of implant
Access Site Bleeding Event	3 (3, 0.9%)	3 (3, 0.9%)		
Arterial Laceration	1 (1, 0.3%)	1 (1, 0.3%)		
Cardiac Arrhythmia – Atrial Fibrillation, Complete AV Block, Pre-Syncope	5 (5, 1.5%)	4 (4, 1.2%)		1 (1, 0.3%)
Cardiac Perforation/Tamponade	2 (2, 0.6%)	2 (2, 0.6%)		
Cardiopulmonary Arrest	1 (1, 0.3%)	1 (1, 0.3%)		
Capture Threshold issue (Intermittent Capture, Threshold Elevation)	6 (6, 1.8%)	3 (3, 0.9%)	1 (1, 0.3%)	2 (2, 0.6%)
Device Dislodgement (Intraprocedural/Postprocedural)				
Due to inadequate fixation	9 (7, 2.1%)	5 (4, 1.2%)	3 (3, 0.9%)	1 (1, 0.3%)
Due to Mechanical Dislodgement	1 (1, 0.3%)	1 (1, 0.3%)		
False Magnet Mode	1 (1, 0.3%)			1 (1, 0.3%)
Heart Failure	1 (1, 0.3%)		1 (1, 0.3%)	
Inability to release and redock the LP	1 (1, 0.3%)	1 (1, 0.3%)		
Inadequate Fixation during Implant with/without LP Migration	3 (3, 0.9%)	3 (3, 0.9%)		
Intermittent or Loss of i2i communication	1 (1, 0.3%)		1 (1, 0.3%)	
Palpitations	1 (1, 0.3%)	1 (1, 0.3%)		
Pericardial Effusion or Rub	3 (3, 0.9%)	3 (3, 0.9%)		
Pleural Effusion	1 (1, 0.3%)	1 (1, 0.3%)		
Urinary Retention	1 (1, 0.3%)	1 (1, 0.3%)		
Total	41 (38, 11.4%)	30 (27, 8.2%)	6 (5, 1.5%)	5 (4, 1.2%)

Results – Higher 12-month composite success rate of acceptable¹ atrial pacing and sensing threshold in < 65 yr group



	Age < 65 yrs % (n/N) 95% CI	Age ≥ 65 yrs % (n/N) 95% CI	P-value ²
12-month composite success rate of acceptable atrial pacing/sensing thresholds*	96.8% (91/94) [91%, 99.3%]	89.5% (229/256) [85%, 92.9%]	0.0307

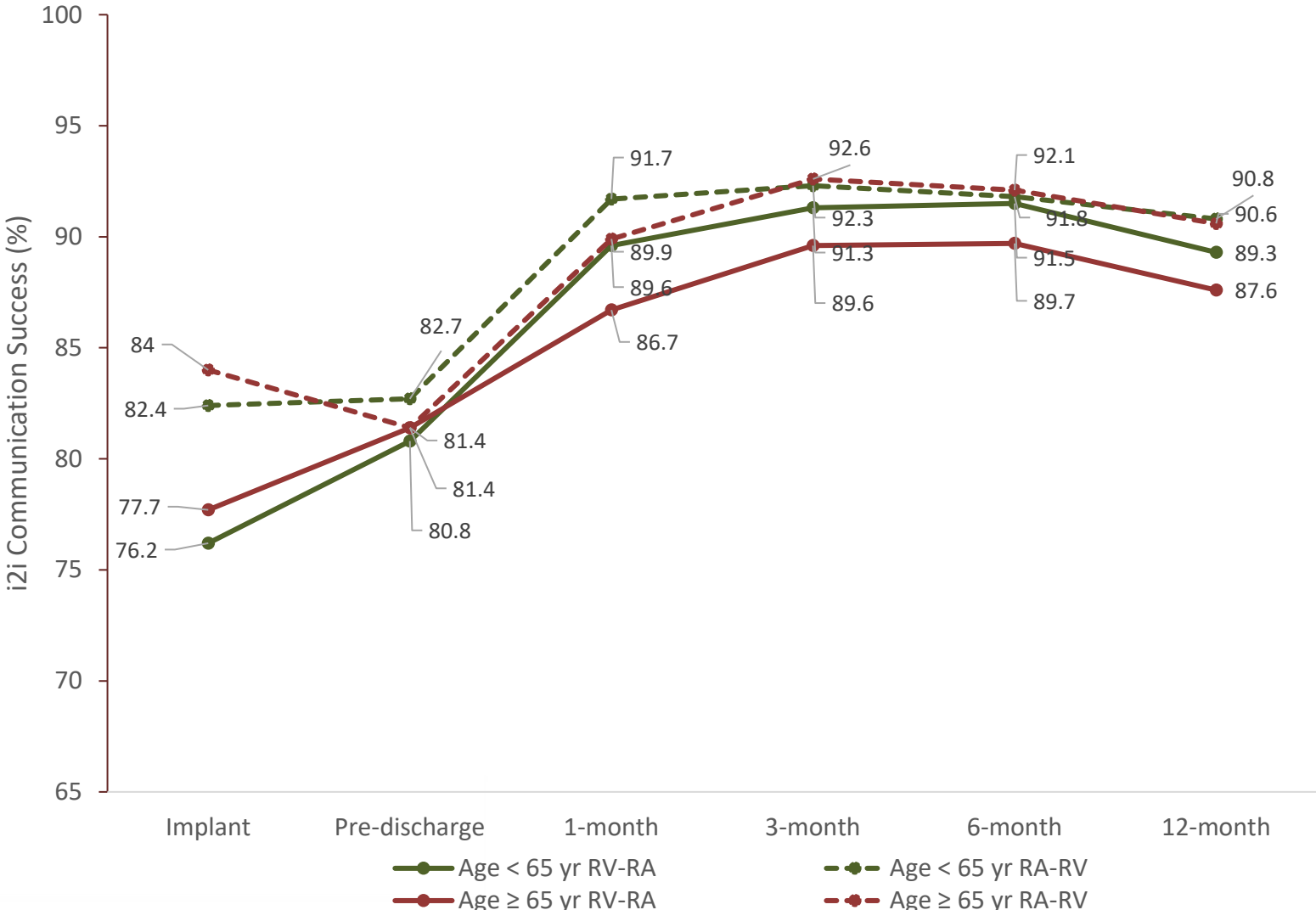
¹ Acceptable atrial pacing/sensing thresholds defined as ≤3.0 V at 0.4 msec and P wave of ≥1.0 mV

