Initial Clinical Experience With A Novel Left Ventricular Quadripolar Lead

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Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

**Affiliation/Financial Relationship**

1. Honoraria for lectures
   - Boston Scientific, Medtronic, Sorin, St. Jude Medical, Sanofi-Aventis

2. Participation in clinical trials
   - Biotronik, Boston Scientific, Medtronic, Sorin, St. Jude Medical
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Prof. G. Boriani, Policlinico S.Orsola-Malpighi, Bologna
Background

- CRT is an efficient therapy for Heart Failure patients.

- It requires the placement of an LV lead in tributary vessels of the Coronary Sinus.

- Implantation of a bipolar LV lead is currently standard practice. Despite improvement in the lead technology over the past decade, this therapy is currently associated with the following challenges:
  - Placement of LV lead in the target vein
  - LV Lead dislodgement
  - Phrenic nerve stimulation (at implantation and chronically)
  - Poor LV pacing thresholds (at implantation and chronically)
  - Impact of LV lead location on CRT response.

- More programmable pacing options may be helpful to overcome these challenges.
Multipolar Quartet™ lead 1458Q

Four independent electrodes. Designed for stylet or over-the-wire placement. Optim™-insulated body with Fast-Pass™ coating.

The lead is connected to the device via 4-pole (IS4) connector.
Multipolar Quartet™ lead:
Pacing options over 5 cm on the left ventricle
# 10 programmable pacing options

<table>
<thead>
<tr>
<th>Conventional Pacing Vectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal 1 to Mid 2</td>
</tr>
<tr>
<td>Distal 1 to RV coil</td>
</tr>
<tr>
<td>Mid 2 to RV coil</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>New Pacing Vectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid 3 to Mid 2</td>
</tr>
<tr>
<td>Mid 3 to Proximal 4</td>
</tr>
<tr>
<td>Distal 1 to Proximal 4</td>
</tr>
<tr>
<td>Mid 2 to Proximal 4</td>
</tr>
<tr>
<td>Proximal 4 to Mid 2</td>
</tr>
<tr>
<td>Mid 3 to RV Coil</td>
</tr>
<tr>
<td>Proximal 4 to RV Coil</td>
</tr>
</tbody>
</table>
Study Design

CRT Implantation per standard practice

During post-implant hospitalization

1 Month Follow-up

Implanters feedback on handling of the Quartet lead
Programming choice at the end of the visit

Electrical performance (thresholds and impedance)
Presence of PNS at 7.5V
Programming choice at the end of the visit

Electrical performance
Presence of PNS at 7.5V and PNS threshold
Programming choice at the end of the visit
Demographics

75 patients indicated for CRT were enrolled prior to implantation

- 80% male
- 66 ± 10 years
- LVEF 27 ± 9%
- 51% had an ischemic etiology
- 68% were de novo implants
Study Flow

75 patients enrolled

71 patients successfully implanted

66 patients with complete data

2 deaths (non device related)

3 patients with incomplete measurements

Adverse events

1 re-intervention due to dislodgment leading to unmanageable PNS
2 bleeding/hematoma
1 non-device-related infection treated with antibiotics
Initial failure to implant due to:
- 1 dissection of coronary sinus
- 1 failure to cannulate the coronary sinus
  → Successful implant in a 2\textsuperscript{nd} attempt
- 1 venous access failure
- 1 case with poor capture thresholds (> 10V) *
- 1 lead with high impedance *

*This was observed in all configurations. No anomaly on lead was revealed during post-implant lead expertise

Initial implant success: 70/75 (93%)
→ Overall implant success: 71/75 (95%)

<table>
<thead>
<tr>
<th>Procedure Time</th>
<th>Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>From CS cannulation to final lead placement</td>
<td>33 ± 47</td>
</tr>
<tr>
<td>From first incision to skin closure</td>
<td>103 ± 54</td>
</tr>
<tr>
<td>Total Fluoroscopy time</td>
<td>19 ±15</td>
</tr>
</tbody>
</table>
# Implanters’ Feedback

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Easy</th>
<th>Normal</th>
<th>Hard</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s native anatomy</td>
<td>22%</td>
<td>33%</td>
<td>42%</td>
<td>3%</td>
</tr>
<tr>
<td>Lead maneuverability</td>
<td>51%</td>
<td>40%</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>Usage of stylet and guidewire with the LV lead</td>
<td>56%</td>
<td>30%</td>
<td>11%</td>
<td>3%</td>
</tr>
<tr>
<td>Questions on interactions with delivery systems</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advancement through the delivery system</td>
<td>58%</td>
<td>34%</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Removal of the delivery system</td>
<td>47%</td>
<td>25%</td>
<td>12%</td>
<td>16%</td>
</tr>
<tr>
<td>Questions on SJ4 header</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Set screw tightening</td>
<td>68%</td>
<td>25%</td>
<td>1%</td>
<td>5%</td>
</tr>
<tr>
<td>Insertion of LV lead into SJ4 LLLL socket</td>
<td>67%</td>
<td>27%</td>
<td>0%</td>
<td>5%</td>
</tr>
<tr>
<td>Visibility of the lead tip in the device header</td>
<td>67%</td>
<td>26%</td>
<td>1%</td>
<td>5%</td>
</tr>
</tbody>
</table>
## Electrical Performance

