Advances in Pacemaker Technology

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Ross Heart Hospital

Disclosures – Modest

• Advisory Board / Steering Committee
  – Biosense-Webster
  – Medtronic
  – Abbot EP
• Research
  – St. Jude
  – Biosense-Webster
  – Medtronic
  – Biotronik
  – Boston Scientific
**Advances Here and Now**

- Leadless Pacing
- His Bundle Pacing
- MRI Safety

**Leadless Devices**

**Size**
- Volume: 0.8 cc
- Length: 25.9 mm
- Width: 20 Fr

**Battery**
- 9-12 years

**Capabilities**
- Pacing Mode: VVIR
- Bipolar sensing
- MRI 1.5 T or 3 T
- Rate Response (3 axis accelerometer)
- Capture Management™
- Device deactivated at EOS
- Communicates with RF

**Size**
- Volume: 1.0 cc
- Length: 42 mm
- Width: 18 Fr

**Battery**
- 10-18 years

**Capabilities**
- Pacing Mode: VVIR
- Bipolar sensing
- MRI 1.5 T
- Rate Response (Temp)
- Remove at EOS vs. deactivate
- Communicates by conductive comm. Via ECG electrodes

**Size**
- Volume: N/A
- Length: 13.5 mm
- Width: 8 Fr

**Battery**
- Ultrasound stimulator

**Capabilities**
- Pacing Mode: Sync LV
- Triggered Via RV Stim

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New Opportunities To:
Reduce Complications Associated With Traditional Pacing Technology

Implant Complications:
2-3% at Implantation with traditional technology
- Pneumothorax, hemotorax, chylothorax
- Pocket hematoma
- Cardiac perforation or Central venous tear
- Subclavian/innominate thrombosis

Pocket Related Complications
4-8% at 5 years with traditional technology
- Infection
- Hematoma
- Erosion
- Pain

Lead Related Complications
5-11% at 5 years with traditional technology
- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

Complication Rates at 6 Months Compare Favorably to Traditional

<table>
<thead>
<tr>
<th>Micra</th>
<th>Nanostim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Perforation 1.6%</td>
<td>1.3% Cardiac Perforation</td>
</tr>
<tr>
<td>CHF 0.9%</td>
<td>1.7% Dislodgment</td>
</tr>
<tr>
<td>1.7% Capture Threshold</td>
<td>1.3% Capture Threshold</td>
</tr>
</tbody>
</table>

NanostimMicra 6 month Serious Adverse Events
Total=6.7%
- 1.3% Cardiac Perforation
- 1.7% Dislodgment
- 1.3 % Capture Threshold

Please note: major complications and all complications definition vary between the above cohorts.

Implant Procedure

Micra Delivery System

- Advance the delivery catheter from femoral vein to the right ventricle
- Position the device and affix to the endocardium
- Undock the device from the delivery catheter leaving the pacemaker tethered to the delivery catheter and check pacing parameters
- Re-dock to the catheter and reposition if necessary
- Cut tether leaving it implanted

Presence of IVC obstruction likely precludes use.

Nanostim Delivery System

Micra Retrieval System

Nanostim Retrieval System

 Advancement to Target and Deployment
Testing fixation

“Pull and hold” test
- 2 tines have 15x the holding force necessary to hold the device in place1

Nanostim Implant

Contrast is injected through the sheath to confirm positioning within the right ventricle. The protective sheath is removed to expose the device helix, and the leadless pacemaker is advanced until it reaches the endocardium at the lower septum.

Forward pressure is gently applied and under fluoroscopy, the control knob is slowly turned until the endopagous anchor has rotated 1 to 2° far.

The Nanostim LP is unlocked from the delivery catheter to put the device in delivery mode. The catheter is gently deflected and undetected to confirm fixation and test sensing and pacing thresholds while the device is naturally intersecting with the bising heart.

