Leadless Pacemakers; State of the Art

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NYU School of Medicine
First External Pacemaker
1952
First Transvenous Temporary Pacemaker
Furman, 1958
First Implantable Pacemaker
Elmqvist, 1958
Estimated rate of adoption for three major innovations in cardiac pacing.

*1971 Transvenous lead estimated percentage of 75% was used to represent the U.S. as a whole.

Kirk Jeffrey, and Victor Parsonnet Circulation.
Background

• Permanent cardiac pacing is the only effective treatment for symptomatic bradycardia.

• Serious adverse events associated with conventional transvenous pacing system procedures range from 7.3%* – 12.4%†, and 4.2%† require reoperation.

• Miniaturized leadless pacing systems are a promising new solution that may reduce risks associated with traditional technology and improve patient satisfaction.

*†Udo et al. FOLLOWPACE. Heart Rhythm 2012;9:729.
Special Article

Totally Self-Contained Intracardiac Pacemaker*

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The Future of Cardiac Pacing
Transcatheter Pacing System
Small, Minimally Invasive Cardiac Pacemaker.

Transcatheter pacemaker is a fully self-contained, miniaturized pacemaker designed to provide patients with advanced pacing technology via a minimally invasive approach.

Intended for Class I or Class II patients needing a single chamber ventricular pacemaker.
Advanced Pacing Technology

• Uses small tines or screw to attach to the heart rather than leads, potentially eliminating a potential source of complications
• 10 year estimated battery life
• Responds to a patient’s activity level and adjusts therapy automatically
• Equipped with efficient patient follow-up capabilities

Minimally Invasive Procedure

• Delivered via a catheter through the femoral vein and positioned inside the right ventricle of the heart
• Does not require a surgical “pocket” created under the skin, potentially eliminating a source of complications, and any visible sign of the device
• Is attached to the wall of the ventricle and can be repositioned if needed
Micra with Delivery System + Introducer
Performance of a Miniaturized Transcatheter Pacing System: First-in-human experience

Philippe Ritter, MD
Larry A Chinitz, MD; Gabor Z Duray, MD, PhD, FESC; Clemens Steinwender, MD, FESC; Kyoko Soejima, MD; Razali Omar, MD; Lluis Mont, MD; Lucas VA Boersma, MD; Reinoud E Knops, MD; MD; Shuyang Zhang, MD; Calambur Narasimhan, MD; John D Hummel, MD; Michael S Lloyd, MD; Timothy A Simmers, MD; Andrew H Voigt, MD; Verla Laager, MA; Kurt Stromberg, MS; J Harrison Hudnall, BS; Matthew D Bonner, PhD; Dwight W Reynolds, MD

Heart Rhythm 2015 – 36th Annual Scientific Sessions
### Comparison of Conventional and Micra TPS Devices

<table>
<thead>
<tr>
<th>Feature</th>
<th>Conventional</th>
<th>Micra TPS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total volume</strong></td>
<td>10.6 cc*</td>
<td>0.8 cc</td>
</tr>
<tr>
<td><strong>Mass</strong></td>
<td>21.5 grams</td>
<td>2.0 grams</td>
</tr>
<tr>
<td><strong>Rate Response</strong></td>
<td>Subcutaneous Accelerometer</td>
<td>Intracardiac Accelerometer</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Model 2090 Programmer</td>
<td>Model 2090 Programmer</td>
</tr>
<tr>
<td><strong>Fixation</strong></td>
<td>Helical coil or tines</td>
<td>Flexible tines</td>
</tr>
<tr>
<td><strong>MR conditional</strong></td>
<td>1.5 T</td>
<td>1.5 T + 3 T</td>
</tr>
<tr>
<td><strong>Battery Service Life</strong></td>
<td>10.3 years†</td>
<td>9.6 years†</td>
</tr>
</tbody>
</table>

