Programming of ICD to Reduce Shocks

2017.6.23
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이우석
37 years ago...

TERMINATION OF MALIGNANT VENTRICULAR ARRHYTHMIAS WITH AN IMPLANTED AUTOMATIC DEFIBRILLATOR IN HUMAN BEINGS

Reductions in Mortality with ICDs

Does ICD Therapy = A Life-Saving Event?

Marked Over-Treatment in Primary and Secondary Prevention Patients

1. Overtreatment in Secondary Prevention
   - AVID 2 year follow-up
     - Control: SCD/Cardiac Arrest/Sustained VT
     - ICD Therapy
     - 10.20% vs. 68% (6.6X)

2. Overtreatment in Primary Prevention
   - MUSTT
     - Annual Rate of Sudden Death
     - Non-ICD: 4.6 vs. ICD: 2.7X
   - SCD-HeFT
     - Annual Rate of Sudden Death
     - Non-ICD: 2.8 vs. ICD: 5.7X
     - 5 yr 60% VT/VF shocks
     - 5 yr 37% SCD

3. References
Prognostic Importance of ICD Shocks

- SCD-HeFT patients who received and ICD (n=811)
- 33.2% received shocks: 15.8% only appropriate, 10.7% only inappropriate and 6.7% both
- Patients who receive shocks for any arrhythmia have a higher risk of death than those who do not receive such shocks

<table>
<thead>
<tr>
<th>Shock Type</th>
<th>Hazard Ratio for Death (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1 App vs. no App</td>
<td><img src="image1.png" alt="Graph" /> 5.68 (3.97–8.12)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥1 Inapp vs. no Inapp</td>
<td><img src="image2.png" alt="Graph" /> 1.98 (1.29–3.05)</td>
<td>0.002</td>
</tr>
<tr>
<td>Both shock types vs. no shock</td>
<td><img src="image3.png" alt="Graph" /> 11.27 (6.70–18.94)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Shocks but not ATP are associated with Higher Mortality

- Retrospective analysis of pooled data
  - PainFREE I and II, EMPIRIC and PREPARE
  - 2,135 pts, EF 31%, 87% CAD, 55% NYHA II/III, 42% NYHA I/ no CHF

Sweeney M. Heart Rhythm 2010; 7: 353 - 360
The Arrhythmia or Comorbidities rather than the Shock itself

- Survival After Shock Therapy according to rhythm shocked
  - Ventricular rhythms and atrial fibrillation: increased risk of death
  - Inappropriate shocks for ST/noise/artifact/oversensing: no difference

![Graph showing survival rates](image)

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>MVT and PMVT</td>
<td>2.77</td>
<td>(1.70 - 4.51)</td>
</tr>
<tr>
<td>NSVT</td>
<td>2.17</td>
<td>(0.82 - 5.70)</td>
</tr>
<tr>
<td>VF/PMVT</td>
<td>2.10</td>
<td>(1.54 - 2.86)</td>
</tr>
<tr>
<td>MVT</td>
<td>1.65</td>
<td>(1.36 - 2.01)</td>
</tr>
<tr>
<td>Atrial fibrillation/flutter</td>
<td>1.61</td>
<td>(1.17 - 2.21)</td>
</tr>
<tr>
<td>Sinus tachycardia/VT</td>
<td>0.97</td>
<td>(0.68 - 1.37)</td>
</tr>
<tr>
<td>Noise/artifact/oversensing</td>
<td>0.91</td>
<td>(0.50 - 1.67)</td>
</tr>
</tbody>
</table>

Powell BD. *J Am Coll Cardiol* 2013; 62: 1674 - 1679
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

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Wathen MS. *Circulation*. 2004;110:2591-2596

ICD Careless Shock Costs Lives!!
Approach to Patient with ICD Shocks

1. Analyze stored and clinical data

   - Tachyarrhythmia
     - SVT (Inappropriate detection)
     - VT/VF (Appropriate detection)
       - Shock unnecessary
         - Shock necessary
       - No Tachyarrhythmia (Oversensing)
         - Intracardiac signals
         - Extracardiac signals
ICD Therapy: different types of shocks