If necessary, the device is repositional by unlocking the delivery catheter and unwrapping the helix. After slightly pulling both the device, steps 3 and 4 are repeated. Once properly positioned, the device is released.
High Implant Success Rate

**Micra**
- 99.2% implant success with 94 implanters
- 98.3% with adequate 6-month pacing capture threshold (95% CI, 96.1 to 99.5; P<0.0001)
- Median implant time was 28 minutes introducer in to introducer out: 22 min after 1st 10 implants

**Nanostim**
- 96% implant success with > 56 implanters
- 90% with adequate 6-month pacing and capture threshold
- Median implant time was 28 minutes

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What Patient Is the Ideal Leadless Candidate?

- **Leadless**: Patients with compromised thoracic vascular access
- **VVIR Pacing**: Permanent Afib, NSR with intermittent brady
- **Limited infection risk**: Chronic immunosuppression, recurrent bacteremia, hemodialysis, mechanical valves, cancer
- **No risk of Pneumothorax, Lead fracture, pocket hematoma**: Severe COPD/pulmonary disease, young, existing lead failure, cachexia, anticoagulation
- **Limited risk of Tricuspid Regurgitation**: Pulmonary hypertension, TR

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Which Device for Which Patient?

- **Micra** has had *no dislodgements* outside the acute implant and is *shorter* than Nanostim with no reported impingement on the Tricuspid Valve.

- **Nanostim** has thinner body and *predesigned removal system* communication unhindered in *obesity*.

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**RV Pacing Can Cause Cardiac Dyssynchrony and CHF**

*ECG showing electrical delay (left bundle branch block) associated with cardiomyopathy resolved with CRT pacing.*

*Block HT Mean LVEF 43%; Freedom From Death, CHF, Increase LVEF. (6.4% LVL complication rate)*

*Curis, et al, NEJM 2013*
Typical Biventricular Pacing Deployment

Attain Success CRT Study:
97% Success Implantation, 2% LV lead Failure

Hummel et al., PACE In Press

His Bundle Target?

Surface ECG I
Surface ECG III
Right Atrium
His Bundle – Junction betwn. RA and RV
Right Ventricle
Typical Appearance of His Pacing Lead

His Bundle Pacing

Sharma et. Al, Heart Rhythm 2016
Outcomes For His Bundle Pacing

- 192 patients receiving pacemakers implanted either HB or RV apical lead
- HB implant success 80%, septal placement for the failures
- In pts with > 40% RV pacing (>60% of pts) heart failure hospitalization was 15% for RV pacing vs. 2% for HB pacing (p=.02)
- No mortality difference

Sharma et. Al, Heart Rhythm 2016

Need for MRI Safe Technology

- 50-75% of patients with a cardiac rhythm device are denied access to MRI scanning procedures.
- ~20% of pacemaker patients need an MRI within 2 years after implantation

1 Kalin R. Current Clinical Issues for MRI Scanning of Pacemaker and Defibrillator Patients. Pacing and Clinical Electrophysiology 2005
2 SureScan Post Approval Study. HRS 2013 presentation
US Available MRI Safe Pacemakers

<table>
<thead>
<tr>
<th>Boston</th>
<th>Biotronix</th>
<th>Medtronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Exclusion Zone (1.5T)</td>
<td>No exclusion zone (1.5T)</td>
<td>No exclusion zone (1.5 or 3T)</td>
</tr>
<tr>
<td>Dual Chamber</td>
<td>Dual-chamber</td>
<td>Dual-chamber</td>
</tr>
<tr>
<td>Single Chamber</td>
<td>Single chamber</td>
<td>Single Chamber</td>
</tr>
<tr>
<td>Automatic Out of MRI Mode</td>
<td>Automatic continuous Post- MRI threshold monitoring and alerts</td>
<td></td>
</tr>
<tr>
<td>Wandless</td>
<td>Wandless</td>
<td>Wanded</td>
</tr>
<tr>
<td>Ingevity</td>
<td>Sterox Leads</td>
<td>5078 Lead</td>
</tr>
<tr>
<td>Minute Ventilation and Accelerometer</td>
<td>Accelerometer</td>
<td>Accelerometer</td>
</tr>
</tbody>
</table>

