State of the Art: What’s new in ICD Therapy

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Disclosures

- Medtronic
  - Consultant
  - Lecturer
- Heart Rhythm Society Consulting Services
  - Consultant
The use of CPR dates back to?

1. 1891
2. 1973
3. 1740
4. 1954
Background

- ICDs reduce mortality
- Many episodes detected as VF by ICDs are rapid, monomorphic VT.
- Shocks are a major cause of patient morbidity
  - ER visits and hospitalizations
- QOL is influenced by shock burden
- ICD programming is complex
Why Avoiding Shocks Is Important

To Reduce Pain and Anxiety and Increase Device Acceptance

To Reduce Healthcare Burden and Improve Patient Quality of Life

Avoiding Shocks May Improve Survival/Heart Failure
What is the current rate of inappropriate shocks?

1. \( \leq 10\% \)
2. 15-30\%
3. 40\%
4. \( \geq 50\% \)
Incidence of Shocks and Inappropriate Shocks\textsuperscript{1,2,3,4}

- By 4-5 years, approximately 1/3 of ICD patients have experienced at least one shock episode with 16-18% receiving at least one inappropriate shock\textsuperscript{2,3,4}

<table>
<thead>
<tr>
<th>Study</th>
<th>Incidence Shocks (% of patients)</th>
<th>Incidence Inappropriate Shocks (% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADIT II</td>
<td>21%</td>
<td>12%</td>
</tr>
<tr>
<td>SCD-HeFT</td>
<td>33%</td>
<td>17%</td>
</tr>
<tr>
<td>COMPANION</td>
<td>24%</td>
<td>9%</td>
</tr>
<tr>
<td>ALTITUDE Long-term Outcome CRT-D at 5 years</td>
<td>33%</td>
<td>17%</td>
</tr>
<tr>
<td>ALTITUDE Long-term Outcome ICD at 5 years</td>
<td>38%</td>
<td>16%</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Daubert JP, et al. Inappropriate ICD Shocks in MADIT II. \textit{JACC} 2008; 51:1357-1365.
\textsuperscript{3} Saxon, Leslie et al. Predictors of Sudden Cardiac Death and Appropriate Shock in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial. \textit{Circulation} 2006; 114; 2766-2772.
Shocks: Predictors of Mortality?

- Large RCTs have proven ICDs modestly reduce mortality
  - Mortality benefit was achieved using shocks, almost exclusively, to reduce SCD

- Recent evidence from these trials indicates an association between shocks for VT/VF and increased risk of heart failure and death

- Questions remain:
  - Why do survival rates after life-saving shocks decline?
  - Why no benefit early post-MI?
  - Are appropriate and inappropriate shocks just a marker of a sicker population?
  - If we reduce shocks, can we improve mortality?
“Among patients with heart failure in whom an ICD is implanted for primary prevention, those who receive shocks for any arrhythmia have a substantially higher risk of death than similar patients who do not receive such shocks.”

JE Poole et al. NEJM 2008; 359:1009-1017

“Chronic management of the HF patient after ICD shock should involve close surveillance throughout the following year for early signs and symptoms of impending decompensated HF.”

JD Mishkin et al. JACC 2009;54:1993-200
MADIT II: Reduced Survival After Shocks

<table>
<thead>
<tr>
<th>Episode Therapy Type</th>
<th>Hazard Ratio</th>
<th>Risk of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT Shocked</td>
<td>3.4 (1.9, 5.9), p&lt;0.001</td>
<td>≈3.4 times increase</td>
</tr>
<tr>
<td>VF Shocked</td>
<td>3.3 (1.3, 8.1), p=0.01</td>
<td>≈3.3 times increase</td>
</tr>
</tbody>
</table>
Benefit vs. Harm: Paradox of Shocks

- Recent worrisome evidence from ICD trials have renewed interest in shock harm.
- Large electrical currents destroy myocytes.
  - Strong defibrillation shocks terminate VF, but cause temporary or permanent damage to the heart.
  - Cardiac biomarkers release (humans)
  - Reduced pump function (animals, humans)
  - Reduced survival time (animals)
- Weaker shocks cause less damage but do not defibrillate.

