What You Should Know About Subcutaneous and Transvenous ICD

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HCM Summit
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ICD in HCM

Class I
ICD should be placed

Prior cardiac arrest
Sustained VT

Class II

Class II A
Family history SD-first-degree relative
LV wall thickness ≥ 30 mm
Recent unexplained syncope

Class II B
NSVT or ↓BP ETT
With other risk modifiers

Class III
ICD not recommended

No prior cardiac arrest or sustained VT
No risk factors
Defibrillator Options

Transvenous

Subcutaneous
Subcutaneous ICD

2002 Concept

2010 Bardy NEJM

2010 BS Acquires Cameron Health

2012 US FDA Approval

2012 EFFORTLESS S-ICD Registry

2012 US IDE Study

2012 US Post Market Study 2013

Circulation US IDE Study 2013

2009 CE Mark Approval

2002 Concept
S-ICD Candidates

- High risk genetic disorders
- \textit{HCM}
- LQTS
- Brugada
- High risk for lead complications
  - Young and active
  - Previous device infections
  - Diabetic and immunocomprised
- No venous access
  - Occluded veins
  - Congenital Heart Disease
- Transvenous leads undesirable
  - Hemodialysis patients
  - Younger Patients
- H/O Endocarditis or bacteremia
Pre-implant evaluation

1. **RECORD**: Supine + Standing
   25 mm/s, 5-20 mm/mV

2. **SELECT** the colored profile. The largest QRS peak *must* be within a Peak Zone.
Proposed strategy to avoid inappropriate shocks in hypertrophic cardiomyopathy (HCM) patients.

**Sensing**

Pass conventional ECG screening ideally in >1 vector, both supine and standing

If no conventional vector passes, try position on the right of the sternum

- Pre-implant: Recommend exercise testing to ensure proper QRS:T wave ratio also during exercise
- Post-implant: Dual zone programming with VF zone >220/min. Consider β-blockade if Hx of AT/AF
- Post-implant 6 weeks: Recommend exercise testing to ensure optimal QRS:T wave ratio & store QRS:T wave template of optimal vector
Maurizi et al Prevalence of subcutaneous implantable cardioverter-defibrillator candidacy based on template ECG screening in patients with hypertrophic cardiomyopathy
Heart Rhythm 2016
The S-ICD System Operation

Single-zone programming allows therapy to be delivered solely on measured heart rate.
Rhythm Discrimination with a Subcutaneous Defibrillator

Freedom from first inappropriate shock according to the number of zones programmed.
Gold et al Heart Rhythm 2014.

HR = 0.38 (0.21, 0.68)
P-value=0.001
Subcutaneous ICD

- **Transvenous leads are the weak link in current ICDs**
- **Prolonged detection/high rate detection is safe and improves outcomes**

2008 Fidelis Lead Recall

Kleemann *et al.* Circulation May 2007
Patients from a broad range of indications have received the S-ICD

- Ischemic (38%)
- Channelopathy (13%)
- Congenital (3%)
- Non-ischemic CM (10%)
- HCM (13%)
- ARVD (3%)
- Idiopathic VF (20%)
S-ICD Conversion Testing at Implant

