Putting It All Together
Pacing Option for Every Patient
Recorded Case Reviews

Heart Rhythm
Bringing the world of EP together.
April 24-27, 2025 • San Diego, CA

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St. Bernards Medical Center
The Heart of Great Medicine
Arrhythmia Research Group
Heart Rhythm Society

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Disclaimers

The views and experience expressed during this presentation are those of the speaker(s) and do not necessarily reflect the views of Abbott. This program is not intended for continuing education credits for any healthcare professional. The information presented is consistent with applicable FDA guidelines.

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Disclosures

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- **54 YO Male admitted with CAD s/p PCI, PAF and symptomatic sinus bradycardia on ILR monitoring**
- **Echo – normal , valves normal**
- **ILR showing multiple symptom transmissions for sinus bradycardia in 40's**
- **ECG – Sinus Rhythm**

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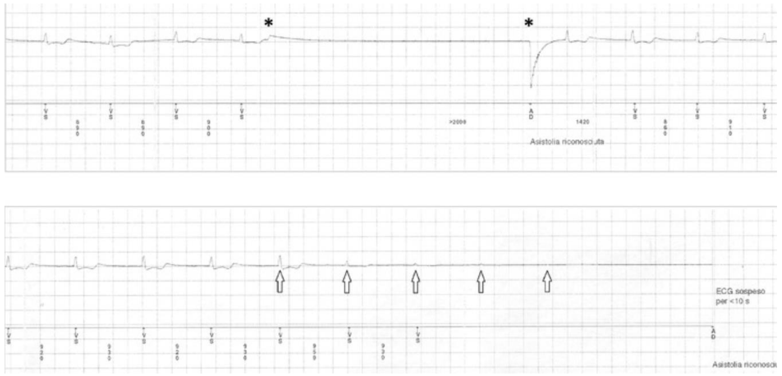
- 72 YO female admitted with Syncope and Shoulder Fracture
- Mild Dementia, COPD on low dose steroids
- Echo – normal , valves normal except moderate AS
- ILR showing multiple long pauses
- ECG – Sinus Rhythm with 1st degree AVB
- BMI < 25



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Treatment Considerations

- **Leadless pacing**
  - **Relatively older patient**
  - **Malignant bradycardia**

- **Aveir DR**[1]
  - **Recovery**
  - **High risk patient**
  - **Current need for Atrial Pacing and potential Ventricular Pacing**

