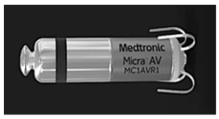
Leadless Pacemakers: What do Anesthesiologists need to Know

Scott Streckenbach, MD
Cardiac Anesthesia Group
Mass General Hospital

1

Leadless Pacemakers



7

Lecture Objectives

1. Review the leadless pacemakers you will encounter
2. Discuss the clinical issues you should understand to confidently take care of patients with these devices
3. Review some electrophysiology principles applicable to all pacemakers

8

Leadless Pacemakers

- **Already Being Implanted:**
  - Medtronic Micra (2016)
  - Medtronic Micra AV (2020)
  - Abbott Aveir VR (2022)
- **Under Clinical Investigation:**
  - Abbott Aveir leadless atrial pacemaker
  - Boston Scientific Empower leadless vent. pacemaker

9

Medtronic Micra

12

Medtronic Micra

17

Transcatheter Insertion: 23 Fr Sheath

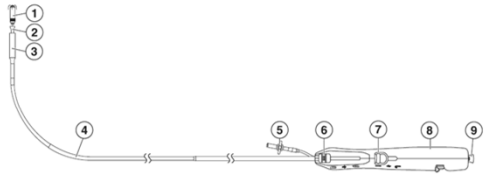
19

Catheter-Based System

20

Transcatheter Insertion

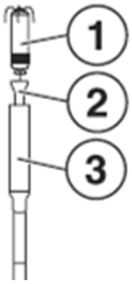
Figure 22. Overview of the Micra transcatheter pacing system



1 Micra device
2 Device recapture cone
3 Device cup
4 Delivery catheter
5 Flush port
6 Device deployment button
7 Catheter curve deflection button
8 Delivery system handle
9 Tether port

21

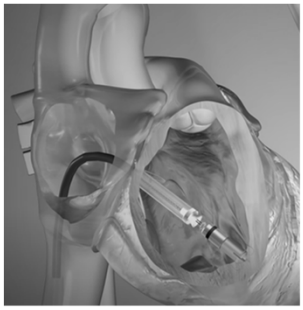
Catheter-Based Implant



22

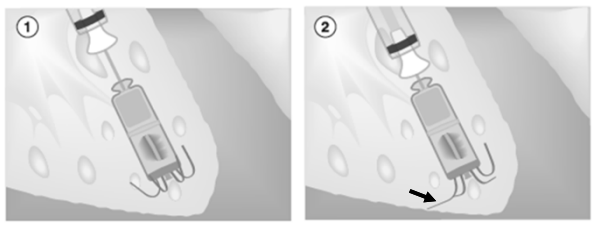
Catheter Based Insertion

1. Delivery catheter with Micra LP advanced into the RV through 23 Fr sheath
2. Once the catheter is in good position, the device cup is retracted over the LP and the tines engage the myocardium
3. Engagement confirmed with a “Pull and Hold” test



26

Pull and Hold Test



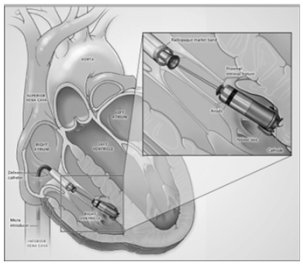
1. Device tines curved toward the device when LP deployed at the implant site.
2. When under traction, the tines should flare outward, indicating adequate myocardial engagement

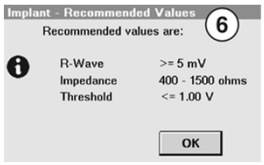
Medtronic Micra User Manual

29

Lead Parameters Assessment

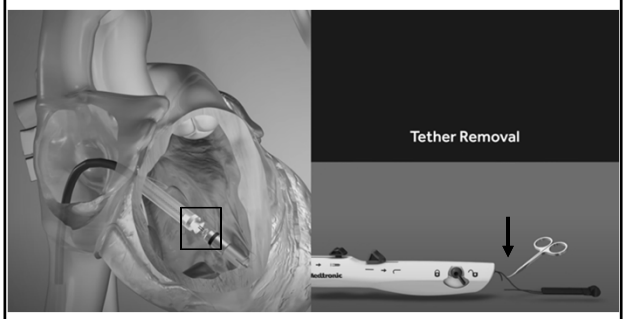
- Lead measurements
  - R-wave amplitude
  - Impedance
  - Capture threshold





