ICD Trouble shooting: Case study

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“Bullet-proof” evidence: ICD does prevent sudden death
<table>
<thead>
<tr>
<th>Investigator</th>
<th>Investigator</th>
<th>Research Funding</th>
<th>Speaker</th>
</tr>
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<tbody>
<tr>
<td>Medtronic, Inc</td>
<td>yes</td>
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<td>St Jude Medical, Inc</td>
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<td>Biotronik, Inc</td>
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<td>Bristol-Myers, Inc</td>
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<td>Atricure, Inc</td>
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<tr>
<td>Sanofi-Aventis, Inc</td>
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Objectives

- Identify ICD system anomalies, and abnormal or unwanted behaviors
- Describe potential causes of ICD system issues
- Recognize resources and data available to aid in troubleshooting an ICD system and its individual parts
- Implement troubleshooting process
- Suggest possible solutions to correcting unwanted behaviors present in an ICD system
ICD System Issues - Acute

**Leads-Connection**

- **Points of Failure**
  - *Acute* (common suspects)
    - Connector
    - Lead Dislodgement/Perforation
EGM in patients in recovery room after ICD implant
Loose set screw
• Witnessed syncopal episode
• In ER
  - Chronic Atrial fibrillation
  - Sustained VT, EF 25%
• Implant Single Chamber ICD (Epic VR+)
  - V capture: 1.125 volts @ 0.5 ms
  - V sensing: 11.4 mV
  - V impedance: 696 ohms
• **2 days post-implant:**
  - V capture threshold: 0.5 V @ 0.5 ms
  - V sensing threshold: > 12.0 mV
  - V impedance: 570 ohms

• **1 week post-implant**
  - Shock in absence of warning symptoms
  - V capture threshold: > 7.5 V @ 1.5 ms
  - V sensing threshold: 1.4 mV
  - V impedance: 435 ohms
VF detected

Fib no longer detected,

Rx suspended
A few moments later:

Shock
Real Time ECG / EGM

Real-Time ECG/EGM Report (Archive)

Patient: [Name]
Epic™+ VR Model: V-196, Serial: 2
Electrogram Date/Time: Aug 31, 2005 9:59 AM
Template Date/Time: Aug 30, 2005 1:10 PM

Position 1: Surface ECG (0.5 mV/cm)
Position 2: V Sense/Pace (1.2 mV/cm, ±8.9 mV)
Position 3: Off
Sweep Speed: 25.0 mm/sec
PA Chest X-ray
IEGM Example:
ICD System Issues

Lead Dislodgement
• Patient received a single chamber ICD 2 weeks ago and now admitted with SOB, syncope, BP 90/40, HR 110

• ICD check showed no ventricular capture
One week post-implant

2 weeks post-implant; dyspnea
Open Chest Repair of Perforation

Tip of lead

Pericardium

Fat layer covering epicardium
• Points of Failure
  - Chronic (common suspects)
    - Device
    - Lead malfunction
- 76 yr old male with ICD implanted 5 years ago received multiple shocks without warning, EGM shown below
VT/VF Episode #15 Report

<table>
<thead>
<tr>
<th>ID#</th>
<th>Date/Time</th>
<th>Type</th>
<th>V. Cycle</th>
<th>Last Rx</th>
<th>Success</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Jan 31 02:55:35</td>
<td>VF</td>
<td>270 ms</td>
<td>VF Rx 6</td>
<td>Yes</td>
<td>5.3 min</td>
</tr>
</tbody>
</table>

- **Interval (ms)**
  - V-V
  - A-A
  - VF = 350 ms
  - FVT = 270 ms
  - VT = 400 ms

- **Time (sec)** [0 = Detection]
VT/VF Episode #15 Report

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- V-V
- A-A
- VF = 350 ms
- FVT = 270 ms
- VT = 400 ms

Time (sec) [0 = Detection]
Chronic ICD System Issues

1st Rib-Clavicle Crush (lead fracture)
Lead Fracture

- Fracture of proximal (outer) conductor
Lead Fracture

Erratic sensing problem (over and undersensing)

Intermittent loss of capture

Elevated Impedance
Which Lead is Better?

