2016 joint annual assembly SSC, SSCC, SSP
New devices in current practice and on the horizon
The Subcutaneous ICD
Nicolas Dayal
Hôpitaux Universitaires de Genève
15th June 2016
Conflicts of Interest

• None
Case description

- Male, 19 years old
- 3 episodes of syncope since childhood
- Family history of SCD in 3rd degree relatives only
- Consults cardiologist for new episode of syncope w/out prodrome whilst descending stairs
- Ambulatory Holter monitoring: numerous runs of polymorphic NSVT
ECG

Bradyarrhénée sinusradicale
Anomalie non spécifique de l'onde T
ECG anormal
Case description

• **TTE**: Dilated LV, LVEF 40-45%. RV normal

• **MRI**: LVEF 39%, diffuse sub-epicardial contrast enhancement in anterior, lateral and inferior walls and centromyocardial on the septal wall. No edema. No infarction. RV normal

• **FDG PET-CT**: homogenous hypermetabolism compatible with inflammation. No signs of sarcoidosis.

• **Myocardial biopsy**: focal cardiomyocyte hypertrophy and disorganization. No myocarditis.

• **Genetic consultation**: pending
Case description

- Patient equipped with Wearable ICD (W-ICD) with planned 3 months follow-up (myocarditis not excluded in view of PET-CT)
- HF treatment
- 3 month follow-up MRI: LVEF 50%, persistence of sub-epicardial contrast uptake.
- No arrhythmias on W-ICD, no syncope.
What next?

- EPS?
- Transvenous ICD? (TV-ICD)
- Subcutaneous ICD? (S-ICD)
- Continue W-ICD 3 months?
- Implantable loop recorder?
→ Patient received S-ICD
Subcutaneous ICD

- 1st generation: SQ-RX (Cameron Health)
- 2nd generation: EMBLEM S-ICD (Boston Scientific)
- Current model: EMBLEM MRI S-ICD (Boston Scientific)
Description

• Pulse generator (130g, 59.5cc)
• Tripolar lumenless lead
  • 8 cm shocking coil
  • Proximal and distal electrode
• Tablet-format programmer

Images courtesy of Boston Scientific
Pre-implantation screening

1\textsuperscript{st} step: exclusion criteria
- Need for durable anti-bradycardia pacing
- CRT-indication
- (Benefit of ATP: monomorphic VT or high risk of VT)

2\textsuperscript{nd} step: screening tool
- Official recommendation: min 1 vector standing/supine\textsuperscript{1}
- Preferably 2 suitable vectors
- Brugada syndrome: role of pharmacological challenge\textsuperscript{2}
- Right parasternal detection\textsuperscript{3}
- Exercise testing: role uncertain in screening\textsuperscript{4}, but important after implantation\textsuperscript{5}

1. EMBLEM\textsuperscript{TM} S-ICD user manual
Cosmetic result
DFT testing

- Recommended by manufacturer, no evidence
- Choice of shock energy from 10-80J in 5J steps
- Recommended minimum DFT 65J

DFT testing
Arrhythmia detection

- 3 sensing vectors: primary, secondary, alternate
- Automatic choice by device (manual override)
- Choice of single or dual zone programming
- Single: shock-only zone (nominal 220bpm)
- Conditional zone: discrimination (nominal 200bpm)
Arrhythmia detection

- **INSIGHT™ algorithm**
  - Phase 1: Detection
  - Phase 2: Certification
    - Threshold adaptation
    - Decay function
    - 4 double-detection algorithms:
      - morphology compared to NSR template
      - morphology compared to previous detection
      - timing measurements between detections
      - morphology relationships between 3 last detections
  - Phase 3: Therapy decision
    - Rate analysis: average of 4 previous beats
    - Static waveform: NSR template (41 points, >50% match)
    - Dynamic waveform: compared to 3 previous beats
    - Width in relation to NSR template: > 20ms
  - Duration criteria: 18/24 before charging
  - Confirmation before shock

INSIGHT™ Algorithm: Architecture

- Subcutaneous signal detection
- Heart rate determined
- HR assessed, therapy confirmed
- S-ECG signal similar to a surface ECG
- 4 double-detection algorithms designed to reduce oversensing
- 3 rhythm discriminators to confirm therapy
Post-implant

