Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)

D.D. Manolatos, MD, PhD, FESC
Electrophysiology and Device Lab
General Hospital Evangelismos, Athens
The Problem:

• 300,000 people die each year in the United States due to sudden cardiac arrest (SCA)
• People who have severe coronary heart disease are at a heightened risk for SCA
• Several studies show that an implantable cardioverter-defibrillator (ICD) can reduce the chance of dying from SCA
A Solution:

- Transvenous implantable cardioverter-defibrillator (T-ICD)
- First human implant in 1980
- Gained FDA approval in 1985
- First were “shock only”
- Now able to provide pacing and have advanced rhythm discrimination
Risks at the time of insertion

- De novo implantation
- Upgrade procedure
- Follow up period time
Delayed risks over the lifetime of the device

- Lead failure
- Lead infection
- Lead extraction
Analysis from Cleveland Clinic evaluated survival in patients who developed a CIED infection and found a 3-fold higher risk of death in those who had an endovascular infection compared to a pocket infection.

- All patients with CIED infections who underwent device and lead removal at the Cleveland Clinic from January 2002 through 2008.
- For patients with CIED infection, 20.3% mortality within the first year:
  - Pocket infection: 12% mortality
  - Endovascular infection: 31% mortality

Kaplan–Meier survival curves over 1 year among TV-ICD patients with pocket infection and endovascular infection following TV-ICD system removal:

- 12% mortality at 1 year
- 31% mortality at 1 year
A New Alternative:

- The subcutaneous implantable cardioverter-defibrillator (S-ICD) was put into commercial use outside the U.S. in 2009.
- The (S-ICD) was approved for observational study by FDA in 2012.
Implantation of S-ICD:

- All components implanted just below the skin
- Only requires 3 or 2 small incisions
- Can be an outpatient procedure
Design of S-ICD:

The S-ICD System is comprised of the following four devices:
1. SQ-RX Pulse Generator
   - 80-J biphasic shock
   - Charge time to 80-J < 14 secs
   - 5 years longevity
   - 30 seconds post-shock pacing
   - Volume 70 cc, mass 145 gr
2. Q-TRAK Subcutaneous Electrode
3. Q-GUIDE Electrode Insertion Tool (EIT)
4. Q-TECH Programmer
S-ICD Screen Test

A

HEART RATE (25 mm/sec): 2 x RR FROM REFERENCE ARROW

14 cm GUIDE (Note: For screening, ECG-electrodes should not extend beyond 14 cm arrows)

B

INCORRECT PROFILE

CORRECT PROFILE

Peak Zones
Ineligibility of S-ICD

- 8-15%
- HCM
- High BMI
- Prolonged QRS duration
- R-T ratio < 3
- TWI in I, II, aVf
Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START study.

- Comparison between S-ICD and multiple transvenous pulse in the classification of various arrhythmias
- All devices accurately and appropriately detected VF.
- S-ISD showed best specificity in discriminating SVT including AF.

*Appropriate ventricular arrhythmia detection is excellent for all ICD systems evaluated; however, specificity of supraventricular arrhythmia discrimination by the S-ICD system is better than discrimination by 2 of 3 TV systems.*
Primary Results From START Comparing Transvenous and Subcutaneous Discrimination of Induced Supraventricular Arrhythmias

Specificity Results for Transvenous* and S-ICD Systems

<table>
<thead>
<tr>
<th></th>
<th>Single Chamber</th>
<th>Dual Chamber</th>
<th>S-ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriately withheld therapy</td>
<td>115</td>
<td>100</td>
<td>49</td>
</tr>
<tr>
<td>Inappropriate shock</td>
<td>35</td>
<td>47</td>
<td>1</td>
</tr>
<tr>
<td>Specificity, %</td>
<td>77</td>
<td>68</td>
<td>98</td>
</tr>
</tbody>
</table>
S-ICD Pooled Analysis Cohort

EFFORTLESS
N = 568*

Both Studies
N = 13

IDE
N = 308

Total Pooled
N = 889

Not Implanted
N = 7

Total Implanted
N = 882

Mean follow-up 22 months

* Includes 314 enrolled prospectively and 254 enrolled retrospectively
S-ICD Pooled Results
Demographics

43% of implanted patients primary prevention with EF ≤35

Pooled Study Implanted Patients (N=882)