- **Necessary (Appropriate) shocks:**
  - Shocks triggered by potentially life-threatening ventricular arrhythmias
  - Necessary shocks: Shock for arrhythmias not terminated by other means including ATP

- **Unnecessary (Avoidable) shocks:**
  - Other painless therapy can be used to terminate arrhythmia
  - Self-terminating non-sustained VT
  - Slow VT – no require therapy

- **Inappropriate Shocks:** Shocks triggered by an inappropriate detection
  - Non-VT arrhythmia
  - Intrinsic and/or extrinsic signal oversensing
  - Device and/or lead malfunction

Koneru JN. Circ Arrhythm Electrophysiol. 2011;4:778-790
Schoels W. Heart Rhythm. 2007;4:879-885
Principle Programming Goals

• Pharmacological treatment and/or catheter ablation
• Treat VT with antitachycardia pacing
• Prevent detection of Nonsustained VT
• Optimize SVT-VT discrimination
• Prevent oversensing
General Measures

- Avoidance of aggravating factors
  - Preventing electrolyte abnormalities
  - Sleep deprivation
  - Caffeine, alcohol
  - Over-the-counter medications
  - Herbal remedies (eg, gingko, ephedra, ginseng, guarana, and yohimbine)
  - Cardiac stimulants (eg, theophylline, cocaine, and amphetamines)

- Underlying heart disease on optimal medical Tx.
Optimal Pharmacologic Therapy in Cardioverter Defibrillator Patients

- OPTIC Study
- Amiodarone plus β-blocker significantly reduced the risk of shock compared with β-blocker alone
  - 38.5% (β-blocker) vs. 24.3% (Sotalol) vs. 10.3% (Amiodarone plus β-blocker)
Catheter Ablation for Electrical Storm

- CA failure (C) (HR, 15.23; 95% CI, 2.0 to 112.8; $P=0.008$) vs. CA success (A) or partial success (B)

Carbucicchio C. Circulation 2008;117:462-469
Reducing unnecessary shocks and inappropriate shocks
Sequence of Event leading to Therapy

Heart rate threshold

Duration/no. intervals

SVT-VT Discriminators

ATP

Tachydetected

VT/VF detected

Charge

Shock

Ignore slow rhythms (VT, SVT)

Ignore non-sustained

Ignore SVT

• Terminate VT
• Allow time→self-term
• Terminate some SVT

Morphology
• onset, stability, other logic
• Single/dual chamber

**Reconfirmation
++Reduction

Cardiac Pacing, Defibrillation and Resynchronization (Third Edition)
Ventricular Rate Precipitating Inappropriate Shock

MADIT II study

PROVIDE study

Daubert JP. J Am Coll Cardiol. 2008;51:1357-1365
Tachyarrhythmia Cycle Length in Appropriate versus Inappropriate Defibrillator Shocks

- Brugada Syndrome, Early Repolarization Syndrome, or Idiopathic Ventricular Fibrillation
- 235ms/255bpm (sensitivity 98.4%, specificity 95.6%)
- Safety problem 4.4%
- 270ms/222bpm (inappropriate shock 70.5% reduction)

# Higher Rate Cutoffs

**MADIT-RIT trial (primary prevention)**

<table>
<thead>
<tr>
<th>Zone 1 ≥ 170 BPM</th>
<th>Zone 2 ≥ 200 BPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional ATP + shock</td>
<td>shock</td>
</tr>
<tr>
<td>High-rate Monitor only</td>
<td>shock</td>
</tr>
</tbody>
</table>

**Inappropriate shock**

Cumulative Probability of First Occurrence of Inappropriate Therapy

Unadjusted P<0.001

**Mortality**

Cumulative Probability of Death

Unadjusted P=0.03

6.6% vs. 3.2%, p=0.01

Lots of Data and Experience Now Suggest
2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus

Slowest Tachycardia Therapy Zone Limit
(185 to 200 bpm)