- Exercise test recommended by manufacturer
- Minimum HR 150bpm if possible (sensitivity auto-increase at 148bpm)
- +/- Template acquisition at peak effort
Shock delivery

- Only 80 J programmable
- Standard polarity: coil to can, reversed if unsuccessful
- Maximum 5 shocks per episode
- Post shock pacing:
  - If asystole > 3.5 seconds
  - 50 bpm for 30 seconds
  - 200mA biphasic transthoracic pulse
### Indications: ESC guidelines

#### Subcutaneous implantable cardioverter defibrillator

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.</td>
<td>IIa</td>
<td>C</td>
<td>157, 158</td>
</tr>
<tr>
<td>The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.</td>
<td>IIb</td>
<td>C</td>
<td>This panel of experts</td>
</tr>
</tbody>
</table>

#### Recommendations on practical aspects of implantable cardioverter defibrillator therapy

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to ICD implantation, patients should be counselled on the risk of inappropriate shocks, implant complications and the social, occupational, and driving implications of the device.</td>
<td>I</td>
<td>C</td>
<td>219.327</td>
</tr>
<tr>
<td>β-Blockers and/or amiodarone are recommended in patients with an ICD, who have symptomatic ventricular arrhythmias or recurrent shocks despite optimal treatment and device re-programming.</td>
<td>I</td>
<td>C</td>
<td>219.403</td>
</tr>
<tr>
<td>Electrophysiological study is recommended in patients with ICDs and inappropriate shocks due to regular supraventricular tachycardias, to identify and treat any ablatable arrhythmia substrate.</td>
<td>I</td>
<td>C</td>
<td>403</td>
</tr>
<tr>
<td>A subcutaneous ICD lead system (S-ICD™) may be considered in HCM patients who do not have an indication for pacing.</td>
<td>IIb</td>
<td>C</td>
<td>407</td>
</tr>
</tbody>
</table>

Priori et al. 2015 ESC VA and SCD guidelines

Elliot et al. 2014 ESC HCM guidelines

---

Indications

**Figure 4** Factors affecting patient selection for the subcutaneous implantable cardioverter defibrillator.

Sensitivity/Specificity

• Sensitivity: approx. 100%\textsuperscript{1,2,3}

<table>
<thead>
<tr>
<th>Lead author (year)</th>
<th>Mean follow-up (months)</th>
<th>Appropriate detection (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bardy (2010)\textsuperscript{12}</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>Dabiri Abkenari (2011)\textsuperscript{41}</td>
<td>9</td>
<td>100</td>
</tr>
<tr>
<td>Olde Nordkamp (2012)\textsuperscript{142}</td>
<td>18</td>
<td>NR</td>
</tr>
<tr>
<td>Aydin (2012)\textsuperscript{43}</td>
<td>8</td>
<td>NR</td>
</tr>
<tr>
<td>Jarman (2012)\textsuperscript{40}</td>
<td>9</td>
<td>100</td>
</tr>
<tr>
<td>Jarman (2013)\textsuperscript{44}</td>
<td>12</td>
<td>100</td>
</tr>
<tr>
<td>Köbe (2013)\textsuperscript{46}</td>
<td>7</td>
<td>NR</td>
</tr>
<tr>
<td>Weiss (2013)\textsuperscript{43}</td>
<td>11</td>
<td>99.8</td>
</tr>
<tr>
<td>Lambiase (2014)\textsuperscript{58}</td>
<td>18.5</td>
<td>NR</td>
</tr>
</tbody>
</table>

• Specificity
  • 98% (START Study\textsuperscript{1} – dual zone S-ICD)
  • EFFORTLESS\textsuperscript{2} registry: 6% shock due to SVT, all in shock zone

Shock efficacy

<table>
<thead>
<tr>
<th>Spontaneous Shock Efficacy</th>
<th>First Shock</th>
<th>Final Shock in episode</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-ICD* EFFORTLESS 3 year Analysis&lt;sup&gt;1&lt;/sup&gt;</td>
<td>88.5%</td>
<td>97.4%</td>
</tr>
<tr>
<td>S-ICD Pooled 2 year Analysis&lt;sup&gt;2&lt;/sup&gt;</td>
<td>90.1%</td>
<td>98.2%</td>
</tr>
</tbody>
</table>