<table>
<thead>
<tr>
<th>Demographic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>50.3 ± 16.9</td>
</tr>
<tr>
<td>Male (n, %)</td>
<td>636 (72.5)</td>
</tr>
<tr>
<td>Ischemic</td>
<td>330 (37.8%)</td>
</tr>
<tr>
<td>Genetic</td>
<td>58 (6.7%)</td>
</tr>
<tr>
<td>Idiopathic VF</td>
<td>40 (4.6%)</td>
</tr>
<tr>
<td>Channelopathies</td>
<td>90 (10.3%)</td>
</tr>
<tr>
<td>NYHA Classification II-IV</td>
<td>327 (37.5%)</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>143 (16.4%)</td>
</tr>
<tr>
<td>Previous Defibrillator</td>
<td>120 (13.7%)</td>
</tr>
</tbody>
</table>
# S-ICD Pooled Results

## S-ICD and TV-ICD Spontaneous Conversion Efficacy

<table>
<thead>
<tr>
<th></th>
<th>Spontaneous Shock Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First Shock</td>
</tr>
<tr>
<td>S-ICD Pooled Data*</td>
<td>90.1%</td>
</tr>
<tr>
<td>ALTITUDE First Shock Study¹</td>
<td>90.3%</td>
</tr>
<tr>
<td>SCD-HeFT²</td>
<td>83%</td>
</tr>
<tr>
<td>PainFree Rx II²</td>
<td>87%</td>
</tr>
<tr>
<td>MADIT-CRT³</td>
<td>89.8%</td>
</tr>
<tr>
<td>LESS Study⁴</td>
<td></td>
</tr>
</tbody>
</table>

* S-ICD Pooled Data excluded VT/VT Storm events

---

**S-ICD Pooled Data**

100% Clinical conversion to normal sinus rhythm

---

Of two “unconverted” episodes

- One spontaneously terminated after the 5th shock
- In the other episode, the device prematurely declared the episode ended. A new episode was immediately reinitiated and the VF was successfully terminated with one shock

---

Figure Legend:

Appropriate ICD Shock

An electrogram from a patient with an S-ICD who received a shock for fast ventricular tachycardia (lightening symbol) with restoration of sinus rhythm with premature beats. S-ICD = subcutaneous implantable cardioverter-defibrillator.
Total annualized incidence rate (percentage of patients) of recurrent MVT in SCD-HeFT was less than 2%.

Over the course of the 45.5 months of follow up only 7% of all patients had more than a single episode of fast monomorph VT > 188 bpm, of which it is not known how many episodes would have been self-terminable by using delayed MADIT-RIT programming settings.
Inappropriate Shocks & Underlying mechanisms

The incidence rate of inappropriate shocks (IAS) with S-ICD is similar or lower than observed in non-controlled programming TV-ICD studies, but underlying reasons are different.

- Main reason for IAS with S-ICD is cardiac signal oversensing, whereas AF/SVT & ST are responsible for most of the IAS with TV-ICD’s.
- Adoption of dual zone index-programming resulted in less IAS for AF/SVT & ST in Effortless compared to IDE.
- Pooled analysis showed only 3 SVT discrimination errors in conditional shock zone, at least one due to a clipped signal.

Figure 2: Inappropriate shocks expressed as % patients with ICD.
S-ICD Pooled Results
Inappropriate Shock by Programming

Significantly Lower Rate of Inappropriate Shocks with Dual Zone Programming

Kaplan-Meier Estimate of Inappropriate Shock by Single or Dual Zone Programming

<table>
<thead>
<tr>
<th>Post-op Days</th>
<th>0</th>
<th>90</th>
<th>180</th>
<th>270</th>
<th>360</th>
<th>450</th>
<th>540</th>
<th>630</th>
<th>720</th>
<th>810</th>
<th>900</th>
<th>990</th>
<th>1080</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of Inappropriate Shock</td>
<td>0.0</td>
<td>0.05</td>
<td>0.10</td>
<td>0.15</td>
<td>0.20</td>
<td>0.25</td>
<td>0.30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p=0.001

<table>
<thead>
<tr>
<th></th>
<th>Dual Zone</th>
<th>Single Zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>No at Risk</td>
<td>688</td>
<td>170</td>
</tr>
<tr>
<td>K-M Est. (%)</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>0-90 Days</td>
<td>634</td>
<td>153</td>
</tr>
<tr>
<td>91-180 Days</td>
<td>576</td>
<td>141</td>
</tr>
<tr>
<td>181-270 Days</td>
<td>546</td>
<td>134</td>
</tr>
<tr>
<td>271-360 Days</td>
<td>494</td>
<td>126</td>
</tr>
<tr>
<td>361-450 Days</td>
<td>441</td>
<td>122</td>
</tr>
<tr>
<td>451-540 Days</td>
<td>378</td>
<td>117</td>
</tr>
<tr>
<td>541-630 Days</td>
<td>279</td>
<td>108</td>
</tr>
<tr>
<td>631-720 Days</td>
<td>180</td>
<td>96</td>
</tr>
<tr>
<td>721-810 Days</td>
<td>120</td>
<td>75</td>
</tr>
<tr>
<td>811-900 Days</td>
<td>89</td>
<td>53</td>
</tr>
<tr>
<td>901-990 Days</td>
<td>66</td>
<td>43</td>
</tr>
<tr>
<td>991-1080 Days</td>
<td>56</td>
<td>36</td>
</tr>
</tbody>
</table>

