Why Doesn’t Everyone Get an MRI Compatible Leadless Pacemaker?

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Baylor College of Medicine

Newer Medical Therapies
NO DISCLOSURES

• I will discuss a product pending FDA approval
Goals and Objectives

• Why can’t EVERYONE - indications, VVIR pacing

• get an MRI COMPATIBLE - studies & evidence

• LEADLESS - limitations & future

• PACEMAKER? - what about ICD, CRT?
Review Topic of the Week

Leadless Cardiac Pacemaker

A Leadless Intracardiac Transcatheter Pacing System

Dwight Reynolds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D., Kyoko Soejima, M.D., Petr Neuzil, M.D., Shu Zhang, M.D., Calambur Narasimhan, M.D., Clemens Steinwender, M.D., Josep Brugada, M.D., Ph.D., Michael Lloyd, M.D., Paul R. Roberts, M.D., Venkata Sagi, M.D., John Hummel, M.D., Maria Grazia Bongiorni, M.D., Reinoud E. Knops, M.D., Christopher R. Ellis, M.D., Charles C. Gornick, M.D., Matthew A. Bernabei, M.D., Verla Laager, M.A., Kurt Stromberg, M.S., Eric R. Williams, B.S., J. Harrison Hudnall, B.S., and Philippe Ritter, M.D., for the Micra Transcatheter Pacing Study Group*

JACC 2015; 66:1179-89
NEJM 2015; 373:1125-35
NEJM 2016; 374: 533-41
Leadless Pacing – 2015 big year

• Conceived in 1970, >2 month canine pacing
  - Transvenous complications – pocket, lead – up to 1 in 8

• Leadless cardiac pacemakers
  - Nanostim Leadless Cardiac Pacemaker (LPS)
  - Micra Transcatheter Pacing System (TPS)
  - Transfemoral deployment
  - Right ventricular apex, bipolar pacing
  - VVI pacing, rate response
  - MRI conditional
<table>
<thead>
<tr>
<th>Head to Head*</th>
<th>MEDTRONIC MICRA</th>
<th>ST JUDE NANOSTIM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FDA approved</strong></td>
<td>Yes</td>
<td>Pending 2016-17</td>
</tr>
<tr>
<td><strong>MRI conditional</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Size</strong></td>
<td>25.9 mm L, 6.7 mm D, 0.8 mL, 2 gm</td>
<td>42 mm L, 5.99 mm D, 1 mL, 2 gm</td>
</tr>
<tr>
<td><strong>Sheath size</strong></td>
<td>23 F inner, 27 F outer</td>
<td><strong>18 F inner</strong>, 4.5 mm outer</td>
</tr>
<tr>
<td><strong>Rate Response</strong></td>
<td>Accelerometer</td>
<td>RV temperature</td>
</tr>
<tr>
<td><strong>Success</strong></td>
<td>99.2% of 725</td>
<td>95.8% of 526</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>98.3% at 6 months</td>
<td>90% (vs 85% historical)</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>½ of TVP vs historical</td>
<td>93.3% (vs 86%)</td>
</tr>
<tr>
<td><strong>Longevity</strong></td>
<td>&gt;12 years</td>
<td>10-19 yrs (100-25% paced)</td>
</tr>
<tr>
<td><strong>Deploy/Retrieve</strong></td>
<td>4 tines / no long term**</td>
<td>Screw / <strong>longest 3.2 years</strong></td>
</tr>
<tr>
<td><strong>Deploy time</strong></td>
<td>37 +/- 21 min</td>
<td>29 +/- 18 min</td>
</tr>
</tbody>
</table>

EHJ 2015; 36:2510-19  
NEJM 2015; 373:1125-35  
NEJM 2016; 374: 533-41
Micra & Nanostim

NEJM 2015; 373:1125-35
NEJM 2016; 374: 533-41
## Safety

<table>
<thead>
<tr>
<th>Complications</th>
<th>Micra</th>
<th>Nanostim</th>
<th>Historical Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major (TPS definition)</td>
<td>4%</td>
<td>4.5%</td>
<td>7.4%</td>
</tr>
<tr>
<td>perforation or effusion</td>
<td>1.6%</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>dislodgement</td>
<td>0%</td>
<td>1.1%</td>
<td>1.5%</td>
</tr>
<tr>
<td>AV fistula</td>
<td>0.6%</td>
<td>0.6%</td>
<td>NR</td>
</tr>
<tr>
<td>infection</td>
<td>0%</td>
<td>0%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

NEJM 2015; 373:1125-35  
NEJM 2016; 374: 533-41
Why can’t EVERYONE...

- Indications for pacing = symptomatic bradycardia

<table>
<thead>
<tr>
<th>Condition</th>
<th>VVI(R) ok?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pers/Perm AF</td>
<td>Yes</td>
</tr>
<tr>
<td>AV block</td>
<td>No (DDD)</td>
</tr>
<tr>
<td>Sick sinus</td>
<td>No (AAI)</td>
</tr>
</tbody>
</table>

- Pers/Perm AF: 64% Yes, 56% No
- AV block: 15% No, 8.7% Yes
- Sick sinus: 18% No, 35% Yes

References:
- NEJM 2015; 373:1125-35
- NEJM 2016; 374: 533-41
Get an MRI COMPATIBLE…

Clinical Utility and Safety of a Protocol for Noncardiac and Cardiac Magnetic Resonance Imaging of Patients With Implantable Cardiac Arrhythmia Devices

How to perform magnetic resonance imaging on patients with implantable cardiac arrhythmia devices

Advances in Arrhythmia and Electrophysiology

Magnetic Resonance Imaging and Implantable Devices

Saman Nazarian, MD, PhD; Roy Beinart, MD; Henry R. Halperin, MD, MA

2. 2017 HRS Expert Consensus Statement on MRI and Radiation Exposure in Patients with CIEDs
Scope: This document will review the safety considerations and management of the CIED patients requiring imaging. The document will also describe the indications and considerations for MRI-conditional CIEDs, as well as protocols and programming for MRI imaging in patients with CIEDs.

Circ 2006; 114:1277-84  
Heart Rhythm 2009; 6:138-43

Circ AE 2013; 6:419-28  
Heart Rhythm Society guidelines
Right Ventricular Anatomy Can Accommodate Multiple Micra Transcatheter Pacemakers

PAMELA OMDAHL, M.B.A.,* MICHAEL D. EGGEN, PH.D.,* MATTHEW D. BONNER, PH.D.,* PAUL A. IAIZZO, PH.D.,† and KENT WIKA, M.S.*

From the *Medtronic, PLC., Mounds View, Minnesota; and †Department of Surgery, University of Minnesota, Minneapolis, Minnesota
PACEMAKER?

• What about cardiac resynchronization?
  - US acoustic energy → WiSE-CRT
  - His bundle pacing with leadless?

• What about S-ICD?
  - Bluetooth integration?
  - Role of anti-tachycardia pacing for VT? MADIT-RIT?
CONCLUSIONS

• Current LEADLESS pacemakers made for VVI
  - We need A-pacing or AV synchrony

• Anatomic considerations
  - IJ approach, occluded femorals, small RVs, systemic V w/ AC?

• Integration with desired therapies
  - Dual chamber, CRT, ICD?
THE END

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