- Charge time: 19.2 ± 5.3s<sup>2</sup> (40% NSVT in these studies)

- DFT testing
  - > 95% conversion at 65j or more.
  - Mean DFT: 36.6 ± 19.8 J vs 11.1 ± 8.5 J (TV-ICD).<sup>3</sup>
  - Role of can and coil position
  - Role of BMI: Failed shocks – BMI < 25 = 5.2%, 25-30 = 13.3%, BMI > 30 = 16.5%<sup>4</sup>

1. Boersma et al. EFFORTLESS 3 year results. LBCT. HRS 2016
Inappropriate shocks (IAS)

- Higher than TV-ICD
- Mainly due to cardiac oversensing, especially T-wave (TWOS)

Priori et al. 2015 ESC VA and SCD guidelines

Slide courtesy of Boston Scientific
Reduction of inappropriate shocks

• Role of dual zone programming\(^1\)

• Role of exercise testing\(^2\)
  • 8 pts with IAS from TWOS, 7 at exercise, 1 during rapid AF
  • After vector change + template during exercise \(\rightarrow\) 87.5% w/out IAS

Reduction in IAS: SMART Pass

- High pass filter, filters out signals < 9Hz
- ECG for rhythm discrimination unchanged
- Signal slightly diminished → disabled in case of small R-waves (<0.5mV)
- Disabled in case of slow heart rates
- Available in EMBLEM™ MRI and retroactively in EMBLEM™ S-ICD

- Validation with data set of 626 EFFORTLESS episodes
- No real-life data yet
Safety and complications

Acute major implant-related: 2% (TV-ICD: VR 1.9%, DR 2.9%)\(^2\)
No systemic infection
No electrode failures

### Table 2: Complications in the first 6 months

<table>
<thead>
<tr>
<th>Description</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>System infection</td>
<td>16</td>
</tr>
<tr>
<td>Electrode movement</td>
<td>7</td>
</tr>
<tr>
<td>Suboptimal electrode position</td>
<td>7</td>
</tr>
<tr>
<td>Erosion</td>
<td>5</td>
</tr>
<tr>
<td>Discomfort</td>
<td>4</td>
</tr>
<tr>
<td>Haematoma</td>
<td>4</td>
</tr>
<tr>
<td>Suboptimal pulse generator and electrode position</td>
<td>4</td>
</tr>
<tr>
<td>Adverse reaction to medication</td>
<td>3</td>
</tr>
<tr>
<td>Inadequate/prolonged healing of incision site</td>
<td>3</td>
</tr>
<tr>
<td>Incision/superficial infection</td>
<td>3</td>
</tr>
<tr>
<td>Pulse generator movement/revision</td>
<td>3</td>
</tr>
<tr>
<td>Suboptimal pulse generator position</td>
<td>2</td>
</tr>
<tr>
<td>Failed defibrillation threshold test</td>
<td>2</td>
</tr>
<tr>
<td>Acute hypoxic respiratory failure</td>
<td>1</td>
</tr>
<tr>
<td>Incomplete electrode connection to the device</td>
<td>1</td>
</tr>
<tr>
<td>Near syncope/dizziness/shortness of breath/confusion</td>
<td>1</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>1</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>1</td>
</tr>
<tr>
<td>Seroma</td>
<td>1</td>
</tr>
<tr>
<td>Suspected worsening of ischaemia</td>
<td>1</td>
</tr>
<tr>
<td>Suture discomfort</td>
<td>1</td>
</tr>
<tr>
<td>Undersensing</td>
<td>1</td>
</tr>
<tr>
<td>Grand total</td>
<td>72</td>
</tr>
</tbody>
</table>