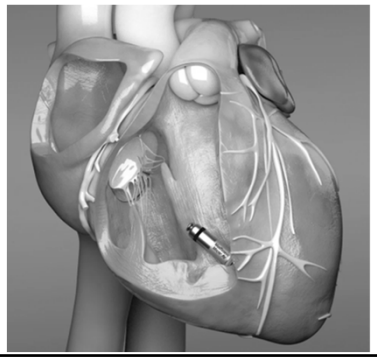
30

Releasing the Micra



34

Medtronic Micra Final Position



36

Implant Video (1:00-2:49)

37

Micra Retrieval

- Medtronic Micra LPs are NOT designed for retrieval after implanation
  - Scar tissue encapsulation can be significant
- You may see patients who have 2 leadless pacemakers: one functioning and the other turned off.

38

Medtronic Micra Pacing Modes

- VVI
- VVIR
- VOO
- OVO
- Device Off

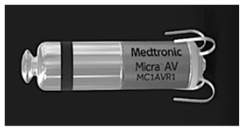
39

Limitation of the Micra

- Unable to track intrinsic atrial rhythm, so primarily limited to patients who are in chronic AF or who rarely need the pacer

40

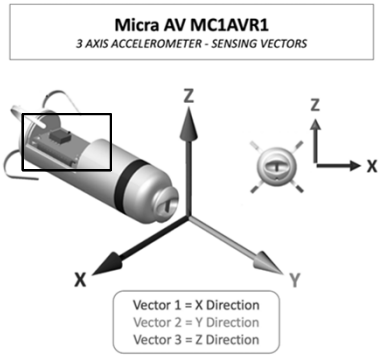
Medtronic Micra AV



- Adds capability to track intrinsic atrial <u>contractions</u> (A-sense, V-pace)
- Uses the accelerometer to detect atrial contraction and then triggers V-pacing if indicated

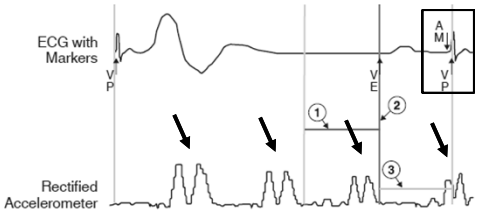
41

3- Axis Accelerometer



43

Four Intracardiac MECHANICAL Events Detected by the Accelerometer



Vent Systole	End Systole	Atrial Diastole	Atrial Systole
TV/MV close	PV/AV close	TV/MV open	Atrial Kick
A1	A2	A3	A4

Medtronic Micra User Manual

48

Atrial Tracking Efficacy

- Imperfect tracking efficacy in patients with AV block
- 70-80% successful atrial tracking is typical for patients with AV block
  - Better when patient supine
  - Worse when patient upright and exercising
- Rate smoothing is deployed to increase the consistency of AV synchrony when the A4 signal is below the threshold.
- THM: You might notice less regular pacing than usual

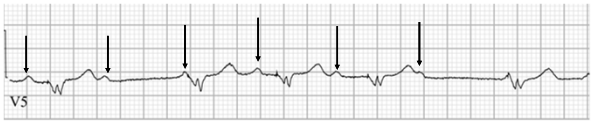
51

A-Sense V-Pace Variability

Arrows denote P-waves.
Poor tracking seen on left. Good tracking seen on right.

52

Poor Tracking



Arrows denote P-waves.

53

Good Tracking

Arrows denote P-waves.