² p-value calculated with Fisher Exact test, are two tailed and not from pre-specified hypothesis testing

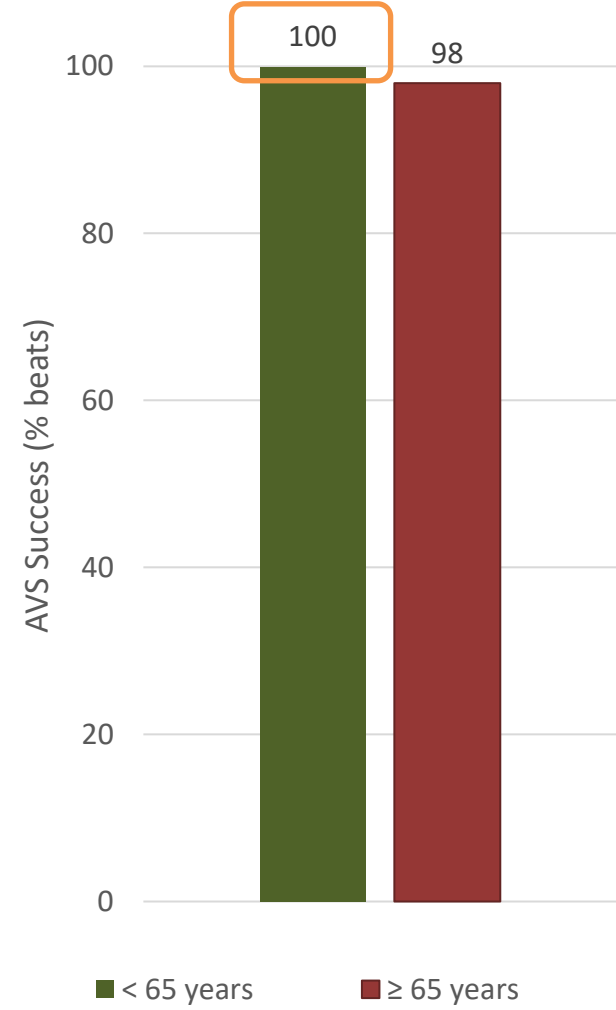
* Analysis completed with available 12-month data.

Results: Similar i2i™ communication success & AVS between age groups

i2i communication success by age group through 12-months
(p-value = NS diff)



AVS success rate at 3-months
between age groups
(p-value=NS diff)



Results – Similar Battery longevity at 12-months for both age groups (All pacing modes)

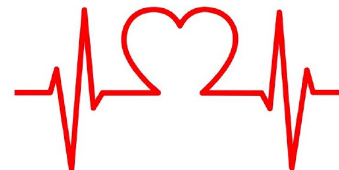
	Projected remaining battery longevity (All pacing modes) Mean ± SD [95% CI] (n)	
	Age < 65 yrs (years)	Age ≥ 65 yrs (years)
Atrial	5.6 ± 3.7 [4.8, 6.4] (86)	5.4 ± 4.1 [4.8, 5.9] (246)
Ventricular	11.2 ± 5.9 [9.9, 12.5] (87)	10.1 ± 5.2 [9.5, 10.8] (247)

Conclusions

- Patients in the < 65 yr group were likely to have a history of a transvenous lead extraction and a shorter atrial implant and total implant procedure time.
- Implant success was high in both age groups
- Both age groups displayed favorable safety and performance outcomes through 12-months
 - *< 65 yr group displayed significantly higher freedom from complication and composite atrial success rate than the ≥65 yr group*
- Specifically, patients <65 yrs demonstrated 100% rate of AVS (despite presumable higher peak heart rates and greater activity)
- Projected remaining battery longevity was similar between the age groups
- **Within this analysis, the AVEIR DR leadless pacing system is especially suitable for younger patients requiring a high percentage of AV Synchrony.**

Limitations

- Age analysis is a post hoc analysis and not pre-specified
- The < 65 yr group is a smaller sample size
- Single arm study





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Thank you!

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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