### Lead author (year) Complications requiring reintervention (%)

<table>
<thead>
<tr>
<th>Lead author (year)</th>
<th>Complications requiring reintervention (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bardy (2010)(^{19})</td>
<td>11</td>
</tr>
<tr>
<td>Dabiri Abkenari (2011)(^{41})</td>
<td>10</td>
</tr>
<tr>
<td>Olde Nordkamp (2012)(^{42})</td>
<td>14</td>
</tr>
<tr>
<td>Aydin (2012)(^{48})</td>
<td>13</td>
</tr>
<tr>
<td>Jarman (2012)(^{40})</td>
<td>19</td>
</tr>
<tr>
<td>Jarman (2013)(^{44})</td>
<td>16</td>
</tr>
<tr>
<td>Köbe (2013)(^{41})</td>
<td>4</td>
</tr>
<tr>
<td>Weiss (2013)(^{57})</td>
<td>1.3</td>
</tr>
<tr>
<td>Lambiase (2014)(^{58})</td>
<td>NR</td>
</tr>
</tbody>
</table>

### Figure 1: Kaplan–Meier analysis of experience quartiles and complications at 180 days. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28); ARR, absolute risk reduction; RRR, relative risk reduction. \(P\) value is Kaplan–Meier trend test.

IDE + EFFORTLESS N = 882\(^1\)

Device longevity

Table 4. Device Longevity

<table>
<thead>
<tr>
<th>Annual Full Energy Charges</th>
<th>Average Projected Longevity (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Use®</td>
<td>7.3</td>
</tr>
<tr>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>5</td>
<td>6.3</td>
</tr>
</tbody>
</table>

*a. The median number of annual full energy charges seen in clinical testing of the first generation S-ICD system was 3.3.*

- Slightly shorter longevity than TV-ICDs…?
Device Longevity

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Before 2006 5-year longevity (%)</th>
<th>Before 2006 6-year longevity (%)</th>
<th>Thereafter 5-year longevity (%)</th>
<th>Thereafter 6-year longevity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All manufacturers**</td>
<td>63.9</td>
<td>44.9</td>
<td>92.1</td>
<td>76.0</td>
</tr>
<tr>
<td>Biotronik**</td>
<td>49.3</td>
<td>50.5</td>
<td>89.1</td>
<td>45.6</td>
</tr>
<tr>
<td>Boston**</td>
<td>65.1</td>
<td>49.2</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Medtronic***</td>
<td>77.2</td>
<td>66.0</td>
<td>91.7</td>
<td>85.9</td>
</tr>
<tr>
<td>St. Jude Medical***</td>
<td>64.5</td>
<td>59.6</td>
<td>94.3</td>
<td>92.6</td>
</tr>
<tr>
<td>Sorin**</td>
<td>59.8</td>
<td>53.3</td>
<td>80.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Intermedics</td>
<td>0</td>
<td>0</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Cameron Health</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

**VVI

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Before 2006 5-year longevity (%)</th>
<th>Before 2006 6-year longevity (%)</th>
<th>Thereafter 5-year longevity (%)</th>
<th>Thereafter 6-year longevity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All manufacturers**</td>
<td>73.7</td>
<td>56.4</td>
<td>92.1</td>
<td>76.0</td>
</tr>
<tr>
<td>Biotronik**</td>
<td>59.8</td>
<td>15.2</td>
<td>89.1</td>
<td>45.6</td>
</tr>
<tr>
<td>Boston**</td>
<td>74.3</td>
<td>53.3</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Medtronic***</td>
<td>86.7</td>
<td>80.1</td>
<td>91.7</td>
<td>85.9</td>
</tr>
<tr>
<td>St. Jude Medical***</td>
<td>70.9</td>
<td>60.1</td>
<td>94.3</td>
<td>92.6</td>
</tr>
<tr>
<td>Sorin**</td>
<td>n.a.</td>
<td>n.a.</td>
<td>80.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Intermedics</td>
<td>0</td>
<td>0</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Cameron Health</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

***DDD

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Before 2006 5-year longevity (%)</th>
<th>Before 2006 6-year longevity (%)</th>
<th>Thereafter 5-year longevity (%)</th>
<th>Thereafter 6-year longevity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All manufacturers**</td>
<td>58.3</td>
<td>21.2</td>
<td>66.3</td>
<td>43.0</td>
</tr>
<tr>
<td>Biotronik**</td>
<td>26.6</td>
<td>0</td>
<td>76.2</td>
<td>44.9</td>
</tr>
<tr>
<td>Boston**</td>
<td>43.5</td>
<td>17.5</td>
<td>97.6</td>
<td>97.6</td>
</tr>
<tr>
<td>Medtronic***</td>
<td>74.1</td>
<td>74.1</td>
<td>46.3</td>
<td>46.3</td>
</tr>
<tr>
<td>St. Jude Medical***</td>
<td>61.3</td>
<td>30.9</td>
<td>45.3</td>
<td>26.5</td>
</tr>
</tbody>
</table>

