Leadless Pacing and Device Diagnostics

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Leadless Pacing

Why?

Current State

Future

Leadless Pacing

Why?

• “In fact, the implanted defibrillator system represents an imperfect solution in search of a plausible and practical application”
Myerburg Paradox

Sometimes you don’t know what you don’t know.

Roughly 200,000 Pacemakers Implanted in the U.S. Annually

Complication Rate 10%

Danish Pacemaker Registry

Lead Related Complications (re-op)
28,860 patients
1997-2008
PPM and CRT-P

5.4% Lead Related Complication
Non VVI device
Operator Experience/Non-Academic Center
Passive Fixation Leads
Procedure Time
FOLLOWPACE

1517 pts from 23 Centers in the Netherlands
5.8 year Follow up
12.4% Acute Complication
9.2% Late complication
  - 15.6% at 1 year
  - 18.3% at 3 years
  - 19.7% at 5 years
0.33% Generator Related

Transvenous Pacing System

Failure Points
Leads, Circuit, Pocket, Access, Header, Connections, Battery, Patient…….
Leadless Pacing System

No Pocket, No leads, No header

Leadless Delivery and Fixation

Catheter Delivery  Nitinol Fixation

MAKE A DIFFERENCE. EVERY DAY.
PMSS/Registry

795 patients
99.6% successful implants
Major Complication rate 1.51%
(Lower than approval trials)

Table 2  Major Complications Through 30 Days Post Implant

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>No. (Patients, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Major Complications</td>
<td>13 (12, 1.51)</td>
</tr>
<tr>
<td>Deep Vein Thrombosis</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Events at Groin Puncture Site</td>
<td>6 (6, 0.75)</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>2 (2, 0.25)</td>
</tr>
<tr>
<td>Incision site hemorrhage</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Persistent lymphatic fistula</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Vascular pseudoaneurysm</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Cardiac Effusion/Perforation</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Pacing Issues</td>
<td>2 (2, 0.25)</td>
</tr>
<tr>
<td>Device dislodgement</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Device pacing issue</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (3, 0.38)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>1 (1, 0.13)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1 (1, 0.13)</td>
</tr>
</tbody>
</table>
Leadless Pacing

Future Directions

Micra Accelerometer Sub Study (MASS)
Micra Atrial Tracking Using a Ventricular Accelerometer (MARVEL)

MASS

A1 – AV Valve Closure
A2 – Aortic and Pulmonic Closure
A3 – Passive Ventricular Filling
A4 – Atrial Contraction

Blanking manually set

Two Sensitivity choices to compensate for S3/S4 Fusion at higher rates
MARVEL

AVS increased from 37.5% to 80% in AV block patients.

MARVEL

LVOT VTI
The CEID as a Diagnostic Tool

CEID as Diagnostic Tools

- Rhythm
- Rate
- Respiratory Rate
- Activity
- Position
- HRV
- Inotropy
- Temperature
- Thoracic Fluid
- Heart Sounds
Thoracic Impedance

Low level current changes

Opti-Vol

60% sensitivity

60% False Positive
**FAST Trial**

Impedance Change vs Daily Weights

156 patients with 537 day follow up

65 HFE’s of which Impedance predicted 76% and weights predicted 22%

Impedance picked up 40 events missed by Weight

Weight picked up 8 events missed by impedance

88% of impedance events were false positives

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**PARTNERS HF**

694 Patients followed for 11.7 months

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cutoff Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid Index</td>
<td>&gt;60 Ohm/days</td>
</tr>
<tr>
<td>AT/AF Duration</td>
<td>&gt; 6h but not persistent</td>
</tr>
<tr>
<td>V rate in AF</td>
<td>&gt; 90 for 24H</td>
</tr>
<tr>
<td>Activity</td>
<td>&lt; 1 H over 1 week average</td>
</tr>
<tr>
<td>Nocturnal HR</td>
<td>&gt;85 bpm for 7 consecutive days</td>
</tr>
<tr>
<td>CRT Pacing</td>
<td>&lt; 90% for 5 of 7 days</td>
</tr>
<tr>
<td>Shocks</td>
<td>Any</td>
</tr>
<tr>
<td>HRV</td>
<td>&lt; 60 ms for 7 consecutive days</td>
</tr>
</tbody>
</table>

5.5 fold increase in HF hospitalization within 30 days

With any 2 positive Criteria or if Fluid index >100
Partners HF
Room for Improvement

Manual Calculation
NYHA III (95%)
All CRT
No Automated Alerts
40% pts Intermediate Risk

MULTISENSE

Heart Sounds
Signs of elevated filling pressure (53)

Respiration
Rapid breathing and reduced tidal volume – shortness of breath

Thoracic Impedance
Fluid accumulation and pulmonary edema

Posture
Increased night elevation angle as indicator of Orthopnea or PND

Activity Response
Physiologic changes as a result of activity – such as signs of dyspnea on exertion

Heart Rate and Arrhythmias
Heart rates as indicator of cardiac status; atrial arrhythmias related to HF status
CEID detected heart sounds

Day Time (Loud S3)

S1
S2
S3

S3 detection and significance

Kaplan-Meier survival curve for event-free time

\[ p<0.0001, \text{HR}=2.9 \text{ (95\% CI: 2 - 4.1)} \]

Kaplan-Meier survival curve for event-free time

\[ p=0.56814, \text{HR}=1.2 \text{ (95\% CI: 0.68 - 2)} \]
Impedance Driven Respiration/MV/RSBI

Minute Ventilation = Rate \times \text{Tidal Volume}

Respiratory Data

Respiration Rate

Tidal Volume

Rapid Shallow Breathing Index
MULTISENSE Combined Data

Heart Sounds
Signs of elevated filling pressure (S3)

Respiration
Rapid breathing and reduced tidal volume (shortness of breath)

Thoracic Impedance
Fluid accumulation and pulmonary edema

Heart Rate
Indicator of cardiac status

Activity
Global patient status and fatigue

900 patients Followed for 1 year
500 patients algorithm development
400 patients validation arm
Followed for 1 year
MULTISENSE Results

70% Sensitivity Detection of HF Event
Alert triggers a mean of 34 days prior to HFE
89% of HFE had alert trigger at least 2 weeks prior
10 fold elevation in HFE in alert state
83% of patient days out of alert state

MULTISENSE with NT-proBNP

23 fold increase in HFE with low BNP in Alert

50 fold increase in HFE with high BNP in Alert

Low BNP out of alert has lowest HFE and were majority of follow up
MULTISENSE
Superior risk stratification
Automatic Calculation
Automated Alerts
Related to patient baseline characteristics

Ongoing outcome trials
Workflow optimization
New applications
Thank You