54

Clinical Example of Micra AV

55

Medtronic Micra AV Pacing Modes

- **VDD**
- VDI
- VVI
- VVIR
- VOO
- ODO
- OVO
- Device off

You will not see VDDR as the rate response sensor can only do one or the other—rate response pacing or detecting the atrial contraction

56

Special Functions/Considerations for the Micra and Micra AV

- Magnet response
- Rate response mode
- MRI Exposure
- Noise Reversion Mode
- Hysteresis
- Battery Life Indicators
- Electrical Reset

60

Magnet Response

- Medtronic Micra/Micra AV pacemakers DO NOT respond to a magnet.
- There is no Reed Switch/Hall Sensor in Micra LPs
- To convert the pacing mode to VOO, must use a standard Medtronic programmer

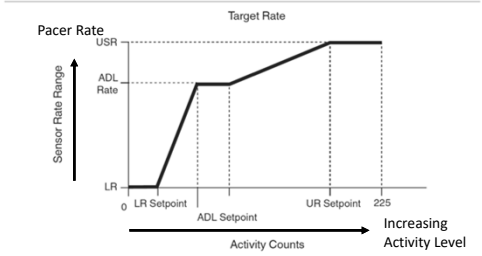
61

Rate Responsive Pacing

- Sensor: Accelerometer
- Same considerations as with any other pacemaker with an accelerometer
- Patient movement will increase the pacing rate

62

Rate Response Mode



Medtronic Micra User Manaul

63

MRI Exposure

- Micra devices are “MRI Conditional”
- Patients may have MRI’s if the appropriate precautions are taken

67

MRI Exposure

- MRI Surescan mode options:
  - ON: VOO
  - OFF: OVO
- If patient pacer dependent—must use ON mode
- If patient rarely pacing and has underlying rhythm, can use OFF Mode

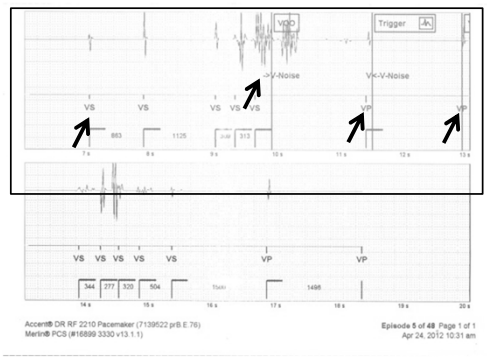
68

Noise Reversion Mode

- Continuous noise during the refractory period triggers the NRM to prevent oversensing-induced asystole
- Device paces VOO until the noise stops

69

EMI-induced NRM activation



73

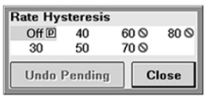
Rate Hysteresis

- Medtronic LPs can be programmed to start pacing at the Lower Rate Limit (Base Rate) ONLY when the intrinsic heart rate falls below an even lower rate (the Hysteresis rate)

81

Rate Hysteresis

- Lower Rate Limit (Base Rate) = 60
- Hysteresis rate = 50



- You might see a non-paced rhythm at 55 and wonder if the pacer is malfunctioning

82

Battery Life Indicators

- RRT 180 days to EOS
  Normal device function
- ERI 90 days after RRT
  Pacer reverts to VVI at 65
- EOS 180 days since RRT, or
  < 2.5 V for 3 consecutive days
  device permanently deactivated

RRT-recommended replacement time
ERI-elective replacement indicator
EOS-end of service

85

Battery Life Indicators

Battery Life Indicators	What does this mean?	What does programmer or report demonstrate?	What happens to the pacemaker?
Recommended Replacement Time (RRT)	180 days until End of Service (EOS)	RRT at (date)	Nothing
Elective Replacement Indicator (ERI)	90 days after RRT and approx. 90 days before EOS.	ERI at (date)	1. Mode to VVI 2. Rate to 65 3. Hysteresis off 4. Device is still programmable
End of Service	90 days after ERI or when the battery voltage is less than 2.5 V for 3 consecutive days	EOS	All functions cease

89

Key Messages

- Always check the Micra battery life preop
  - If at **ERI** strongly encourage consulting the EP team to ensure the battery will make it through the case
  - If cannot do this, ensure backup pacing option
- If a Micra LP is pacing at **65**, it is likely at ERI

91

Electrical Reset

- Exposure to strong magnetic field or high intensity EMI causes the pacer to power off and reset
- Paces VVI at 65 upon reset
- Must use Medtronic programmer to re-establish intended mode and rate