**n.a., not applicable; n.s., not significant in this period; not implanted in the two hospitals, or time point not reached. ICD, implantable cardioverter-defibrillator.

Remote monitoring

- LATITUDE™ system
Recent developments: MRI compatibility

- April 2016: CE mark for full body MRI compatibility
  - 3rd gen: EMBLEM™ MRI S-ICD
  - 2nd gen: EMBLEM™ S-ICD backwards compatibility

- → 1.5T
- → No exclusion (cardiac MRI: artefacts for LV ?)\(^1\)
- → No time limitation for MRI exam
- → MRI-mode: suspends tachycardia therapy
- → Automatic timeout after 6, 9, 12 or 24h. Manual exit possible

- NB: Beeper volume can be disabled permanently.
  - After MRI, home monitoring highly recommended or in-office control 1x3 months\(^2\)

---

2. EMBLEM MRI S-ICD User manual
Recent developments: AF Monitor™

AF Monitor™ Algorithm
AF Monitor™ uses Ventricular scatter and HRDI algorithms to identify and classify rhythm\(^1\) (based on internal bench testing).

Both Ventricular Scatter and HRDI algorithms need to be met in a 192 beat window for the rhythm to be classified as AF\(^1\).

Heart Rate Distribution for Patient in NSR

Heart Rate Density Index = 91%
Heart Rate Mode = 60bpm

Heart Rate Distribution for Patient in AFib

Heart Rate Density Index = 23%
Heart Rate Mode = 90bpm

© 2020 Boston Scientific Corporation or its affiliates. All rights reserved. All trademarks are the property of their respective owners. CRM-382002-AA APR2016

Slide courtesy of Boston Scientific
Recent developments: AF Monitor™

• Validation cohort: 99 with AF, 79 without AF
  • Specificity: 100% (79/79)
  • Sensitivity: 94.9% (94/99)
  • False negatives: short (<8 min) episodes, stable ventricular rate

Boersma et al. Abstract AB05-02, HRS 2016
Future developments: Leadless pacing/ATP

- First in animal experience with ATP enabled-leadless pacemaker + S-ICD¹

S-ICD in Switzerland

- 65 implants (17000 worldwide)
- Price: around 35,000 Chf (TV ICD around 20-24,000Chf)
Future devices: Extravascular ICD

- Substernal coil to reduce shock energy
- Product under development
- 2 industry studies (Medtronic) presented at HRS 2016
  - Defibrillation: feasibility study\(^1\) 16 pts, 92.9% successful defibrillation at 35J. (S-ICD Mean DFT: 36.6 ± 19.8J in CE study\(^2\))
  - Pacing: SPACE trial\(^3\): 24 patients, decapolar EP catheter, 17/24 consistent capture, median threshold 2.9V (2.2-8)

# Advantages/Disadvantages

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less lead failure</td>
<td>No anti-bradycardia pacing or CRT</td>
</tr>
<tr>
<td>No systemic infection</td>
<td>No ATP</td>
</tr>
<tr>
<td>Preserved vascular access</td>
<td>Lack of long term follow-up</td>
</tr>
<tr>
<td>No/less fluoroscopy</td>
<td>Shorter battery life</td>
</tr>
<tr>
<td>No risk of transvenous lead extraction</td>
<td>Higher risk of IAS</td>
</tr>
<tr>
<td>Predictability of implantation</td>
<td>Limited programming options</td>
</tr>
<tr>
<td>Less procedural risk</td>
<td>Higher cost</td>
</tr>
</tbody>
</table>
Conclusion

- S-ICD is a promising technology
- Still early in development
- Long term-follow-up and prospective trials lacking
- Need for better understanding of ideal candidates
- Leadless pacing/ATP promising
- Useful tool to have in arsenal of therapeutic options
- Not yet a solution for all ICD candidates
Acknowledgments