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Pre-Discharge</th>
<th>1 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Impedance (Ω)</td>
<td>Capture Threshold at 0.5 ms (V)</td>
</tr>
<tr>
<td>Distal 1 to Mid 2</td>
<td>933 ± 224</td>
<td>1.4 ± 1.3</td>
</tr>
<tr>
<td>Distal 1 to RV coil</td>
<td>583 ± 123</td>
<td>1.3 ± 1.3</td>
</tr>
<tr>
<td>Mid 2 to RV coil</td>
<td>431 ± 149</td>
<td>1.5 ± 1.2</td>
</tr>
</tbody>
</table>
## Incidence of Phrenic Nerve Stimulation

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Pre-Discharge</th>
<th>1 Month</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Presence of PNS at 7.5V</td>
<td>Presence of PNS at 7.5V</td>
<td>PNS Threshold at 0.5ms (V)</td>
</tr>
<tr>
<td>Distal 1 to Mid 2</td>
<td>17%</td>
<td>19%</td>
<td>4.5 ± 1.5</td>
</tr>
<tr>
<td>Distal 1 to RV coil</td>
<td>17%</td>
<td>19%</td>
<td>3.6 ± 2.1</td>
</tr>
<tr>
<td>Mid 2 to RV coil</td>
<td>18%</td>
<td>25%</td>
<td>3.7 ± 1.9</td>
</tr>
</tbody>
</table>
A good pacing option = No PNS at 7.5V and Capture threshold ≤ 2.5V

97% of patients with Quartet have one pacing option that fits this criteria. If patients were limited to conventional programming this would fall to 89%.

With Quartet 89% of patients have three good pacing options. Only 53% of patients would have this much flexibility with conventional programming.
A good pacing option = No PNS at 7.5V and Capture threshold ≤ 2.5V

Across the whole population Quartet provides an average of 6.0 ± 2.7 pacing options

- Conventional configurations: 2.2 ± 1.0
- New Quartet configurations: 3.8 ± 2.2
- Bipolar configurations: 3.5 ± 1.8
- Extended bipolar configurations: 2.5 ± 1.2
At 1-month, 6 patients presented with challenging pacing characteristic (PNS at 7.5V or Capture Threshold $\geq 5V$) in all conventional configurations.$^\wedge$.

<table>
<thead>
<tr>
<th>Nb of pacing configurations (No PNS, Threshold &lt; 5V)</th>
<th>Conventional</th>
<th>New Quartet</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3.5 $\pm$ 1.9 [1 – 6]</td>
<td></td>
</tr>
</tbody>
</table>
Configuration programming in clinical practice

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Final Programmed configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Implantation</td>
</tr>
<tr>
<td>Conventional</td>
<td>67%</td>
</tr>
<tr>
<td>New Quartet</td>
<td>33%</td>
</tr>
</tbody>
</table>

Use of new Quartet configurations was driven by:
  - Optimization of the electrical characteristics (57%)
  - Management of PNS (31%)

8 out of 10 configurations were programmed at 1-month
Conclusions

Pacing via the Quartet lead is associated with:
- high implant success rate (95%)
- stable performance over a 1-month period
- increased number of usable pacing configurations

Thus this novel quadripolar lead technology
- Will help optimizing pacing characteristics (impedance, outputs)
- Provides good alternatives in case of common complications (PNS, ↑ threshold)
- Can prevent invasive re-interventions
- May improve hemodynamics and CRT response
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THANK YOU FOR YOUR ATTENTION!
Evolution of CRT Pacing

<table>
<thead>
<tr>
<th>Generation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Past</strong></td>
<td></td>
</tr>
<tr>
<td><strong>1st Generation</strong></td>
<td>Unipolar or bipolar simultaneous Bi-V stimulation</td>
</tr>
<tr>
<td><strong>2nd Generation</strong></td>
<td>Unipolar or bipolar sequential Bi-V stimulation (V-V Timing)</td>
</tr>
<tr>
<td><strong>3rd Generation</strong></td>
<td>Quadripolar selected Site Stimulation (Bi-V)</td>
</tr>
<tr>
<td><strong>2010</strong></td>
<td></td>
</tr>
<tr>
<td><strong>4th Generation</strong></td>
<td>Quadripolar multisite sequential LV and RV Stimulation</td>
</tr>
</tbody>
</table>
Multisite LV Pacing

Select the Pulse Configuration, Pulse Amplitude and Pulse Width for each pace pulse, and the delay between them.

LV1
- Pulse Amplitude: 2.5 V
- Pulse Width: 0.5 ms
- Distal tip 1 - Mid 2

LV2
- Pulse Amplitude: 2.5 V
- Pulse Width: 0.5 ms
- Mid 2 - RV Coil

RV
- Pulse Amplitude: 2.5 V
- Pulse Width: 0.5 ms
- Bipolar

Delay
- LV1: 5 ms
- LV2: 10 ms
- RV: 130 ms

Multisite Post Ventricular Atrial Blanking

Multisite PVAE may affect tracking of organized atrial arrhythmias and inhibit auto mode switching

Multisite Triggering
Multisite Triggered LV2 Pulse Configuration, Additional Settings...
Quartet provides up to 10 good pacing options

A good pacing option = No PNS at 7.5V and Capture threshold ≤ 2.5V