PainFree SST Trial Primary Results

Inappropriate shock rates in patients with single or dual- and triple chamber ICDs using a novel suite of detection algorithms

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Clinical Research Manager, Medtronic
Biomedica Summit 2014
Medtronic is the world’s largest medical technology company

• Founded: 1949

• Employees: 46,000

• People benefited from our medical therapies: more than 9 million last year

• Medtronic BRC, NL
campus of international talents with a leading edge role in driving access to Medtronic therapies from idea to market adoption.
Implantable Cardioverter Defibrillator

Major functions of an ICD

- **Senses** appropriate cardiac signals
- **Detects** dangerous rhythms
- **Provides** therapy
- **Paces** if necessary
ICD therapies

• Low power (Pacing therapies)
  - Brady arrhythmia pacing
  - Anti-tachycardia Pacing (ATP)

• High power (Shock therapies)
  - Cardioversion
  - Defibrillation
Modern ICD trials show inappropriate shock rates up to 10%
SmartShock Technology

**WHY**
Only shock to save a life

**HOW**
Reduce inappropriate shocks by targeting the causes

**WHAT**
Medtronic SmartShock Technology
Medtronic SmartShock Algorithms in VR-ICD

Causes of Inappropriate Shock\(^1\)

- SVT: 55%
- Oversensing: 35%
- NSVT: 10%

SmartShock Technology

- Supraventricular Tachycardia
- Wavelet* (already included in previous devices)
- SVT discriminators in VF zone
- T-wave Discrimination
- Lead Integrity Alert
- Lead Noise Discrimination
- Non-sustained Ventricular Tachycardia Confirmation+

1 Wilkoff 2004 JCE
Objective
Inappropriate shock free rate at 1y post implant in Protecta single and dual- or triple chamber ICDs

Design
Worldwide interventional clinical study; 2791 subjects with a Protecta device in 126 sites

Population
All patients indicated for, undergoing replacement or an upgrade to or already implanted with a Protecta ICD
Study overview

Enrollment Phase I (n=246)
- Visit at 1, 3 and 6mo
- Safety and detection performance

Enrollment Phase II (n=2536)
- Required programming PHD
- Follow up visit every 6mo

Dual and triple chamber ICD (n=2007)
- FU ≥ 1year (n=1308)
- FU < 1year (n=699)

Single chamber ICD (n=757)
- FU ≥ 1year (n=712)
- FU < 1year (n=45)

Inappropriate shock free rate at 1 year

References:
1. Auricchio 2011 Europace, 2. Wollmann 2014 Pace
Results
## Geographical distribution

<table>
<thead>
<tr>
<th>Region</th>
<th>Single chamber</th>
<th>Dual and triple chamber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe (West, Central)</td>
<td>342 (48%)</td>
<td>841 (64%)</td>
</tr>
<tr>
<td>Canada</td>
<td>142 (20%)</td>
<td>234 (18%)</td>
</tr>
<tr>
<td>US</td>
<td>123 (17%)</td>
<td>121 (9%)</td>
</tr>
<tr>
<td>Middle-East</td>
<td>47 (7%)</td>
<td>99 (8%)</td>
</tr>
<tr>
<td>Japan</td>
<td>31 (4%)</td>
<td>7 (0.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>24 (3%)</td>
<td>6 (0.5%)</td>
</tr>
</tbody>
</table>
## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Single chamber</th>
<th>Dual and triple chamber</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICD system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Chamber (n (%))</td>
<td>712 (100%)</td>
<td>599 (45.8%)</td>
</tr>
<tr>
<td>Dual Chamber (n (%))</td>
<td></td>
<td>709 (54.2%)</td>
</tr>
<tr>
<td>Triple Chamber (n (%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age (years ± SD)</strong></td>
<td>61.9±12.3</td>
<td>65.3 ± 12.1</td>
</tr>
<tr>
<td><strong>Male sex (n (%))</strong></td>
<td>576 (81%)</td>
<td>1068 (81.7%)</td>
</tr>
<tr>
<td><strong>Primary Prevention Indication (n (%))</strong></td>
<td>470 (66%)</td>
<td>921 (70.4%)</td>
</tr>
<tr>
<td><strong>Secondary Prevention Indication (n (%))</strong></td>
<td>242 (34%)</td>
<td>387 (29.6%)</td>
</tr>
<tr>
<td><strong>Device replacements or upgrades (n(%))</strong></td>
<td>143 (20%)</td>
<td>440 (33.6%)</td>
</tr>
<tr>
<td><strong>Cardiac history</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic Cardiomyopathy (n (%))</td>
<td>305 (43%)</td>
<td>588 (45.0%)</td>
</tr>
<tr>
<td>Nonischemic Cardiomyopathy (n (%))</td>
<td>171 (24%)</td>
<td>464 (35.5%)</td>
</tr>
<tr>
<td><strong>Hx of AF, any</strong></td>
<td>155 (22%)</td>
<td>423 (32.3%)</td>
</tr>
<tr>
<td><strong>LVEF (mean ± SD)</strong></td>
<td>33.2 ±13.5%</td>
<td>31.3% ± 12.8%</td>
</tr>
<tr>
<td><strong>NYHA class (n (%))</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>174 (25%)</td>
<td>158 (12.1%)</td>
</tr>
<tr>
<td>II</td>
<td>325 (46%)</td>
<td>527 (40.3%)</td>
</tr>
<tr>
<td>III</td>
<td>94 (13%)</td>
<td>475 (36.3%)</td>
</tr>
<tr>
<td>IV</td>
<td>8 (1%)</td>
<td>21 (1.6%)</td>
</tr>
</tbody>
</table>
97.6% inappropriate shock free rate at 1 year

Shock free rate = 97.6% (CI: 96.4% - 98.8%)
19 inappropriately shocked episodes in 15 patients

Inappropriate Shocks in single chamber
Inappropriate shocks in dual and triple chamber

98.2% inappropriate shock free rate at 1 year
### Results: Causes of Inappropriate Shocks

<table>
<thead>
<tr>
<th>Cause</th>
<th>Single chamber n=19</th>
<th>Dual or triple chamber n=36</th>
</tr>
</thead>
<tbody>
<tr>
<td>AF/AFL</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Oversensing (lead noise, EMI)</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Noise due to lead dislodgement</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Other SVT</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Committed shock after appropriate therapy</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Incessant Non-Sustained VT</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>T-wave oversensing</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>
Results: Mortality

- Single chamber
  Mortality Rate = 2.4% (CI: 1.5% - 3.6%); 16 deaths

- Dual and triple chamber
  Mortality Rate = 5.3% (95% CI: 4.1-6.6%); 66 deaths
ICDs with SmartShock algorithms provide a low inappropriate shock rate in a real world patient population.

Only 2.4% and 1.8% of patients with a single and dual/triple chamber device had an inappropriate shock in the first year of implant.
Acknowledgements

Steering Committee
PainFree SST investigators
Episode review committee
Medtronic staff
and study participants