Legend:
- Solid line: Dual Zone
- Dashed line: Single Zone
S-ICD Pooled Results

Complications

<table>
<thead>
<tr>
<th>Post-op Days</th>
<th>0</th>
<th>90</th>
<th>180</th>
<th>270</th>
<th>360</th>
<th>450</th>
<th>540</th>
<th>630</th>
<th>720</th>
<th>810</th>
<th>900</th>
<th>990</th>
<th>1080</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Complications</td>
<td>1.0</td>
<td>0.9</td>
<td>0.8</td>
<td>0.7</td>
<td>0.6</td>
<td>0.5</td>
<td>0.4</td>
<td>0.3</td>
<td>0.2</td>
<td>0.1</td>
<td>0.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Kaplan-Meier Estimate of Freedom from Complications Following S-ICD Implantation

<table>
<thead>
<tr>
<th>No At Risk</th>
<th>878</th>
<th>791</th>
<th>731</th>
<th>707</th>
<th>650</th>
<th>591</th>
<th>525</th>
<th>414</th>
<th>217</th>
<th>162</th>
<th>123</th>
<th>105</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-M Estimate (%)</td>
<td>99.0</td>
<td>93.4</td>
<td>92.3</td>
<td>92.0</td>
<td>91.4</td>
<td>90.9</td>
<td>90.6</td>
<td>90.2</td>
<td>90.0</td>
<td>89.7</td>
<td>89.7</td>
<td>88.9</td>
</tr>
</tbody>
</table>

Acute Major Complications (% of patients)

<table>
<thead>
<tr>
<th>S-ICD Pooled Data</th>
<th>TV-ICD NCDR Analysis (Peterson et al, JAMA 2013)</th>
<th>Meta-analysis (van Rees et. al. JACC 2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 %</td>
<td>3 - 5 %</td>
<td>(Hematoma, Lead or Device Mal-position or Displacement, Pneumothorax)</td>
</tr>
</tbody>
</table>

S-ICD Pooled Results
Complications and Infection with Device Removal by Enrollment Order

Six month incidence of complications

- Incidence of Type I-III Complication (p = 0.05)
- Infection Requiring Device Removal (p = 0.08)
PRAETORIAN TRIAL

• 1<sup>st</sup> multicenter, randomized trial to directly compare S vs T-ICDs
• 700 pts enrolled
• Non inferiority study
• Composite primary end-points: inappropriate shocks and device-related complications
• Secondary end-points: shock efficacy and mortality
• What is the ATP role?
S-ICD as a first choice:

- Pediatric or GUCH patients with no venous access
- Acquired stenosis or obstruction of central veins
- Previous endocarditis or device infection
- Patients at very high risk of infection of endovascular leads: dialysis, immunodeficiencies, cancer, need of a chronic indwelling catheter
- Patients candidates to cardiac transplantation.
S-ICD as a reasonable choice:

- Young patients with an active lifestyle and a long life expectancy
- Inherited genetic arrhythmogenic syndromes (Brugada, Long and Short QT, Early Repolarisation)
- Hypertrophic cardiomyopathy
- Prosthetic heart valves (infection risk). Women (“cosmetic” issue).
- Primary prevention patients with ischemic/non ischemic dilated cardiomyopathy
- Secondary prevention patients survivors of out-of-hospital VF
When to avoid the S-ICD:

• Failed pre-implant screening (up to 7% of cases)
• Symptomatic bradycardia requiring permanent pacing
• Previously implanted unipolar pacemaker (sensing/detection pitfalls)
• Systolic heart failure and left bundle branch block indicated for CRT
• Recurrent sustained monomorphic VT treatable with ATP
• Anatomic characteristics: thin patients with poor subcutaneous tissue, “pectus excavatum”.
2015 ESC Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of SCD

Two levels of recommendation:

1. Class IIa to stimulate a clinical workflow in which S-ICD is considered for all ICD-indicated patients without an acute pacing requirement: supported by clinical evidence

2. Class IIb to provide additional guidance to the stratification process of patients who could benefit most from the S-ICD: supported by expert opinion
ΑΚΤΙΝΟΛΟΓΙΚΗ ΕΙΚΟΝΑ
A novel substernal lead
A novel substernal lead
THANK YOU FOR YOUR ATTENTION