*Medtronic model ADSR01 with 30 cm by 6 Fr lead
†Projected based on ADSR01 and Micra use conditions of 100% pacing at 60 bpm, 1.5 V at 0.24 ms, and 500 Ω
The Micra Transcatheter Pacing Study: Primary Objectives

Safety: Freedom from major complications related to the Micra TPS and/or procedures at 6-month post-implant

- Assumed performance >90%
- Lower confidence interval >83%

Performance: Demonstrate low and stable thresholds at the 6-month visit

- Assumed performance of 89% with threshold <= 2V and no increase of >1.5V (relative to implant)
- Lower confidence interval >80%

The Micra Transcatheter Pacing Study

Patients: *De novo* pacemaker with Class I or II guideline indication* for ventricular pacing

Enrollment:

- The current presentation gives the results of the early performance analysis that served for CE Mark
- 23 centers (Asia Pacific, Europe, United States)
- 37 implanters

Study Prespecified Analyses

Early Performance
N = 140
(60 pts to 3 months)

Primary Objectives
N = 700+
(300 pts to 6 months)

Long-term Performance
N = 700+
(700+ pts to 12 months)

Study enrollments completed
Patient Flow Diagram

**Implant attempted** \( (n = 140) \)

- Successful Micra TPS implant \( (n = 140) \)
- Failed Micra TPS implant \( (n = 0) \)

**Follow-up** (average 1.9 ± 1.8 months)

- Death* \( (n = 1) \)
- Lost to follow-up \( (n = 0) \)
- Discontinued intervention \( (n = 0) \)

**Analyzed for early performance objectives** \( (n = 140) \)

*One patient death occurred 139 days post-implant, was not cardiovascular related, and was determined to be unrelated to the procedure or system.*
Results: Micra TPS Implant

• 100% implant success (140 of 140 attempts)

• Mean implant time was 37 ± 21 min (introducer in / introducer out)

• Anticoagulation approach
  – All catheters heparinized
  – Baseline Status: 44% patients on anticoagulant, 29% on anti-platelet
  – Intra-procedure: 40% received Heparin IV bolus

Site Placement

- Apex 77%
- Septum 16%
- Mid-septum 6%
- RVOT 1%
Micra TPS Deployments During Implant

- Median of 1 deployment per procedure
  - 59% successful in first deployment
  - 81% successful within two deployments
  - 96% successful within four deployments
Results: Safety (n=140)

- Serious Adverse Event rate 5.7%
  - 7.3% SAE at 1 month in Medtronic reference dataset
  - 12.4% complication at 2 months in FOLLOWPACE
- 2 patients with prolonged hospitalization (1.4%)
- No unforeseen events (0%)
- No device telemetry issues (0%)
- No dislodgements (0%)
- No infections (0%)
- No reoperations (0%)
- No related deaths (0%)
Serious Adverse Events

<table>
<thead>
<tr>
<th>DYSRHYTHMIAS</th>
<th>Resulting in death, re-operation, or hospitalization</th>
<th>N (pts, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transient AV block</td>
<td>No</td>
<td>2 (2, 1.4%)</td>
</tr>
<tr>
<td>RBBB</td>
<td>No</td>
<td>1 (1, 0.7%)</td>
</tr>
<tr>
<td>VT</td>
<td>No</td>
<td>1 (1, 0.7%)</td>
</tr>
<tr>
<td>VF</td>
<td>No</td>
<td>1 (1, 0.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CARDIAC</th>
<th>Resulting in death, re-operation, or hospitalization</th>
<th>N (pts, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardial effusion, no tamponade</td>
<td>1 hospitalization prolonged &gt;48 hrs for both events in same patient*</td>
<td>1 (1, 0.7%)</td>
</tr>
<tr>
<td>Acute MI</td>
<td></td>
<td>1 (1, 0.7%)</td>
</tr>
<tr>
<td>Pericarditis</td>
<td>No</td>
<td>1 (1, 0.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OTHER</th>
<th>Resulting in death, re-operation, or hospitalization</th>
<th>N (pts, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial pseudoaneurysm</td>
<td>1 hospitalization prolonged &gt;48 hrs†</td>
<td>1 (1, 0.7%)</td>
</tr>
</tbody>
</table>