94

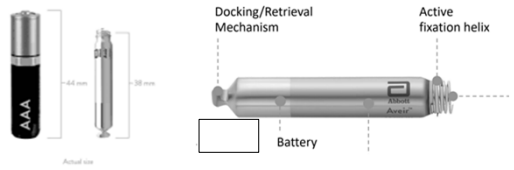
Medtronic Micra and Micra AV Summary

- Micra: VVI or VVIR
- Micra AV: VDD or VVIR
- Accelerometer
- Magnet does NOT work
- Must use Medtronic Programmer to modify settings

98

Abbott Aveir VR Leadless Pacemaker

- FDA approved in 2022 for RV pacing



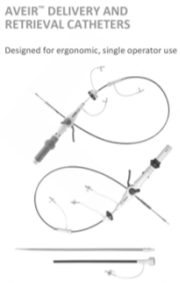
- 2.4 g and 38 mm
- Has a Reed Switch
- Active fixation helix

Tang, et al JCTVA 36 (2022):4501-04

100

Abbott Aveir VR Leadless Pacemaker

- Also implanted into the RV with a steerable catheter-based system
- Active fixation mechanism used to secure the lead into the mid to lower interventricular septum



102

Testing Occurs prior to Implantation

- The cathode is exposed despite the presence of the active helix
- Pacemaker parameters can be tested prior to screwing in the lead
- 83% of the time, no repositioning needed

Abbott Aveir Physicians Manual

103

Active Fixation Mechanism

- Slightly higher risk of cardiac perforation
- Relatively easier extraction
  - Chronic retrieval success 88% at 0-9 years

Abbott Aveir Physician's Manual

118

AVEIR VR LP Pacemaker Modes

- VVI
- VVIR
- VOO
- OVO
- Pacing Off

- Must use an Abbott programmer to adjust pacemaker settings

120

Magnet Response

- The Abbott Aveir VR pacemaker DOES RESPOND to a standard magnet
- Place magnet over center of heart (RV septum)
  - 5 beats VOO at 100
  - Then VOO at rate based on remaining battery life
    - Starts at 100 and decreases gradually to 85 until the RRT is reached.

121

Magnet Rate--Battery Voltage

- If Voltage > 3 V then paces at 100

Table 13. Pacing rates following magnet detection (prior to RRT)

Battery Voltage	Magnet Rate
3.0 > V_{batt} ≥2.9 V	97 bpm
2.9 > V_{batt} ≥2.8 V	94 bpm
2.8 > V_{batt} ≥2.7 V	91 bpm
2.7 > V_{batt} ≥2.6 V	88 bpm
2.6 > V_{batt}	85 bpm

The effectiveness of magnets varies. If one magnet does not cause magnet response, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the pulse generator can also help.

Abbott Aveir Technical Manual

122

Magnet Efficacy may be Suboptimal

- Abbott recognizes that magnet use may be more challenging than with standard pacemakers
  - "If one magnet does not elicit a response, a second magnet may be placed on top of the 1st magnet to increase the magnetic field strength"
  - "Press hard"

Tang, et al JCTVA 36 (2022):4501-04

123

What to do if the Magnet does not Work?

Table 13. Pacing rates following magnet detection (prior to RRT)

Battery Voltage	Magnet Rate
3.0 > V_{batt} ≥2.9 V	97 bpm
2.9 > V_{batt} ≥2.8 V	94 bpm
2.8 > V_{batt} ≥2.7 V	91 bpm
2.7 > V_{batt} ≥2.6 V	88 bpm
2.6 > V_{batt}	85 bpm

The effectiveness of magnets varies. If one magnet does not cause magnet response, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the pulse generator can also help.