94% < 21 seconds in each group

% of Episodes

Mean ± SD

HCM: 15.2 ± 3.3 (n=89)
Non HCM: 14.7 ± 3.1 (n=682) P=ns

### Table 1  Detailed demographics of HCM and non-HCM populations in the pooled analysis

<table>
<thead>
<tr>
<th>Category</th>
<th>HCM (n = 99)</th>
<th>Non-HCM (n = 773)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y) (Range)</td>
<td>41.6 ± 15.8 (11–85.2)</td>
<td>51.3 ± 16.8 (7–88)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Male (%)</td>
<td>74.7</td>
<td>72.2</td>
<td>ns</td>
</tr>
<tr>
<td>Height (cm) (Range)</td>
<td>175.4 ± 9.3 (152–202)</td>
<td>174.5 ± 10.4 (137–208.0)</td>
<td>ns</td>
</tr>
<tr>
<td>Weight (kg) (Range)</td>
<td>86.8 ± 19.6 (34–153.3)</td>
<td>86 ± 23.2 (18–230.9)</td>
<td>ns</td>
</tr>
<tr>
<td>BMI (Range)</td>
<td>28.4 ± 6.2 (19–48.7)</td>
<td>28.2 ± 6.7 (15.2–69)</td>
<td>ns</td>
</tr>
<tr>
<td>LVEF (%) Range</td>
<td>65.1 ± 9.9 (34–86)</td>
<td>36.2 ± 15.6 (10–80)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Primary prevention (%)</td>
<td>87.9</td>
<td>67.5</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Evaluation of subcutaneous ICD early performance in hypertrophic cardiomyopathy from the pooled EFFORTLESS and IDE cohorts Heart Rhythm 2016
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Pooled HCM S-ICD (% pts)</th>
<th>Pooled non-HCM S-ICD (% pts)</th>
<th>HCM TV-ICD meta-analysis (% pts)</th>
<th>HCM S-ICD event rate (% pts/y)</th>
<th>HCM TV-ICD meta-analysis event rate (% pts/y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate shocks</td>
<td>3</td>
<td>7.3</td>
<td>13.7 (9.9–17.5)</td>
<td>1.7</td>
<td>3.3 (2.2–4.4)</td>
</tr>
<tr>
<td>Inappropriate shocks</td>
<td>12.5</td>
<td>10.7</td>
<td>19 (12.6–25.4)</td>
<td>6.9</td>
<td>4.8 (2.2–6.7)</td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>1.6</td>
<td>3.1 (1.2–5)</td>
<td>1.1</td>
<td>0.6 (0.1–1)</td>
</tr>
<tr>
<td>Erosion</td>
<td>0</td>
<td>1.4</td>
<td></td>
<td></td>
<td>0.6 (0.1–1)</td>
</tr>
<tr>
<td>Lead displacement</td>
<td>1</td>
<td>0.5</td>
<td>2.7 (1.6–3.9)</td>
<td>0.6</td>
<td>1.5 (0.9–1.1)</td>
</tr>
<tr>
<td>Lead displacement/malposition/suboptimal system position</td>
<td>3</td>
<td>1.8</td>
<td>2.7 (1.6–3.9)</td>
<td>1.5</td>
<td>1.5 (0.9–1.1)</td>
</tr>
<tr>
<td>Lead malfunction</td>
<td>0</td>
<td>0</td>
<td>6.2 (4.1–8.3)</td>
<td>0</td>
<td>1 (0.5–1.4)</td>
</tr>
<tr>
<td>Conversion success rates</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Induced VT/VF</td>
<td>98.9</td>
<td>98.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous VT/VF</td>
<td>100</td>
<td>98</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
ICDs in HCM Pts.

Total ICDs
305

Total SubQ ICDs
32

Pts. w/ Shocks Received
7

Pts. w/ No Shocks Received
24 (+1 limited info)

Appropriate Shocks
1

Inappropriate Shocks
6

Pts. w/ Shocks Received
32 (+4 limited info)

Pts. w/ No Shocks Received
174 (+63 limited info)

Appropriate Shocks
34

Inappropriate Shocks
3
ICD with Subcutaneous Leads

- Advantages
  - No transvenous lead complications
  - Fluoroscopy not required for implant
  - Ultra far field signals for arrhythmia discrimination

- Disadvantages
  - Post shock pacing only (No Brady, CRT, ATP)
  - No remote monitoring
  - Larger Pulse generator
Patient Groups for S-ICD Implantation

- **S-ICD is preferred device**
  - Channelopathies (long-QT syndrome, Brugada, hypertrophic cardiomyopathy)
  - No venous access (occluded veins or congenital anomalies)
  - High risk of complications for transvenous systems have (dialysis, pediatric, and immunocompromised)
  - Previous device infections or lead failures
  - History of endocarditis

- **S-ICD should be strongly considered**
  - Young patients
    - Life expectancy >10 y
  - Primary prevention indicated patients with ischemic/nonischemic heart failure
  - Prosthetic valves
    - Women (preferred generator placement lateral wall)
  - Selected secondary prevention indicated patients (survivors of out-of-hospital VF, no evidence of monomorph VT

- **S-ICD should be avoided**
  - Systolic heart failure and LBBB who are indicated for CRT
  - Symptomatic bradycardia requiring pacemaker
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