Prolonged Detection
(At least 6-12 seconds or for 30 intervals)

Discrimination algorithms to distinguish SVT for VT
(faster than 200 bpm and potentially up to 230 bpm)

Use of ATP
(At least 1 ATP, up to 230 bpm, A minimum of 8 stimuli,
Burst, 84%-88% of TCL)

Reduced Shocks in ICD patients
Strategic Programming Reduces Shocks

- PREPARE: Prospective, cohort controlled study (MIRACLE ICD, EMPIRIC trial – NID 12/16, 18/24)
- 700 primary prevention ICD or CRT-D patients programmed to **A**TP **f**or fast **VT** (182-250 bpm), **NID 30/40**, VT monitor (<182 bpm)
- Reduction of unnecessary and inappropriate shocks, improved survival

Wilkoff BL. J Am Coll Cardiol 2008; 52: 541-550
CRT-D with NID programmed to 30/40

- RELEVANT: 324 primary prevention pts. with non-ischemic etiology with CRT-D programmed to: **NID 30/40 or 12/16 (control)**
- Study arm showed:
  - Better event-free survival to first delivered therapy for total, appropriate and inappropriate episodes
  - Lower total number of delivered shocks
  - Reduced HF hospitalization

Gasparini M. *Eur Heart J* 2009; 30(22): 2758-2767
As many arrhythmias would terminate without therapy, this programming strategy resulted in a 50% reduction in inappropriate ICD therapies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants (N)</th>
<th>Short detection controls</th>
<th>Prolonged detection intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADIT-RIT</td>
<td>1500</td>
<td>2.5 s (170–199 bpm)</td>
<td>60 s (170–199 bpm)</td>
</tr>
<tr>
<td></td>
<td>Randomized</td>
<td>1 s (≥200 bpm)</td>
<td>12 s (200–249 bpm)</td>
</tr>
<tr>
<td></td>
<td>Primary prevention</td>
<td>2.5 s (≥250 bpm)</td>
<td>2.5 s (≥250 bpm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Conventional Therapy (N = 514)</th>
<th>High-Rate Therapy (N = 500)</th>
<th>Delayed Therapy (N = 486)</th>
<th>P Value for High-Rate Therapy vs. Conventional Therapy</th>
<th>P Value for Delayed Therapy vs. Conventional Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate therapy</td>
<td>517</td>
<td>185</td>
<td>196</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Shock</td>
<td>71</td>
<td>72</td>
<td>53</td>
<td>0.35</td>
<td>0.15</td>
</tr>
<tr>
<td>Antitachycardia pacing</td>
<td>446</td>
<td>113</td>
<td>143</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Inappropriate therapy</td>
<td>998</td>
<td>75</td>
<td>264</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Shock</td>
<td>105</td>
<td>25</td>
<td>49</td>
<td>0.001</td>
<td>0.16</td>
</tr>
<tr>
<td>Antitachycardia pacing</td>
<td>893</td>
<td>50</td>
<td>215</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Long detection programming
ADVANCE III trial

- VVI ICDs: 545 pts. With ICMP & NICMP, ICD programmed to: NID 30/40 or 18/24 (control)
- Study arm showed:
  - Reduced overall shock by 40%, appropriate shock by 51%
  - Reduced all-cause mortality

Gasparini M. JACC: Clinical Electrophysiology 2017 (2017 HRS late breaking)
Completely asymptomatic patient. Seen for routine follow-up.
Lots of Data and Experience Now Suggest
2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus

Slowest Tachycardia Therapy Zone Limit
(185 to 200 bpm)

Prolonged Detection
(At least 6-12 seconds or for 30 intervals)

Discrimination algorithms to distinguish SVT for VT
(faster than 200 bpm and potentially up to 230 bpm)

Use of ATP
(At least 1 ATP, up to 230 bpm, A minimum of 8 stimuli,
Burst, 84%-88% of TCL)

Reduced Shocks in ICD patients
Causes of Inappropriate ICD Therapy
The ALTITUDE REDUCES Study