What A Shock Feels Like
**SCD-HeFT: Shocks and Increased Death Risk**

<table>
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<tr>
<th>Shock Type</th>
<th>Hazard Ratio</th>
<th>Risk of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1 appropriate versus none</td>
<td>5.68 (3.97-8.12) P &lt; 0.001</td>
<td>~ 6 times higher</td>
</tr>
<tr>
<td>≥ 1 inappropriate versus none</td>
<td>1.98 (1.29-3.05) P = 0.002</td>
<td>~ 2 times higher</td>
</tr>
<tr>
<td>Both shock types versus none</td>
<td>11.27 (6.70-18.94) P &lt; 0.001</td>
<td>~ 11 times higher</td>
</tr>
</tbody>
</table>

ATP During Charging

**With ATP During Charging**

- Detection 18/24
- ATP
- Capacitor Charging
- Shock 13.6 s
- Confirmation/Synchronization

**Without ATP During Charging**

- Detection 18/24
- ATP
- Redetection
- Shock 18.7 s
<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>NID</th>
<th>ATP efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PainFree RX</td>
<td>Ischemic CMP</td>
<td>12/16</td>
<td>77%</td>
</tr>
<tr>
<td>PainFree RX II</td>
<td>Ischemic and non-ischemic CMP</td>
<td>18/24</td>
<td>72% Improved QOL</td>
</tr>
<tr>
<td>Empiric</td>
<td>Primary and secondary prevention</td>
<td>18/24</td>
<td>&quot;non-inferior&quot; to physician selected</td>
</tr>
<tr>
<td>PREPARE</td>
<td>Primary prevention</td>
<td>30/40</td>
<td>PREPARE &quot;programming&quot; reduced shocks by 63%</td>
</tr>
</tbody>
</table>
ATP During Charging

**With ATP During Charging**
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Newer Technologies...
The S-ICD® System

Protection Without Touching The Heart
Subcutaneous ICDs have no leads

1. True
2. False
A new category of implantable defibrillators

Transvenous (TV) ICDs

- Provides effective defibrillation for ventricular tachyarrhythmias
- Provides Brady pacing
- Provides ATP for patients with incessant monomorphic VT
- Provides atrial diagnostics
- Familiar implant technique

The S-ICD System

- Provides effective defibrillation for ventricular tachyarrhythmias
- No risk of vascular injury
- Low risk of systemic infection
- Preserves venous access
- Avoids risks associated w/ endovascular lead extraction
- Fluoroscopy not required
Suitable for a diverse patient population

The S-ICD System is an effective solution for a majority of primary and secondary ICD candidates.

- Ideal option for patients with primary electrical or structural heart disease.
- Appropriate for patients with bipolar pacemaker therapy, as well as those with prior transvenous systems.

**Indications for Use**

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have:

- symptomatic bradycardia
- incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing
Ideal Device Placement
S-ICD System Highlights

- 80 joule (delivered) biphasic shock
- Charge time to 80J ≤ 10 seconds
- 5.1 year longevity
- 30 seconds post-shock pacing
- Single electrode connection
- Full featured episode storage
Defibrillation without transvenous leads

The S-ICD System:

• Completely subcutaneous

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

• Placed strictly by anatomical landmarks, removing the need for fluoroscopy at implant

• Sophisticated algorithms provide performance equal to, if not better than, transvenous ICDs

Sophisticated Rhythm Detection Technology

Three far-field sensing vectors

- Primary, Secondary, Alternate
- Automatic or manual selection
- Morphologically rich signal similar to a surface ECG
- Sense electrodes positioned away from large muscle groups

Maximum flexibility to solve sensing issues non invasively

- Sense vector reprogramming
The Subcutaneous Signal

The S-ICD System captures high-resolution, morphologically rich signals similar to a surface ECG.
Studies have shown that the S-ICD System’s dual zone programming using the INSIGHT algorithm reduces the likelihood of inappropriate shocks. The INSIGHT algorithm identifies and evaluates a heart rhythm rather than individual heart beats to effectively discriminate VT/VF. Similar to PREPARE Study programming, the INSIGHT algorithm only initiates therapy for longer duration tachyarrhythmias.

2) Wilkoff, et. al. Results From the PREPARE. JACC. Vol. 52, No. 7, 2008
Therapy Delivery

Episodes
• Up to 5 shocks per episode @ 80J
• 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
One Month Post-Operative Pictures

[Images of post-operative results]
S-ICD (IDE) Study met both effectiveness and safety endpoints

**Primary effectiveness endpoint met***
- 100% conversion rate of induced arrhythmias in evaluable patients

**Primary safety endpoint met***
- 99% 180-day Type I Complication-Free Rate

*Both endpoints met even under worst case sensitivity analysis

### Additional Study Results:
- 100% spontaneous VT/VF episodes (n=109) converted with 80J shock or spontaneously converted
- 0 patients experienced a shock due to discrimination error in Conditional Shock (dual) zone
- 79% of patients were primary prevention indication
- 63% of patients with VT/VF rhythms meeting criteria to charge avoided therapy delivery without any reports of syncope
  - Algorithm prevents therapy for VT/VF rhythms that are likely to spontaneously terminate
- 95% implanted using only anatomical landmarks (no medical imaging)
- 99% of implanted patients had no electrode or pulse generator movement throughout follow-up period

Remote Monitoring

MEDTRONIC CARELINK® NETWORK

Medtronic CareLink Network connects healthcare professionals and their patients to provide healthcare solutions built on our advanced medical and information technology.

