New Devices in current practice and on the horizon: Leadless Pacemakers
PD Dr. Tobias Reichlin, SGK Lausanne, 15. Juni 2016
Pacemaker: once & today

New York Daily News Juni 1959
Which device complications have you personally seen in the past year?

A) Pneumothorax
B) Electrode-Revision
C) Pocket-Infection
D) at least 2 of them
E) none of them
Leadless Pacing: possible at all?

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331 1970

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D., PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible...
Percutaneous Implantation of an Enteral 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. Tomacruz, M.D., Paul A. Friedman, M.D., N.A. Mark Estes III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkett, M.D., Rachel Barber, M.D., James Porterfield, M.D., James E. Ip, M.D., and Anivhas R. Dukkipati, M.D., for the LEADLESS II Study Investigators*

Leadless Intracardiac Transcatheter Pacing System

Reddy VY, NEJM, 2015
Reynolds D, NEJM, 2015
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.,

A Leadless Intracardiac Transcatheter Pacing System

Dwight Reynolds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D.,

Reddy VY, NEJM, 2015
Reynolds D, NEJM, 2015
Leadless Pacing 2016

23Fr introducer + dilator over the wire

Catheter at RV apex
Leadless Pacing 2016
Methods

- **Nanostim (SJM):**
  - Prospective Multicenter Study
  - Class I or II Indication for a Pacemaker
  - Safety End Point: Device-associated Major complications
  - Efficacy End Point: 6 months FU: stable low Pacing-Threshold ($\leq 2.0V/0.4ms$) & Sensing $\geq 5.0mV$

- **Micra (MDT):**
  - Prospective Multicenter Study
  - Class I or II Indication for a Pacemaker
  - Safety End Point: Device-associated Major complications
  - Efficacy End Point: 6 months FU: stable low Pacing-Threshold ($\leq 2.0V/0.4ms$)
## Results

<table>
<thead>
<tr>
<th></th>
<th>Nanostim (SJM)</th>
<th>Micra (MDT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>526</td>
<td>725</td>
</tr>
<tr>
<td><strong>Indikationen</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VHF mit AV-Block</td>
<td>56%</td>
<td>64%</td>
</tr>
<tr>
<td>SR mit AV-Block</td>
<td>9%</td>
<td>15%</td>
</tr>
<tr>
<td>Sinusbradykardie &amp; Pausen</td>
<td>35%</td>
<td>18%</td>
</tr>
<tr>
<td>Alter</td>
<td>76</td>
<td>76</td>
</tr>
<tr>
<td>Männliches Geschlecht</td>
<td>62%</td>
<td>59%</td>
</tr>
<tr>
<td>LVEF</td>
<td>58%</td>
<td>59%</td>
</tr>
</tbody>
</table>
# Results: Safety

<table>
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<tr>
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<th>Micra (MDT)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>526</td>
<td>725</td>
</tr>
<tr>
<td><strong>Erfolgreiche Implantation</strong></td>
<td>96%</td>
<td>99%</td>
</tr>
<tr>
<td><strong>Dauer</strong></td>
<td>29 min</td>
<td>28 min</td>
</tr>
<tr>
<td><strong>Fluoroskopie-Zeit</strong></td>
<td>14 min</td>
<td>6 min</td>
</tr>
<tr>
<td><strong>Komplikationen</strong></td>
<td>6.5%</td>
<td>4.0%</td>
</tr>
<tr>
<td><strong>Perforation</strong></td>
<td>1.5%</td>
<td>1.6%</td>
</tr>
<tr>
<td><strong>Dislokation</strong></td>
<td>1.1%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Zweiteingriff wg. erhöhter Schwelle</strong></td>
<td>1.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td><strong>Leistenkomplikation</strong></td>
<td>1.3%</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Tod</strong></td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Resultate: Safety

Reynolds D, NEJM, 2015
## Results: Efficacy after 6 Months

<table>
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<tr>
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<th>Nanostim (SJM)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>526</td>
<td>297</td>
</tr>
<tr>
<td>Gute Pacing Werte</td>
<td>90.0%</td>
<td>98.3%</td>
</tr>
<tr>
<td>Mittlere Reizschwelle</td>
<td>0.58V / 0.40ms</td>
<td>0.54V / 0.24ms</td>
</tr>
<tr>
<td>Mittleres Sensing</td>
<td>9.2 mV</td>
<td>15.3 mV</td>
</tr>
<tr>
<td>Mittlere Impedanz</td>
<td>???</td>
<td>627 Ohms</td>
</tr>
</tbody>
</table>
Unresolved issues w/ leadless Pacing

• Who is the optimal candidate for leadless pacing?
• Who should implant leadless pacemakers?
• Future:
  • Will there be other pacing options than VVI?
  • Will there be better options at ERI?
VVI Pacing Mode

- Switzerland 2015: 5170 first PM-Implants
  - 44 Leadless Pacemakers (<1%)

Range in centres >100 implants: 13% - 49%

www.pacemakerstiftung.ch
Battery Longevity

- Current projected Battery Longevity: 8-10 years

Then what?
- Extraction and Reimplant?
- Add another one?
Who is the optimal candidate for leadless Pacing?

✓ Permanent AF
✓ Patient not expected to survive Battery Longevity

Who is the worst candidate for standard pacing?

✗ Hemodialysis
✗ Previous device infections
✗ Anatomy I: Vascular access occlusions
✗ Anatomy II: pediatric patients
Who should implant leadless PMs?

- Switzerland 2015: 72 centres implanting standard PM
- Leadless pacing \textbf{NOT so simple:}
  - femoral vs. pectoral access
  - large bore long sheaths and wires
  - Navigation of large catheters in the heart
- Perforations are rare, but likely more severe -> Cardiac surgery on site helpful

\textbf{-> Special and thorough training needed for operators and their entire team!}

www.pacemakerstiftung.ch
### Will there be other pacing options?

<table>
<thead>
<tr>
<th>St. Jude Medical</th>
<th>Medtronic</th>
<th>Boston Scientific</th>
</tr>
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<tbody>
<tr>
<td>Atrial Device -&gt; AAI &amp; DDD</td>
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<td>Combination S-ICD &amp; leadless ATP</td>
</tr>
<tr>
<td>Miniaturized Device -&gt; pediatric Population</td>
<td>VDD Device</td>
<td>also available as stand alone VVI-PM</td>
</tr>
<tr>
<td>(RAO)</td>
<td>Longer Antenna for far field atrial sensing</td>
<td></td>
</tr>
<tr>
<td>Leadless CRT ???</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Medtronic**
- Combination S-ICD & leadless ATP

**Boston Scientific**
- Combination S-ICD & leadless ATP
- also available as stand alone VVI-PM
Will there be better options at ERI?

Science Fiction: Energy harvesting from the beating heart

Summary Leadless Pacing

- Technically fascinating new possibility for pacing
- High Potential for the future, but currently only VVI. DDD & VDD likely coming in ~1 yr
- Concerns: Complication rate in routine clinical practice & management @ ERI
- For now, an additional pacing option for selected patients (i.e. permanent AF in the elderly)