Abbott Aveir Technical Manual p. 65

124

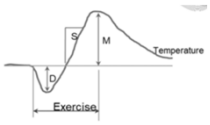
The Magnet Response can be Turned Off

- As is the case with standard Abbott pacemakers, the magnet response can be turned OFF
  - This programming is rare
- To know for sure how the Aveir VR LP will respond to a magnet, use a programmer to interrogate the pacer or check for a response to a magnet

125

Rate Response Mode

- The Aveir uses a temperature sensor:



- This sensor could theoretically lead to pacing rate changes during the cooling/warming associated with surgery

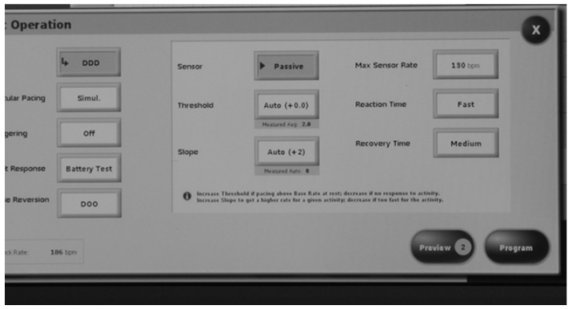
127

Rate Response Mode

- The AVEIR LP rate response mode can be programmed to On, Off, and *Passive*
  - This is consistent with all Abbott pacemakers
- Always program to "Passive" rather than "Off".

130

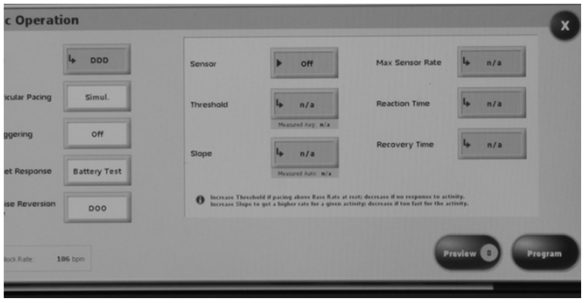
Using "Passive Option"



Passive option maintains patient-specific settings

131

Using "Off" Option



Off option can revert patient-specific settings to manufacturer presets

132

MRI Safety

- Aveir VR LPs are MRI conditional (1.5 and 3.0 Tesla)
- Patients may have MRI's if the appropriate precautions are taken

133

Noise Reversion Mode

- Continuous noise during the refractory period triggers the NRM
- Pacemaker converts to temporary VOO pacing

136

Hysteresis

- Abbott's hysteresis rate is set at some increment below the base rate
  - Base Rate 60
  - Hysteresis: -5, -10 etc.

137

Battery Life

- Recommended Replacement Time (RRT) Indicator:
  - When the daily battery voltage test yields 2.71 V or less for three consecutive days, the RRT is triggered
  - Device has approximately 9.5 months prior to EOS
  - RRM sensor turns off
  - Magnet induced pacing rate reduced to 65
- EOS occurs when voltage falls below 2.2 V

EOS=End of Service

138

Electrical Reset

- Significant EMI or MRI exposure without appropriate precautions can cause an acute power surge and subsequent electrical reset
- Pacer "reboots" in VVI with rate=70 and ventricular output at 6 V
- Must use programmer to re-establish baseline settings

140

Abbott AVEIR Summary

- Typically programmed VVI or VVIR
- No atrial tracking
- DOES respond to a magnet
- Uses a temp sensor for RRM
- At RRT, the magnet rate is 65

141

Leadless Devices in Clinical Trials

- Abbott AVEIR right atrial LP (Dual Chamber Pacing System)
- Boston Scientific EMPOWER RV LP

142

AVEIR Dual Chamber Pacemaker

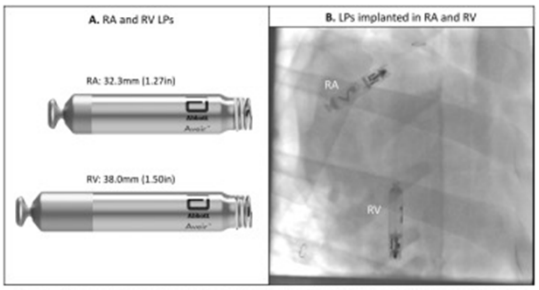


Figure 1 – Shown are (**A**) the length comparison between the RV and shorter RA LPs and (**B**) fluoroscopy of paired LPs implanted in the RA and RV chambers.