Conclusions

- Leadless pacemakers represent an opportunity to reduce complications for patients requiring single chamber pacing

- His Bundle Pacing may replace CRT pacing for many patients with heart block

- MRI safety of devices will become the norm, but in this transition era always have the device rep or clinic involved.
Complications Include Malfunction and Death

Device Malfunctions
- ICD prematurely reached ERI after an MRI scan; required device replacement – MAUDE database, 2006¹
- Pacemaker in back-up mode after exposure to MRI scan; required device replacement – MAUDE database, 2009²
- MAGNASAFE Registry had one ICD device failure requiring replacement due to device with Tachycardia therapy left on during MRI scan – MAGNASAFE Registry, 2014³

Patient Deaths
- "As many as four patients with pacemakers are reported to have died after they inadvertently underwent MR imaging."⁴
- "To date, 10 deaths have been attributed to MRI procedures in patients with pacemakers."⁵

References:
1. FDA Maude Database. Report Number 2017865-2009-02795
2. FDA Maude Database. Report Number 2124215-2007-18811
3. MAGNASAFE Final Results presentation. American Heart Association Meeting. November 2014
Why 3T?

Brain: stroke
  • Increased sensitivity for detection of ischemic lesions, especially in patients with multiple cerebral embolisms

• Spine: Image quality

• Liver: Effects of fatsaturation are improved at 3.0 T MRI because of stronger chemical shift between fat and water

• Breast: Improved spatial and temporal resolution

• Cardiac: Images provide better visual delineation of perfusion abnormalities and cardiac ischemia evaluation

**MYCARELINK SMART™**

*Smart Phone users
  - Iphone and Droid

“Carelink Email and texts patients to ensure compliance
Testing Electricals

Electrode tissue interface allows for low and stable chronic thresholds\(^1\)

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Dislodgement of Nanostim

- Noted in 1.1% (6/526)
- 1-14 days post implant
- 4 embolized to PA
- 2 embolized to RFV
- All retrieved percutaneously
- 4/526 (0.8%) elevated thresholds at follow up and replaced

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Lealess Results

Leadless II

- Performance data for both primary endpoints were reported for the primary cohort of 300 patients followed for six months.
- Serious adverse event rates were similar to historical rates reported for traditional single-chamber pacemakers.
- 93.3% of patients were free from serious adverse device events at 6 months post implant.
- Performance goals for appropriate pacing and sensing were met.
- 93.4% of patients with successful LP implants achieved pre-specified pacing capture and sensing thresholds through 6 months post implant.
- Failures (n = 19 total) were primarily due to R-wave amplitude at 6 months < 5 mV and less than the value at implant (n=16 – none requiring intervention). Pacing threshold > 2 V at 0.4 msec was the failure reason for 4 patients (3 received a transvenous pacemaker, 1 also included above for failure due to R-wave amplitude).
Testing Fixation

“Pull and hold” test

- 2 tines have 15x the holding force necessary to hold the device in place\(^1,2\)

Baseline Characteristics

Micra Patients Older, More Comorbidities\(^1\)

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<th>Micra</th>
<th>Historical Control</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>75.9 ± 10.9</td>
<td>71.1 ± 12.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male gender</td>
<td>58.8%</td>
<td>55.1%</td>
<td>0.08</td>
</tr>
<tr>
<td>Hypertension</td>
<td>78.6%</td>
<td>67.2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AF</td>
<td>72.6%</td>
<td>36.6%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Valvular Disease</td>
<td>42.2%</td>
<td>19.2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28.6%</td>
<td>21.9%*</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CAD</td>
<td>28.0%</td>
<td>38.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CHF</td>
<td>17.0%</td>
<td>15.0%</td>
<td>0.20</td>
</tr>
<tr>
<td>COPD</td>
<td>12.4%</td>
<td>7.2%*</td>
<td>0.001</td>
</tr>
<tr>
<td>Vascular Disease</td>
<td>7.3%</td>
<td>10.1%</td>
<td>0.032</td>
</tr>
</tbody>
</table>


\(^*\)P-value from \(t\)-test (continuous variables) or Fisher’s Exact Test (categorical variables).