Benefit of SVT-VT discrimination

Fischer A. Heart Rhythm. 2012;9:24-31
**Enhanced Detection Criteria**

**SVT versus VT**

- **Sudden Onset → Activate!**
  - Discriminates *sinus tachycardia* from VT

- **Stability → Activate!**
  - Discriminates *atrial fibrillation* from VT

- **Ventricular EGM Morphology → Activate if it works!**
  - Cave: SVT with aberrancy

- **Sustained Rate Duration → Deactivate (or ≥ 5 min)!**

- **Activate up to ≥ 200 bpm**
Method for analysis in Dual and single chamber ICD

A  Dual Chamber

- Analyze atrial and ventricular rates
  - A > V
    - Ventricular morphology
    - Ventricular interval stability
    - AV association
      - Conducted AFib/AFlu
      - VT + AFib/AFlu
  - A = V
    - Ventricular morphology
    - AV interval
    - Chamber of onset
    - Response to ATP*
      - SVT (1:1 AV conduction)
      - VT (1:1 VA conduction)
  - V > A
    - VT

B  Single Chamber

- Ventricular electrogram morphology
  - Uniform and identical to sinus morphology
    - SVT
  - Variable or minimal difference from sinus morphology
    - • Abrupt onset → VT*
      - • Irregularly irregular → AFib
  - Uniform and distinctly different from sinus morphology
    - VT
SVT limit

  - The safety of empirical programming at 200 bpm

- **MADIT II (2008)**
  - Approximately 50% of SVT > 170 bpm

- **INTRINSIC RV (2012)**
  - SVT (19% - 200 to 250 bpm)

- **PainFree SST (2015)**
  - Up to 222-230 bpm
Choosing Single or Dual-Chamber ICDs

SVT versus VT

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Dual-chamber n/N</th>
<th>Single-chamber n/N</th>
<th>OR (fixed) 95% CI</th>
<th>Weight %</th>
<th>OR (fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1+1 Trial</td>
<td>39/375</td>
<td>59/289</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PINAPPS</td>
<td>32/145</td>
<td>28/117</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detect SVT</td>
<td>196/750</td>
<td>175/531</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1270</td>
<td>937</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total events: 257 (Dual-chamber), 262 (Single-chamber)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: Chi² = 3.89, df = 2 (P = 0.14), I² = 48.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 4.38 (P &lt; 0.0001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Theuns DA. Int J Cardiol. 2008;125:352-357

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Randomized study

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% CI)</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theuns et al. 2004</td>
<td>1.09 (0.42, 2.87)</td>
<td>29.89</td>
</tr>
<tr>
<td>Friedman et al. 2006</td>
<td>1.06 (0.73, 1.56)</td>
<td>46.38</td>
</tr>
<tr>
<td>Almendral et al. 2008</td>
<td>0.23 (0.07, 0.78)</td>
<td>23.72</td>
</tr>
<tr>
<td>Overall (I²-squared = 65.2%, p = 0.057)</td>
<td>0.74 (0.33, 1.68)</td>
<td>100.00</td>
</tr>
<tr>
<td>Combined effect: p = 0.48</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis

Lots of Data and Experience Now Suggest
2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus

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Reduced Shocks in ICD patients
ATP for Fast VTs Reduces Shocks II

- PainFREE Rx II: 634 prim./sec. prevention ICD pts. randomized to empirical ATP or shock for fast VTs (188-250 bpm), NID 18/24
- ATP successfully terminated 3 out of 4 Fast VTs
- ATP is highly effective, equally safe and improves QoL

**ATP Arm**
- n=284 episodes
- ATP success 72%
- ATP failed 28%

**Shock Arm**
- n=147 episodes
- Shocked 64%
- Spontaneous Termination 34%
- ATP 2%

Wathen MS. *Circulation* 2004; 110: 2591-2596
ATP in the Fast VT Zone

2 bursts (5 + 8 pulses at 84% of VT CL) followed by max. shock → max. shock alone

