 Requirement for surgical reinterventions in ICDs

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J. Thijssen¹, C.J.W. Borleffs¹, M.K. de Bie¹, J.B. van Rees¹, G.H. van Welsenes¹, L. van Erven¹, J.J. Bax¹, S.C. Cannegieter², M.J. Schalij¹
From the Department of Cardiology¹ and Department of Clinical Epidemiology ², Leiden University Medical Centre, Leiden, the Netherlands
ICD Therapy

- Effective treatment
  - Secondary prevention of SCD
  - Primary prevention of SCD

- > 360,000 implants in 2010 worldwide
• Limited service life
  • Life span: 5-7 years

• 70% requires 1\textsuperscript{st} replacement
• 40% requires 2\textsuperscript{nd} replacement
Research Question

• To assess differences in the requirement for surgical re-intervention in first implanted ICDs vs. replacement ICDs
Patient Selection

- 22-1-1992 to 28-8-2008

- End-point: Pocket related complication requiring surgical re-intervention
**Patient Selection**

- **All ICDS**
  - N=3328

- **Thoracic ICDs**
  - N=3226

- **Abdominal ICDs**
  - N=102 (3.0%)

- **Included ICDs**
  - N=3161

- **Lost to follow up**
  - N=65 (2.0%)
### Patient Characteristics

#### ICD type & Number of devices

<table>
<thead>
<tr>
<th>ICD type</th>
<th>Number of devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Chamber</td>
<td>532</td>
</tr>
<tr>
<td>Dual Chamber</td>
<td>1447</td>
</tr>
<tr>
<td>CRT-D</td>
<td>1182</td>
</tr>
</tbody>
</table>

#### Manufacturer & Number of devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Number of devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>199</td>
</tr>
<tr>
<td>CPI/Guidant</td>
<td>1606</td>
</tr>
<tr>
<td>Medtronic</td>
<td>1080</td>
</tr>
<tr>
<td>St Jude/Ventritex</td>
<td>276</td>
</tr>
</tbody>
</table>

#### Patient characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>62±13 year</td>
</tr>
<tr>
<td>Male</td>
<td>2518 (80%)</td>
</tr>
<tr>
<td>Primary indication</td>
<td>62%</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>33±15 %</td>
</tr>
<tr>
<td>QRS</td>
<td>124±37 ms</td>
</tr>
<tr>
<td>Renal Clearance</td>
<td>96±38 ml/min</td>
</tr>
</tbody>
</table>
Distribution ICDs

<table>
<thead>
<tr>
<th>ICD</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st ICD</td>
<td>2415</td>
</tr>
<tr>
<td>2nd ICD</td>
<td>609</td>
</tr>
<tr>
<td>3rd ICD</td>
<td>107</td>
</tr>
<tr>
<td>4th ICD</td>
<td>24</td>
</tr>
<tr>
<td>5th ICD</td>
<td>6</td>
</tr>
</tbody>
</table>
**First ICD vs. Replacement ICD**

- Risk for re-intervention: 1.9 per 100 ICD-years
  - 1.5 per 100 ICD-years in first implanted ICDs
  - 3.3 per 100 ICD-years in replacement ICDs
  - RR 2.2 (p<0.001)
Re-Interventions

Cumulative event rate within 3 years:
- 3.9% in first implanted ICDs
- 7.5% in replacement ICDs

ICDs at risk:
- First ICD: 2415, 1748, 1299, 912
- Replacement ICD: 746, 514, 372, 235
# Events rates consecutive ICDs

<table>
<thead>
<tr>
<th>N=3161</th>
<th>1st ICD</th>
<th>2nd ICD</th>
<th>3rd ICD</th>
<th>4th ICD</th>
<th>5th ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of ICDs</td>
<td>2415</td>
<td>609</td>
<td>107</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>Events</td>
<td>90</td>
<td>46</td>
<td>5</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Totals years implanted</td>
<td>5949</td>
<td>1406</td>
<td>236</td>
<td>37</td>
<td>4.3</td>
</tr>
<tr>
<td>Events per 100 ICD years (95% CI)</td>
<td>1.5 (CI 1.2-1.9)</td>
<td>3.3 (CI 2.4-4.4)</td>
<td>2.1 (CI 0.7-4.9)</td>
<td>8.1 (CI 1.7-18.3)</td>
<td>23.3 (CI 0.6-129.6)</td>
</tr>
</tbody>
</table>

**Events per 100 ICD years**

- **1st ICD**: 1.5 (CI 1.2-1.9)
- **2nd ICD**: 3.3 (CI 2.4-4.4)
- **3rd ICD**: 2.1 (CI 0.7-4.9)
- **4th ICD**: 8.1 (CI 1.7-18.3)
- **5th ICD**: 23.3 (CI 0.6-129.6)
Infectious vs Non-Infectious

- Risk for re-intervention: 1.9 per 100 ICD-years

- Re-interventions
  - N=145

- Infectious cause
  - N=95

- Non-infectious cause
  - N=50
Infectious Causes

- N=95
- N=57
- N=27
- N=11

Total
Pocket infection
Decubic ulcers, relocation
Decubic ulcers, explantation

Background
Research Questions
Methods
Results
Discussion
Conclusion
Q and A
Results Infectious Causes

- Risk for re-intervention: 1.2 per 100 ICD-years
  - 0.9 per 100 ICD-years in first implanted ICDs
  - 2.3 per 100 ICD-years in replacement ICDs

- RR for surgical re-intervention in replacement ICDs: 2.5 (p<0.001)
Non-Infectious Causes

- Hematoma: N=50
- Relocation, migration: N=31
- Relocation, complaints: N=10
- N=9

Background
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Results Non-Infectious Causes

- Risk for re-intervention: 0.7 per 100 ICD-years
  - 0.6 per 100 ICD-years in first implanted ICDs
  - 1.0 per 100 ICD-years in replacement ICDs

- RR for surgical re-intervention in replacement ICDs: 1.7
  (p<0.112)
Conclusion

• Requirement for re-intervention: 1.9% per year

• Positive correlation between number of replacements and risk of surgical re-intervention
  • RR for infectious cause surgical re-intervention in replacement ICDs: 2.5 (p<0.001)
  • RR for non-infectious cause surgical re-intervention in replacement ICDs: 1.7 (p<0.112)