Leadless defibrillation

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Introduction

• ICD therapy is indicated in patients at risk of sudden cardiac death or after an aborted episode of sudden cardiac death

• ICD devices: sophisticated units, therapy platforms monitoring condition of patients and systems

• Connected to one or more leads......
Lead Performance

• Lead performance is still a serious issue

• Lead related complications are frequent
  – Thrombosis
  – Fracture
  – Perforation
  – Morbidity/Mortality related to lead extraction/manipulation
  – Risk higher in younger patients
Subclavian Crush
Pneumothorax
Occluded Subclavian Vein
Sprint Fidelis
Lead Performance LUMC, Borleffs et al.
None of these studies reflect impact of Sprint Fidelis.
Thrombosis

• Lead thrombosis may cause serious local and systemic complications

• LUMC data (van Rooden et al)
  – 145 patients
  – Cumulative incidence after 1 year: 23.4%
  – Most <3 months after implant
  – ICD: 51.7%, Pacemaker: 48.3%
Subcutaneous ICD system
Different lead and ICD configurations
The S-ICD System...

Totally subcutaneous system does not require electrodes “in or on” the heart

System is placed strictly by anatomical landmarks without a need for fluoroscopy

>800 systems implanted to date
The S-ICD System

*Implant procedure...*

- Ideal device placement
The S-ICD System

*Implanted system...*
The S-ICD System

S-ICD Therapy...

80J (delivered)

Biphasic shock

Charge time is approximately 9 seconds to maximum output

Mean time to shock: 14±2,5 sec (NEJM 2010)
The S-ICD System

• Three sense vectors
  – Provides maximum sensing flexibility
  – Allows the system to analyze a “surface” equivalent ECG for rhythm classification

• Shock vector
  – Encompasses the entire left chest
  – Tolerant of a wide variety of cardiac size/orientation
S-ICD System Components

SQ-Rx Pulse Generator...

Volume: 69 cc
Weight: 145 grams
Thickness: 15.7 mm
Energy: 80J (delivered)
Waveform: Biphasic
DFT: 36.6 vs 11.1
Longterm: 55
2 pocket revisions
4 lead revisions
12 shocks (appropriate)

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**Table 1. Clinical Characteristics of 55 Patients in the European Clinical Trial of a Subcutaneous Implantable Cardioverter–Defibrillator (ICD).**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age — yr</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>56±13</td>
</tr>
<tr>
<td>Range</td>
<td>22–84</td>
</tr>
<tr>
<td>Male sex — no. (%)</td>
<td>44 (80)</td>
</tr>
<tr>
<td>Body-mass index†</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>28±5</td>
</tr>
<tr>
<td>Range</td>
<td>17–40</td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.34±0.13</td>
</tr>
<tr>
<td>Range</td>
<td>0.14–0.73</td>
</tr>
<tr>
<td>Cause of cardiac disease — no. (%)</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>37 (67)</td>
</tr>
<tr>
<td>Nonischemic cardiomyopathy</td>
<td>10 (18)</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Other condition</td>
<td>6 (11)</td>
</tr>
<tr>
<td>Previous cardiac surgery — no. (%)</td>
<td>17 (31)</td>
</tr>
<tr>
<td>Indication for ICD — no. (%)</td>
<td></td>
</tr>
<tr>
<td>Primary prevention</td>
<td>43 (78)</td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>12 (22)</td>
</tr>
</tbody>
</table>

* Plus–minus values are means ±SD.
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
ICD electrodes...

**TRANSVENOUS**
- Exposed to >30 million cardiac contractions/yr
- Requires durability and flexibility

**SUBCUTANEOUS**
- Exposed to low stress and motion
- Designed to be stronger and less prone to failure
Indications

• Subcutaneous ICD system

• Transvenous lead system
Appropriate therapy.

Patients (%)

Patients at risk

Primary prevention

Secondary prevention

<table>
<thead>
<tr>
<th>Years</th>
<th>Primary prevention</th>
<th>Secondary prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1302</td>
<td>832</td>
</tr>
<tr>
<td>1</td>
<td>903</td>
<td>621</td>
</tr>
<tr>
<td>2</td>
<td>581</td>
<td>509</td>
</tr>
<tr>
<td>3</td>
<td>386</td>
<td>393</td>
</tr>
<tr>
<td>4</td>
<td>231</td>
<td>304</td>
</tr>
<tr>
<td>5</td>
<td>130</td>
<td>224</td>
</tr>
</tbody>
</table>

P < 0.0001
Appropriate therapy

• Secondary prevention patients:
  – 50% therapy after 5 years
  – 35% shocks, rest terminated with ATP

• Primary prevention patients:
  – 40% therapy after 5 years
  – 20% shocks, rest terminated with ATP
How to select patients

- Depending on the etiology?
- Non CRT candidates
- Non pacing-dependent patients
- Younger patients with genetic disorders?
Ischemic heart disease patients

- Mechanism of arrhythmias: reentry
- Anti Tachycardia Pacing may be indicated in many post mi patients

- Indicated in patients with occluded venous access
- Preserved LVEF patients?
Non-ischemic cardiomyopathy

- Non-reentrant arrhythmias?
- In patients without VT: S-ICD?

Indicated in patients with occluded venous access
In patients without VT
S-ICD vs ICD

- No bradycardia support < 30 sec
- No ATP
- No CRT&DDD
- Sensing: acceptable
- Removal: easier at lower risk
- DFT: higher
- Lead problems?

- Bradycardia support both post shock+VP
- ATP
- CRT&ATP
- Sensing: good
- Removal: requires skills and experience
- DFT: lower
- Lead problems frequent
Conclusions

• First generation subcutaneous devices: promising results
• At this time rather bulky compared to normal ICDs
• Not suitable for many primary and secondary prevention patients with ischemic heart disease
• Primary target: non-ischemic cardiomyopathy patient? Younger patients?