\(^†\)Data parameter not collected across all trials.
High Implant Success Rate

- 99.2% implant success (719 of 725 attempts) with 94 implanters

- Median implant time was 28 minutes introducer in to introducer out
  - 22 min after 1st 10 implants

Primary Objectives Met

Safety (n=725):
- 96.0% freedom from device or procedure-related major complications at 6 months (95% CI, 93.9 to 97.3; P<0.0001)
  - No dislodgements
  - No systemic infections

Efficacy (n=297)
- 98.3% with adequate 6-month pacing capture threshold (95% CI, 96.1 to 99.5; P<0.0001)

Micra Major Complications (N=725)

<table>
<thead>
<tr>
<th>Event</th>
<th>Death</th>
<th>Loss of Device Function</th>
<th>Hospitalization</th>
<th>Prolonged Hospitalization</th>
<th>System Revision</th>
<th>Total Events</th>
<th>No. Patients (Kaplan-Meier at 6 Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep vein thrombosis</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>AV fistula / pseudoaneurysm</td>
<td>2</td>
<td></td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>5 (0.7%)</td>
<td></td>
</tr>
<tr>
<td>Cardiac perforation / effusion</td>
<td>3</td>
<td></td>
<td>9</td>
<td>11</td>
<td>11</td>
<td>11 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>Elevated thresholds</td>
<td>1</td>
<td></td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2 (0.3%)</td>
<td></td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Cardiac failure</td>
<td>3</td>
<td></td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3 (0.9%)</td>
<td></td>
</tr>
<tr>
<td>Metabolic acidosis</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Pacemaker syndrome</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Presyncope</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Syncope</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Total major complications</td>
<td>1</td>
<td></td>
<td>13</td>
<td>18</td>
<td>3</td>
<td>28</td>
<td>25 (4.0%)</td>
</tr>
</tbody>
</table>

Not mutually exclusive as a single event may meet more than one major complication criterion.

51% Fewer Major Complications With Micra Vs Transvenous Pacemakers

To adjust for differences in patient populations, propensity matching to a subset of the historical control confirmed a reduction in major complications with Micra (HR: 0.46; 95% CI: 0.28 to 0.74).


Physicians Consistent With Guidelines
Indications for Pacing (N=725)¹

Reasons for selecting VVIR
- Infrequent pacing expected
- Advanced age
- Sedentary lifestyle
- Anatomical limitations
- Co-morbidities increasing complication risk

Consistent with Guideline Recommendations for VVI Pacing*³

Early Intracardiac Pacemaker Concepts
Breaking News From the EP World

FDA approves Micra-First Approved Leadless Pacemaker in the USA

Cardiac Pacing Milestones

<table>
<thead>
<tr>
<th>External Pacemaker</th>
<th>Implantable Pacemaker</th>
<th>Rate Responsive Pacemaker</th>
<th>MRI Conditional Pacemaker</th>
<th>Intracardiac Pacemaker</th>
</tr>
</thead>
</table>
New Opportunities To:
Reduce Complications Associated With Traditional Pacing Technology

Pocket Related Complications
4-8% at 5 years with traditional technology\(^1,2\)
- Infection
- Hematoma
- Erosion
- Pain

Lead Related Complications
5-11% at 5 years with traditional technology\(^1,2\)
- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

---

Micra Pacing Capsule

Size
- Volume: 0.8 cc
- Length: 25.9 mm
- Width: 20 Fr

Battery
- 12+ years estimated average longevity\(^1\)

Capabilities
- Pacing Mode: VVIR
- Bipolar sensing
- MRI SureScan\(^+\), allowing 1.5 T or 3 T full body MRI scans
- Capture Management\(^*\)
- Rate Response
- Diagnostics: battery status, threshold, impedance, % paced
- Device can be manually deactivated and automatically deactivates at EOS

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\(^+\) Historical Control for Micra Study (6 pacemaker studies).