→ programming 2 ATPs in the Fast VT zone reduces the proportion of patients with shocks in the FVT zone by 73%

Martinez-Sanchez. J Am Coll Cardiol. 2005;45:460-469
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Reduced Shocks in ICD patients
Ventricular Oversensing

- Non-arrhythmic (noise, artifact, oversensing)

<table>
<thead>
<tr>
<th>Intracardiac signal</th>
<th>Physiologic</th>
<th>Non-Physiologic</th>
</tr>
</thead>
<tbody>
<tr>
<td>T wave oversensing</td>
<td>Lead failure</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Extracardiac signal</th>
<th>Myopotentials</th>
<th>EMI</th>
<th>Lead-Connector</th>
</tr>
</thead>
</table>
Ventricular Oversensing

P-wave oversensing

R-wave double counting

T-wave oversensing

EMI

Myopotential

Lead Fracture

Swerdlow CD. PACE. 2005;28:1322-1346
T-wave Oversensing

- The commonest cause of ventricular oversensing
- Approximately 6% of shocks in SCD-HeFT were due to TWOS.
Avoid T Wave Oversensing

- Large R waves at implantation
- Minimum Sensing Threshold (0.4 mV → 0.6 mV)
- Filtering
- Dedicated programming options

**Decay delay**

**Threshold start**
To Minimize T-Wave Oversensing

<table>
<thead>
<tr>
<th>Concept</th>
<th>Algorithmic/T-wave Derivative</th>
<th>Altered Sensing Vector</th>
<th>Signal Filtering</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONCEPT</td>
<td>Differentiation of sense EGM enlarges R-wave to T-wave amplitude ratio</td>
<td>Integrated bipolar electrograms often have a larger R-T wave ratio</td>
<td>A high pass filter will remove more T-wave than R-wave energy</td>
</tr>
</tbody>
</table>

**Before**

- RV tip to RV ring EGM
- Filtered & Rectified EGM

**After**

- Differential EGM
Reducing Shocks Due to RV Lead Noise
(Lead and connection problems)

- Cumulative lead malfunction incidence is 4.6% at 10 years across manufacturers
- Lead malfunction resulted in inappropriate shocks in 76% of the cases
- Indicating failure of the integrity of the ICD system and usually requires system revision
- Connection (header, adapter, or setscrew) problems, lead insulation failure, conductor fracture
- Intermittent “noise”

Lead and Connector Noise

- High-frequency components typically result in intervals within 20ms of the ventricular blanking period (130-150ms) and many intervals below 200ms.
- Substantial variability in amplitude or frequency occurs.
- High-amplitude signals saturate the amplifier.
- The noise signal is limited to the sensing electrogram unless the problem relates to the RV coil in an integrated bipolar lead or to both sensing and high-voltage conductors or connectors.
RV Lead Noise Discrimination

- Lead-noise oversensing is typically isolated to the near field sensing signal
- Compare near-field sensing signal:
  - Far field EGM used to confirm senses

Swerdlow CD. Circ Arrhythm Electrophysiol. 2014;7:1237-1261

Compares far-field cardiac activity to sensed event
Operation of RV Lead Integrity Alert

- **Abrupt ↑ Impedance**: Specific
- **SIC ≤130 ms >30 in 3 days**: Sensitive
- **2 NST <220 ms in 60 days**: Moderately specific

**Response**: Automatic Δ VF Detection

**Participants**:
- Patients
- Clinicians

Δ NID Δ to 30/40

Swerdlow CD. Circ Arrhythm Electrophysiol. 2014;7:1237-1261
Summary
Safe Shock Reduction Strategies

Summary

Combined approach to reduce all types of unnecessary shocks:

1. Higher rate cutoffs (200 BPM)
2. Longer detection time (at least 6-12 seconds or for 30 intervals)
3. Multi-detection zone
4. SVT discrimination algorithms (200 BPM, upto 230 BPM)
5. T wave oversensing algorithm
6. Lead noise algorithm
7. Burst ATP (minimum 8 stimuli) to a cycle length of 240ms
Thank you for your attention.