**TOTAL**                     |                                                      | 3 (2, 1.4%)|
|                               |                                                      | 9 (8, 5.7%)|

*Occurred in patient with 18 deployments who had 3 vessel disease
†Resolved after thrombin injection
R-Wave Sensing Amplitude

Mean ± standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
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<tbody>
<tr>
<td>Implant (n=138)</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Pre-HD (n=138)</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>1-month (n=95)</td>
<td>2</td>
<td>21</td>
</tr>
<tr>
<td>3-month (n=59)</td>
<td>2</td>
<td>21</td>
</tr>
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</table>
Pacing Capture Threshold

Mean ± standard deviation

Volts (at 0.24 ms)

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant (n=135)</td>
<td>0.25</td>
<td>3.50</td>
</tr>
<tr>
<td>Pre-HD (n=126)</td>
<td>0.25</td>
<td>3.00</td>
</tr>
<tr>
<td>1-month (n=88)</td>
<td>0.25</td>
<td>2.13</td>
</tr>
<tr>
<td>3-month (n=60)</td>
<td>0.25</td>
<td>1.25</td>
</tr>
</tbody>
</table>

P-Value <0.001 (vs 2.0V)
Pacing Impedance

Mean ± standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant (n=140)</td>
<td>450</td>
<td>1540</td>
</tr>
<tr>
<td>Pre-HD (n=140)</td>
<td>440</td>
<td>1130</td>
</tr>
<tr>
<td>1-month (n=96)</td>
<td>420</td>
<td>1080</td>
</tr>
<tr>
<td>3-month (n=60)</td>
<td>450</td>
<td>1000</td>
</tr>
</tbody>
</table>
Expected Micra TPS Longevity

Based on use conditions of 60 patients followed to 3 months

• Median pacing = 49% (IQR 10%, 75%)
• Median pacing capture threshold at 0.24 ms = 0.38 V (IQR 0.38 V, 0.57 V)
• Median pacing impedance = 640 Ω (IQR 540 Ω, 725 Ω)

Battery longevity estimated at an average of 12.6 years (range 8.6 – 14.4 years)*

*Estimate does not include pacemaker dependent patients and assumes thresholds remain stable for device lifetime.
Conclusions

Early performance of first 140 patients provides initial evidence that Micra TPS can safely and effectively be applied.

- 100% implant success in wide range of patients
- No procedural-related deaths
- Serious adverse event rate with Micra TPS appears to be in line with traditional systems
- Electrical performance is excellent and remains stable at 3 months, with expected average longevity of $\geq 10$ years

Long-term safety and benefit will be further evaluated in the ongoing trial.
A Leadless Intracardiac Transcatheter Pacing System

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Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes, III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., Srinivas R. Dukkipati, M.D., for the LEADLESS II Study Investigators

N Engl J Med
Volume 373(12):1125-1135
September 17, 2015
The Leadless Cardiac Pacemaker.

Conclusions

• The leadless cardiac pacemaker met prespecified pacing and sensing requirements in the large majority of patients.

• Device-related serious adverse events occurred in approximately 1 in 15 patients.
RV Apex: From RAO to LAO
(Rotational Fluoroscopy)
Septal Non Apical Position
Septal, Not Free Wall
Deliver the Micra
TUG TEST
Positioning Troubleshooting

LAO-30

RAO-30
Positioning Troubleshooting

LAO 45
- LAO image appears septal
- The cup is in the apex because it is riding along the septum.
Septal Location/Not Apical
SEPTAL PACING
Future of Leadless Pacing

- Dual Chamber Devices
- CRT
- Epicardial Placement
- Non-Vascular Placement