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18 mm electrode to ring spacing

18 mm electrode to ring spacing

Proximal Retrieval Feature

FlexFix\(^\text{™}\) Nitinol Tines

Anode

Cathode

Retrievable Mitral Tines
Comparison To Traditional Pacing Technology

<table>
<thead>
<tr>
<th></th>
<th>Conventional</th>
<th>Micra TPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total volume</td>
<td>10.6 cc</td>
<td>0.8 cc</td>
</tr>
<tr>
<td>Rate Response</td>
<td>Subcutaneous Accelerometer</td>
<td>Intracardiac Accelerometer</td>
</tr>
<tr>
<td>Communication</td>
<td>Model 2090 Programmer</td>
<td>Model 2090 Programmer</td>
</tr>
<tr>
<td>Fixation</td>
<td>Lead w/ helical coil or tines</td>
<td>FlexFix™ Nitinol Tines</td>
</tr>
<tr>
<td>MR conditional</td>
<td>1.5 T</td>
<td>1.5 T + 3 T</td>
</tr>
<tr>
<td>Battery Service Life</td>
<td>10.3 years*</td>
<td>12.5 years†</td>
</tr>
</tbody>
</table>

*Medtronic model ADSR01 with 30 cm by 6 Fr lead
†Projected based on ADSR01 use conditions of 100% pacing at 60 bpm, 1.5 V at 0.24 ms, and 500 Ohm

Micra Procedure

- Micra Delivery System
- Introducer and Dilator
- Guide Wire
- Needle

Navigation To Target Location

Integrated delivery system facilitates implant procedure

Device Deployment
Testing Fixation

“Pull and hold” test

• 2 tines have 15x the holding force necessary to hold the device in place\(^1,2\)

The Micra TPS Global Clinical Trial\(^1\)

Study Design:

• Prospective, non-randomized, single-arm, multi-site, FDA IDE study\(^2\)

• Pre-defined historical control group for comparison †
  — 2667 patients from 6 trials of commercially available technology

• 725 patients, 94 implanters, 56 centers, 19 countries, 5 continents
  — North America, Europe, Asia, Australia, Africa

• VVIR patients: Class I or II guideline indication for de novo ventricular pacing with no restriction by comorbidity (e.g. COPD)\(^2\)
The Micra TPS Global Clinical Trial

Primary Objectives (6 months):

- **Safety**: Freedom from device or procedure-related major complications
  - Death, permanent loss of therapy, hospitalization, prolonged hospitalization, or system revision
  - Target performance >90%, lower CI >83%

- **Efficacy**: Demonstrate low and stable pacing thresholds
  - ≤ 2V and no increase of >1.5V (relative to implant)
  - Target performance >89%, lower CI >80%

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<tr>
<td>(N=725)</td>
<td>(N=2667)</td>
<td></td>
<td></td>
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<tr>
<td>Age (years)</td>
<td>75.9 ± 10.9</td>
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†Data parameter not collected across all 6 trials.
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  - No systemic infections

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<td>Acute myocardial infarction</td>
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</tr>
<tr>
<td>Cardiac failure</td>
<td>3</td>
</tr>
<tr>
<td>Metabolic acidosis</td>
<td>1</td>
</tr>
<tr>
<td>Pacemaker syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Presyncope</td>
<td>1</td>
</tr>
<tr>
<td>Syncope</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total major complications</strong></td>
<td><strong>28</strong></td>
</tr>
</tbody>
</table>

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### 51% Fewer Major Complications With Micra Vs Transvenous Pacemakers

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- **Reasons for selecting VVIR**
  - Infrequent pacing expected
  - Advanced age
  - Sedentary lifestyle
  - Anatomical limitations
  - Co-morbidities increasing complication risk

- **Consistent with Guideline Recommendations for VVI Pacing**
  - Bradycardia with Permanent or Persistent AT / AF (64%)
  - AVB (15%)
  - SND (18%)
  - Other (4%)

³Gillis et al., 2012