Heart Rhythm May 2022

144

DDD Pacing Options

AV Pacing

Atrial Tracking

NEJM June 22, 2023

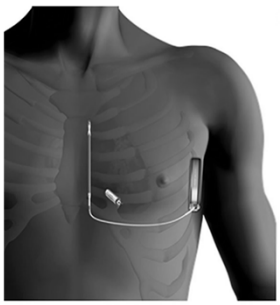
147

Boston Scientific Empower LP

- Empower leadless pacemaker (LP) will communicate with Boston Scientific S-ICD's
  - Will provide VVI pacing that the S-ICD cannot
  - The S-ICD can detect VT and use the Empower LP to deliver ATP prior to delivering shocks

150

Leadless ICD with Pacing Capability



This combination will provide a completely leadless alternative to a transvenous ICD

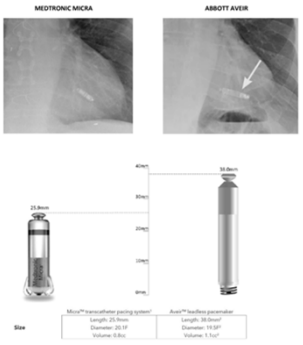
151

CXR Assessment of Leadless Pacemakers

- If the patient has a LP, you should be able to determine the type:
  - Medtronic MICRA or MICRA AV
  - Abbott AVEIR

