Korea Real Experience with the S-ICD System

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Transvenous ICD Limitations

Anatomical limitations
- Venous access issues

Implant risks
- Pericardial effusion/cardiac tamponade, perforation, pneumothorax, lead dislodgement, endocarditis, systemic infection, death

Lead failure risks
- Inappropriate shock/loss of therapy

Explant risks
- Vessel dissection, perforation or occlusion, valve damage, bleeding, tamponade, systemic infection, death

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NCDR ICD Registry: Device-Related Complications*

- Pneumothorax: 0.37, 0.37, 0.25
- Hematoma: 0.45, 1.39, 2.40
- Cardiac tamponade: 0.68, 0.68, 0.51
- Mechanical complications: 0.66, 0.86, 0.81
- Device-related infection: 0.66, 0.66
- Post-index ICD: 0.81, 0.81
- Any complication: 3.85, 5.94

*Up to 90 days post-implant

Year after implantation
- 1st: 290, 290
- 2nd: 15/746
- 3rd: 15/579
- 4th: 12/442
- 5th: 13/323
- 6th: 17/252
- 7th: 14/168
- 8th: 15/110
- 9th: 8/98
- 10th: 7/98

p < 0.001
Subcutaneous ICD Therapy

EMBLEM™ MRI S-ICD System

• Entirely subcutaneous

• Does not require leads in the heart, leaving the vasculature untouched

• Placed using anatomical landmarks, reducing the need for fluoroscopy at implant

• Sophisticated algorithms provide effective detection and treatment of VT/VF

Cases:
The First Experiences
In Severance Hospital
Case 1. M/49

- HCMP
  - maximal thickness: 18mm
- Sustained VT
- Syncope
- ICD implantation for secondary prevention on Jan 2015
4 months later...

- Fever & pus drainage from pocket wound
- Erythema (+) / Tenderness (+)

→ ICD & lead extraction
S-ICD implantation on Oct 2016
S-ICD implantation on Oct 2016
Case 2. M/56

- HCMP
  - maximal thickness: 37mm
- Nonsustained VT
- ICD implantation on Oct 2009
- G/C on Jul 2016
1 week after G/C...

- Fever & Chill
- G(+) cocci from blood culture
- Echogenic mobile material in RA on TEE
< Operative findings >
- ICD lead infection으로 제거되지 않아 open heart로 제거함
- V-lead 에 1x1cm sized vegetation (+)
  → Removal
S-ICD implantation on Oct 2016
S-ICD implantation on Oct 2016
In the AP view, the sensing rings are parallel to one another and about 1 cm from the sternal midline. The pulse generator is at the mid-axillary line.
X-ray landmarks

- In the left lateral view, the sensing rings appear to lie on the sternal surface.
- The ideal position of the pulse generator is between the 5\(^{th}\) and 6\(^{th}\) intercostal space at the mid-axillary line.
- The inferior edge of the device should not be below the xyphoid.
Mark landmarks

Suggested Marking
• Device placement / location and pocket incision
• Xyphoid incision
• Suprasternal notch
• Sternal midline
• Mid-axillary line

• The system placement should reflect the original screening configuration.
• Confirm the ideal placement with Fluoroscopy while the Demo Device and Electrode are taped to patients skin surface.
Implanting the system
Completing the implantation

- Pocket antibiotics flush or antiseptic is recommended.
- Close pocket tissue layers & sternal incisions in standard fashion.
  - At least two layers of closure
- Apply standard wound dressings.
  - Pressure dressing
  - Include antimicrobial per preference or policy
X-ray assessment

Electrode too lateral

Electrode tip too superficial
Sensing the subcutaneous signal

✓ 3 Far-Field Sensing Vectors:
  ✓ Detect the cardiac rhythm (3 different perspectives of electrical activity)
  ✓ Capture high-resolution signals similar to a surface ECG
  ✓ Utilizes both timing and morphology template
Sensing the subcutaneous signal

Automatic Setup Analyzes:

- QRS and T-wave amplitudes
- QRS:T-wave ratios (amplitude and timing)
- Patient posture
- QRS morphology and width
• Episodes
  – Up to 5 shocks per episode @ 80 J
  – Up to 128 seconds of S-ECG storage per episode
  – Storage of up to 44 episodes

• Adaptive Shock Polarity
  – System remembers the polarity of the last successful shock and automatically selects this shock polarity for the first shock of an episode
Therapy delivery

Induction

- Induction capability directly from the S-ICD® System programmer
- 200 mA @ 50 Hz
- Programmable first shock energy

Post-Shock Pacing

- Transthoracic pacing
- Delivered for up to 30 seconds post-shock
- Demand based pacing @ 50 ppm using 200 mA
## S-ICD Study