I am a Health Care Professional
I am a Patient, Family Member or Friend

LATITUDE®
Patient Management

For Medical Professionals
LATITUDE remote login
For patients and medical professionals using LATITUDE’s remote follow-up capabilities.

For Medical Professionals
LATITUDE in-clinic login
For medical professionals using LATITUDE’s in-clinic capabilities.

For Patients and Families
Remote Monitoring: The Basics

- Vendor specific transmitters
  - Wanded
  - Wireless
  - Analog phones \rightarrow Cellular!
- Data repositories
  - National Servers
- Internet based access
  - Provider
  - Patient
Remote Monitoring

- 24/7 Surveillance
  - Alert notification
- Routine Follow-up
  - Scheduled transmissions
- Clinical management
- Device Troubleshooting
- Warehouse for digitized ICD data
  - Assess programming practices
Staying connected!

- Patient data is accessible via Smart phone App
Clinical Trials in Remote Monitoring

- TRUST Study May 2009
  - Biotronik
- CONNECT Study September 2009
  - Medtronic
- ALTITUDE Study December 2010
  - Boston Scientific
Patient Guidelines

- Provided at the time of discharge
- Sets expectations
  - Scheduling
  - Data review
  - Shocks
  - Emergency care
  - Traveling
  - Insurance
  - Contact information

Brigham and Women’s Hospital
Patient Guidelines for Remote Monitoring
You have been prescribed a Remote Monitor to transmit your ICD information to our clinic using a standard phone line. The Remote Monitor will be sent to you on behalf of our clinic.

Scheduling Your Device Visits
You will now have two different types of appointments with our clinic.

A Remote Visit
This is when you will use your Remote Monitor and send your device data for our clinic to review.
Our clinic will schedule a Remote appointment to occur approximately one time every three to four months and will alternate with an office visit. You will be provided a date to send your data using the monitor. You may send at any time during scheduled day.

Clinic Visit
A “Clinic Visit” is a face-to-face personal visit at the clinic.
Our clinic will schedule one to two office visits per year.

Reviewing Your Device Data
Your device data will be sent to a secure server where our clinic staff can view it using a password protected website.
When you use your Remote Monitor on your scheduled day, we will review the data the next business day.
After we review your data, we will send you a confirmation letter with your next appointment date/time within 7-14 days.
If it is necessary for you to be seen by a clinician, you will be contacted within 24 hours after sending your device data to schedule an office visit.
If you call the clinic and are instructed to send your data at a time other than your regularly scheduled time, we will review the data within 48 hours.
PLEASE NOTE: You will not be routinely contacted regarding your transmission unless we have NOT received you transmission or if there is an issue that needs further attention.
Case Study: Managing patients with Remote Data

- 70 year-old male with ischemic CMP
  - CABG
  - LV dysfunction – EF 15%
  - NYHA Class III HF
  - PAF
  - On amiodarone for PAF and OMT for HF
- ICD to CRTD upgrade in August 2009
  - SJM Promote +3211-36Q
- Late October 2010 – amiodarone dose reduced to 200 mg qod
- 12/6/10 – Merlin.net alert for “low percent of bi-ventricular pacing” (<90%)
83% biventricular pacing
Managing the data....

- Scheduled for elective TEE and cardioversion in December 2010
- Remained on amiodarone 200 mg qod
- January 31, 2011 – Merlin.net alert for “low percent of bi-ventricular pacing”
PVC burden from 12/6/10 was 2.3%
Increased PVC burden

Amiodarone increased to 200 mg 5 days/week

Obtain 24 holter to assess PVC morphology
Consider PVC ablation
Managing Patients with CIED Devices

- Education
- Confirm optimized medical therapy per HF guidelines
- Ensure appropriate follow-up
  - Device Clinic
  - Remote Monitoring
- Make sure they have a “shock plan” in place
- Local support group or on-line group
The Future of ICD Therapy

- Devices designed for accuracy
  - Treat only those events requiring intervention
    - ATP for treating a majority of events
  - Reduce or eliminate inappropriate shocks
  - Shock reduction may improve survival and improve QOL for ICD patients
- S-ICD Therapy
  - Primary Prevention patient
- Remote Monitoring
  - Standard of Care for device patients
  - Outcomes data
  - Guidelines