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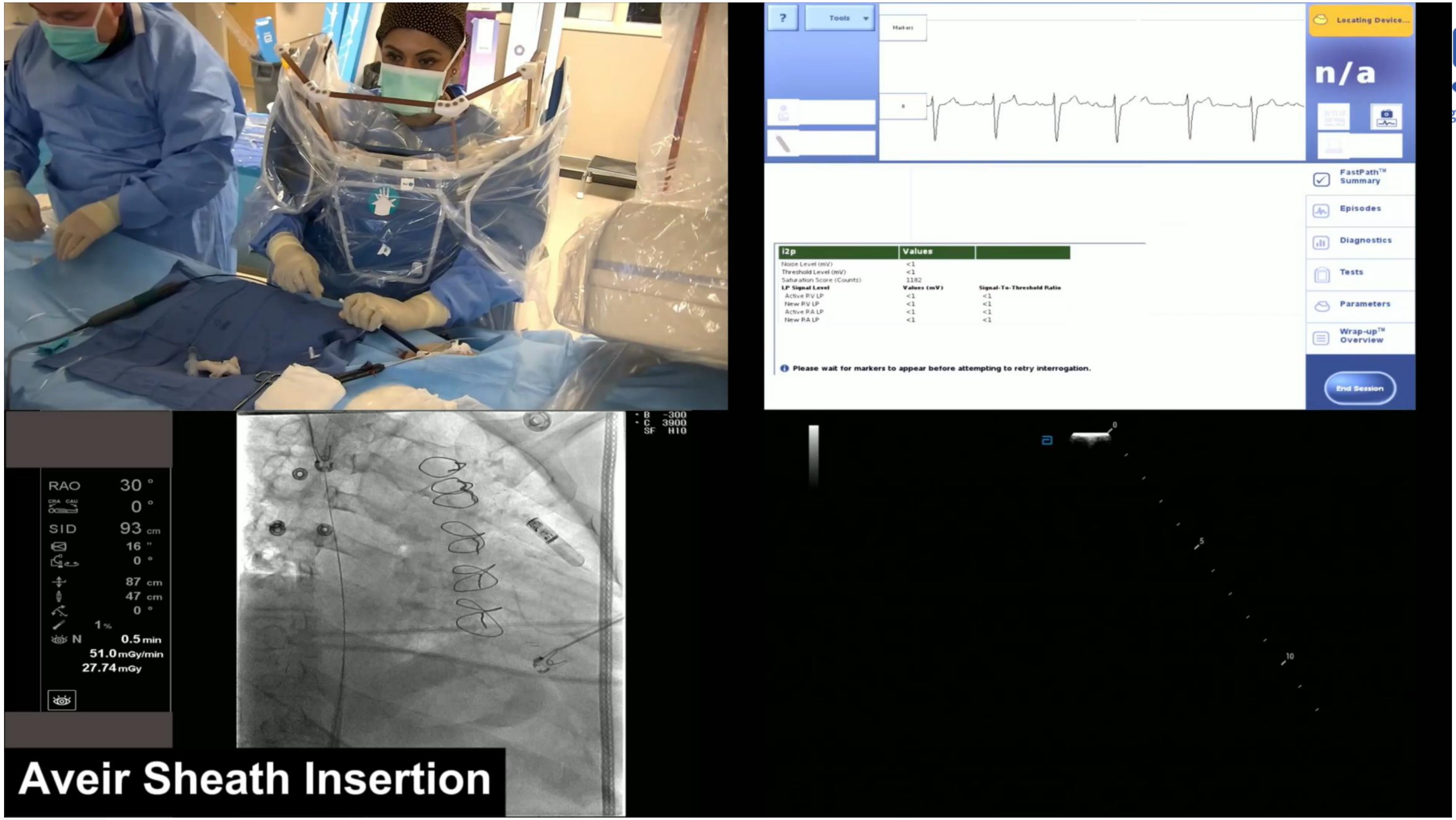
1. **Aveir DR**
AVEIR(Tm) DR LP System *[Tes Sawyer]*



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Summary

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- Two distinct devices
- Sensing and pacing in both the right atrial and right ventricular chambers
- Atrioventricular synchrony (AVS) via implant-to-implant (i2i™) communication
- Upgradeable to match the patient's pacing needs today and over time
- 1.5T and 3T MRI Compatible

Advancement of leadless pacing into other cardiac chambers and device to device communication, with introduction of the DR system[1] has opened up possibilities towards complete elimination of transvenous leads in many patients.

A Paradigm Shift

THANK YOU
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1. system
DR LP System [Tes Sawyer]

HRS Late Breaking Clinical Trial (LBCT) Presentation

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FIRST-IN-HUMAN RESULTS

ABBOTT ANNOUNCES FIRST-IN-WORLD LEADLESS PACING PROCEDURES IN THE LEFT BUNDLE BRANCH AREA OF THE HEART

- Abbott's investigational AVEIR™ Conduction System Pacing (CSP) leadless pacemaker system is specifically designed to deliver pacing to the left bundle branch area, activating the heart's natural conduction system
- The device has received U.S. Food and Drug Administration Breakthrough Device Designation, which expedites the review of innovative technologies
- By creating a new pacing approach for the left bundle branch area of the heart, Abbott continues to pursue technologies to revolutionize care for people with slow or irregular heart rhythms

ABBOTT PARK, Ill., Dec. 17, 2024 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the successful completion of the world's first in-human leadless left bundle branch area pacing

- Session Title: LB-495068 Late-Breaking Clinical Trials and Science: Clinical Innovations
- Session Date/Time: April 27, 2025 from 11:15 AM to 12:15 PM
- Presenter: Dr. Vivek Reddy
- Presentation: **A Leadless Pacemaker System for Left Bundle Branch Area Pacing – First in Human Experience**
- Presentation Time: 11:45 AM to 11:55 AM

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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.

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: 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; 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.

™ Indicates a trademark of the Abbott group of companies.
‡ Indicates a third-party trademark, which is property of its respective owner.

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1. **v2.0**
Mandatory update to v1.0 [Deanna Gish]

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