<table>
<thead>
<tr>
<th>S-ICD™ System Study</th>
<th>Study Type</th>
<th>Patients</th>
<th>Sites</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility and Proof of Concept Studies¹</td>
<td>Acute</td>
<td>78 + 49</td>
<td>Not reported</td>
<td>Study completed: 2005 Published in NEJM</td>
</tr>
<tr>
<td>Initial Human Validation Study¹</td>
<td>Chronic Safety and Performance</td>
<td>6</td>
<td>2 (NZ)</td>
<td>Study completed: 2008 Published in NEJM</td>
</tr>
<tr>
<td>CE Clinical Study¹</td>
<td>Chronic Safety and Performance</td>
<td>55</td>
<td>8 (OUS)</td>
<td>Study completed: 2011 Published in NEJM</td>
</tr>
<tr>
<td>IDE Clinical Study²</td>
<td>Chronic IDE</td>
<td>330</td>
<td>33 (US, EU, NZ)</td>
<td>Study completed: 2011 Published in Circulation</td>
</tr>
<tr>
<td>EFFORTLESS Registry³,⁴</td>
<td>Chronic Post-Market OUS Registry</td>
<td>1,000</td>
<td>50 (EU)</td>
<td>1000 patient enrollment completed end 2014</td>
</tr>
<tr>
<td>Post Approval Study⁶</td>
<td>Chronic Post-Market Trial</td>
<td>Goal; 1616</td>
<td>Multi-center (US)</td>
<td>Enrolling</td>
</tr>
<tr>
<td>PRAETORIAN Trial (Investigator Sponsored Research funded by a grant from Boston Scientific)⁵</td>
<td>Chronic Post-Market Randomized Trial</td>
<td>Goal: 850</td>
<td>Multi-center (EU, US)</td>
<td>Enrolling Investigator-initiated, randomized, controlled, multi-center, prospective 2-arm trial (S-ICD System vs. TV-ICD Systems)</td>
</tr>
<tr>
<td>UNTOUCHED⁷</td>
<td>Chronic Post-Market Trial</td>
<td>Goal = 1100</td>
<td>Multi-center (EU, US)</td>
<td>MADIT II/SCD-HeFT indications</td>
</tr>
</tbody>
</table>

7. Understanding Outcomes With the EMBLEM™ S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED): https://clinicaltrials.gov/ct2/show/NCT02433379
Implant and Midterm Outcomes of the S-ICD Registry: The EFFORTLESS Study

N = 985
FU: 3.1 ± 1.5 years

<table>
<thead>
<tr>
<th>Table 2: Complications</th>
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</thead>
<tbody>
<tr>
<td>Description</td>
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<tr>
<td>-----------------------</td>
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<tr>
<td>Infection requiring device removal</td>
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<tr>
<td>Erosion</td>
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<tr>
<td>Inappropriate shock: oversensing</td>
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<tr>
<td>Other procedural complications</td>
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<tr>
<td>Hematoma</td>
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<tr>
<td>Discomfort</td>
</tr>
<tr>
<td>Suboptimal electrode position</td>
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<tr>
<td>Electrode movement</td>
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<tr>
<td>Premature battery depletion</td>
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<tr>
<td>PG movement</td>
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<tr>
<td>Unable to convert during procedure</td>
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<tr>
<td>Incision/superficial infection</td>
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<tr>
<td>Other technical complications</td>
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<tr>
<td>Suboptimal PG and electrode position</td>
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<tr>
<td>Inability to communicate with the device</td>
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<tr>
<td>Inappropriate shock: SVT above discrimination zone (normal device function)</td>
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<tr>
<td>Suboptimal pulse generator position</td>
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<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Boersma L et al. J Am Coll Cardiol 2017;70:830–41
KM curves: freedom from device- and procedure-related complications

Primary vs. Secondary Prevention

Primary Prev: EF ≤35%, vs. >35%

Boersma L et al. Heart rhythm 2017;14:367–75
Summary (1)

- **Patient Screening**
  - Use the **ECG screening tool** to verify the acceptability of the surface ECG for rhythm detection and discrimination.
  - A patient is considered suitable for an S-ICD System if at least one ECG lead is acceptable in **two patient postures**.

- **Patient Preparation**
  - Use **X-ray landmarks** to plan pulse generator and electrode placement.
  - **Mark** incision sites and the sternal midline before patient draping.
Summary (2)

• Implant Considerations
  – Close the deep tissue layer before induction testing to ensure good tissue-electrode contact.
  – To prevent tissue dryness/trapped air, keep incisions moist before and during incision closure.
  – To expel any trapped air, apply firm pressure during inner layer closure.

• Patient Care
  – To prevent infection, consider prophylactic antibiotics.
  – Adjust pulse generator placement as needed to ensure patient comfort.
Thank you for your attention!