• Y. Bouix and K. Mamdouh, Boston Scientific.
Thank you for your attention
Extra slides
X-ray
S-ICD – Other device interactions

• First single-center experience:¹
  • 10 patients with TV-PM, epicardial PM, CCM or vagus nerve stimulators
  • 100% Successful implants
  • No device interaction (17 month follow-up)

Stored episodes

- Treated: 20 episodes, up to 128 seconds per episode
- Untreated: 15 episodes, up to 128 seconds
- AF: 7 episodes, up to 44 seconds
SUMMARY REPORT

Patient Name: [Redacted]
Last Follow-up Date: 24/03/2016
Follow-up Date: 21/04/2016
Implant Date: 17/03/2016

Device Model#: A209 EMBLEM™ S-ICD
Device Serial#: 110653
Electrode Model#: 3401
Electrode Serial#: A127182

Programmable Parameters

Current Device Settings
- Therapy: ON
- Shock Zone: 220 bpm
- Conditional Shock Zone: 200 bpm
- Post Shock Pacing: OFF

Gain Setting: 1X
Sensing Configuration: Alternate
Shock Polarity: STD

Initial Device Settings
- Therapy: ON
- Shock Zone: 220 bpm
- Conditional Shock Zone: 200 bpm
- Post Shock Pacing: OFF

Gain Setting: 1X
Sensing Configuration: Alternate
Shock Polarity: STD

Parameter changes this session: NO

Episode Summary

Since Last Follow-Up
- Untreated Episodes: 0
- Treated Episodes: 0
- # of Shocks Delivered: 0

Since Implant
- Untreated Episodes: 0
- Treated Episodes: 0
- # of Shocks Delivered: 1

Battery Status

Electrode Impedance Status
Recent developments: MRI compatibility

- First published study of MRI in S-ICD\(^1\)
- 15 patients, 22 MRI scans, all body.
- 1.5T
- No interaction
- No device malfunction

Eligibility

- Rates of failure of ECG screening:
  - 7-8% for one acceptable vector\textsuperscript{1,2}
  - 15% for 2 vectors\textsuperscript{3}
- Primary and secondary vectors: approx 80% success
- Alternate vector: 40-50% (perpendicular?)
- Variable predictors of failure:
  - Negative T-waves in I, II, avF (45%ppv)
  - RBBB (OR 1.5 /20ms)
  - Obesity (OR 1.5 /10Kg)
  - HCM (OR 12.6)
  - R:T < 3 (OR 14.5)

Specific subgroups: TV-ICD extraction

- Higher mortality after device infection, persists for 3 years\(^1\)
- “Sicker” patients:
  - renal failure,
  - coagulopathy,
  - weight loss.

- Relapse rate after TV-ICD re-implantation: 1.9-2.6% at 1 year\(^2\)

1. Sohail et al. PACE 2015; 38:231–239
Specific subgroups: TV-ICD extraction

- Retrospective analysis of IDE + EFFORTLESS Registries

### Table 3: Complication rates according to patient cohort

<table>
<thead>
<tr>
<th>Complication description</th>
<th>Reimplantation: Prior TV-ICD infection (n = 75)</th>
<th>Reimplantation: Prior TV-ICD, no infection (n = 44)</th>
<th>No prior TV-ICD explantation (de novo) (n = 747)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All complications</td>
<td>12 (10.7%)</td>
<td>4 (6.8%)</td>
<td>90 (9.6%)</td>
<td>0.78</td>
</tr>
<tr>
<td>Device system infection</td>
<td>1 (1.3%)</td>
<td>2 (4.5%)</td>
<td>14 (1.6%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Erosion</td>
<td>1 (1.3%)</td>
<td>1 (2.3%)</td>
<td>10 (1.2%)</td>
<td>0.83</td>
</tr>
<tr>
<td>Incision/superficial infection</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>3 (0.4%)</td>
<td>0.79</td>
</tr>
</tbody>
</table>

Values are number of events or n (%). TV-ICD = transvenous implantable cardioverter-defibrillator.

Implantation procedure