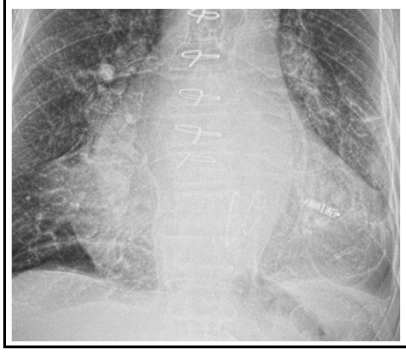
152

Size Discrepancy



153

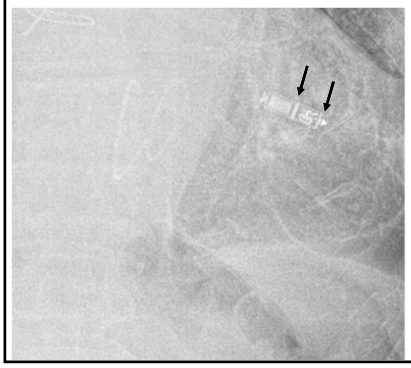
Medtronic Micra CXR



Pertinent features:
1. Line in the middle
2. Bare cathode
3. May see tines

154

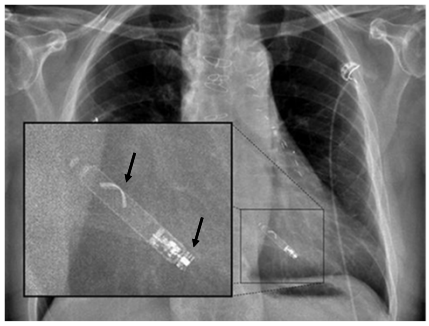
Medtronic Micra CXR



Pertinent features:
1. Line in the middle
2. Bare cathode
3. May see tines

155

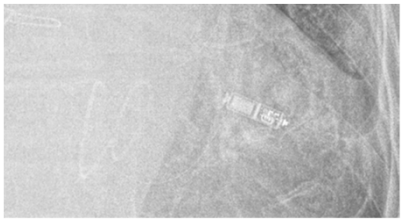
Abbott AVEIR VR CXR



Pertinent Features
1. "V"
2. Active helix

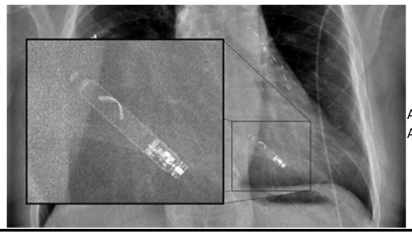
156

1. Shorter
2. Mid-Line
3. Bare cathode



Medtronic Micra

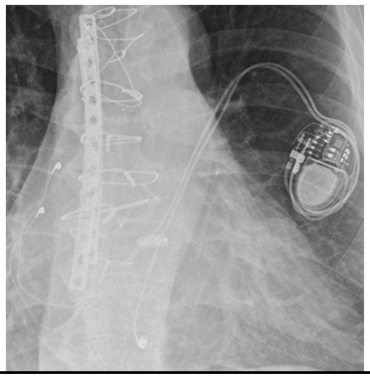
1. Longer
2. "V"
3. Active helix



Abbott Aveir

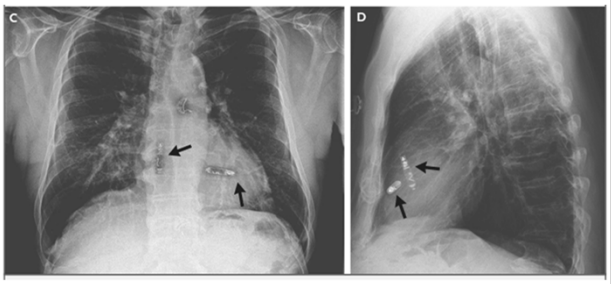
158

Sometimes it is difficult to see the Leadless Pacemaker



159

AVEIR Dual Chamber Pacing System



NEJM June 22, 2023

160

Anesthesia for LP Implantation

- Catheter for device delivery is large
- Need femoral access
- Takes 1-3 hours
- Typically done with MAC but occasionally with GA or nursing sedation
- Complications infrequent but can be significant

161

Leadless Pacemaker Complications

- Cardiac Perforation
  - May be higher incidence and severity than standard pacemaker
  - Typically presents during insertion, but may occur weeks to months later
  - Tx is catheter drainage or cardiac surgery
- Have good IV access and active blood bank sample and immediate access to cardiac surgery

163

FDA Letter to Health Care Providers Nov 17, 2021

- "Since 2016, 300 medical device reports describe a perforation, and over 90 of these described a perforation resulting in death"

166

Perioperative Management

- Obtain Device Information:
  1. Device manufacturer and model
  2. Device settings
     1. Mode
     2. Rate
     3. RRM
  3. Lead tests
  4. % pacing (pacer dependence)
  5. Magnet response

168

Perioperative Management

- Determine Surgical Plan:
  1. Need for cautery
     1. None
     2. Bipolar
     3. Monopolar
  2. Patient position
  3. Location of incision
  4. Duration

171

Perioperative Management

- Determine management plan:
  1. Leave device alone
  2. Suspend the RRM--programmer
  3. Increase the pacing rate--programmer
  4. Convert the pacer to VOO
     - Medtronic—programmer
     - Abbott—magnet or programmer

172

Converting Leadless Pacemakers to VOO

- Converting the Micra or AVEIR to VOO ever-so-slightly increases the risk of R-on-T
- Converting the Micra AV to asynchronous pacing increases the risk of R-on-T **and** results in loss of A-V synchrony, which might significantly compromise BP.

173

General Concerns for Patients with Leadless Pacemakers

1. Use Bipolar Cautery
2. Place electrocautery return pad optimally
3. Use lowest effective cautery output
4. Monitor patient continually, esp. if pacer VOO
5. Have access to a defibrillator and temp pacing
6. Consult with EP Service if placing a PA line within 1-3 months of implant—consider fluoroscopy
7. Test magnet for Abbott devices if planning to use intraop

175

Summary

1. There are 3 leadless pacemakers being implanted (LPs): Micra, Micra AV, Aveir.
2. The Medtronic Micras and Abbott Aveir can deliver VVI, VVIR, and VOO pacing.
3. The Medtronic Micra AV can track atrial contractions and deliver VDD pacing.
4. The Micra AV uses its accelerometer to identify the atrial contraction.
5. Medtronic LPs DO NOT respond to a magnet. To convert to VOO pacing, a Medtronic programmer is needed.
6. Abbott LPs DO respond to a magnet with VOO pacing.
7. All LPs can include a rate response mode (Med: Accelerometer; Abbott: Temp).
8. All LPs can safely be exposed to MRI if required precautions are followed.
9. At ERI, the Medtronic LPs will pace at 65; Abbott's RRT magnet rate is 65.
10. Medtronic and Abbott LPs can be differentiated by a CXR or magnet response.
11. Abbott is developing a leadless atrial pacemaker, which will permit DDD pacing.
12. Bost Scientific is developing a leadless ventricular pacemaker that will communicate with its S-ICD.

179

180