<table>
<thead>
<tr>
<th>Lead</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>STJ Riata 8F</td>
<td>0.09 mm</td>
</tr>
<tr>
<td>BIO Linox SD</td>
<td>0.15 mm</td>
</tr>
<tr>
<td>STJ Riata 8F</td>
<td>0.15 mm</td>
</tr>
<tr>
<td>MDT Sprint</td>
<td>0.28 mm</td>
</tr>
<tr>
<td>Fidelis 6949</td>
<td>0.22 mm</td>
</tr>
</tbody>
</table>
Chronic ICD System Issues-Case 6

EEGM2: HVA to HVB

Marker Annotation

VV-V Interval (ms)

VF Rx 1 Defib
ICD System Issues

Insulation Break

- **Common Behavior**
  - Lead impedance
    - Low
    - Can be intermittent
  - Capture threshold
    - Sudden rise or loss
    - Can be intermittent
  - Sensing
    - Over/undersensing
    - Can be intermittent
• 65 year old male with ischemic heart disease, s/p MI 3 years previously and LV Ejection Fraction of 25%
• ICD implanted 10 months ago
• When seen, system reported 40 high voltage therapy episodes not associated with any warnings.
• CXR - showed no obvious ICD issues
Presenting EGM

[Heart rate monitoring graph with annotations]

- 25.4 J
- VF Rx 2 Defib
- 34.8 J
- VF Rx 4 Defib
Case 4 - Analysis

V Tach

Spontaneous Termination
Return of Sinus Rhythm

Sinus Rhythm

HV Therapy

HV Therapy
Segment of Stored EGM

AECM
Intervals for identification of VT/VF

VEGM

A-A or P-P intervals (ms)

Identification of detected events

Ventricular intervals R-R (ms)

Delivery of shock

R-R intervals (ms)
AEGM

F” = rate in “fib zone”

32 | 52 | 82 | 74 | 40
|559|563|559|570|563
|281|273|281|281|281|281|281|289|563

T wave oversensing
• Allows sensing of fine VF waves
• Prevents sensing of T-waves, cross-chamber events, and pacing artifacts
Sensitivity

* in Medtronic devices

**Atrial**

- Auto Adjusting Sensitivity (time constant = 200ms)
- Programmed Sensitivity

**Ventricle**

- Auto Adjusting Sensitivity (time constant = 450ms)
- Programmed Sensitivity
Auto-Adjusting Sensitivity

* in Medtronic devices

Decay Constant

One Decay Constant

Time

1/X

2/X

1/3

1/3

1/3

1/3
Auto-Adjusting Sensitivity

* in Medtronic devices

Rectified EGM

Post-sensed sensitivity adjustment → 75%
Post-pacal sensitivity adjustment → 4.5x
Programmed sensitivity → 0.3 mV
Post-pace blanking

Marker Channel™ Telemetry

Changing Threshold Post-Pace Post-Sense

V PACED V PACED V SENSE V PACED V SENSE

Ventricular Channel Shown
<table>
<thead>
<tr>
<th>Medtronic ICD</th>
<th>Atrial Sensitivity</th>
<th>Ventricular Sensitivity</th>
</tr>
</thead>
</table>
| Post-atrial sensed event | Increased to 75% of peak EGM amplitude (max 8x set value)  
Decay constant: 200ms | No adjustment |
| Post-atrial paced event | No adjustment | No adjustment |
| Post-ventricular sensed event | No adjustment | Increased by 0.45 mV  
Decay constant: 60ms |
| Post-ventricular paced event | Increased by 4x set value  
Decay constant: 60ms | Decay constant: 450ms  
Increased to 4.5x set value (max 1.8mV)  
Decay constant: 450ms |
Primary prevention, single chamber ICD
Double counting of intrinsic QRS

T wave oversensing

Case #2: Sweep Speed adjusted to assist with troubleshoot
Sensing and Refractory Periods

Native QRS after being processed by sense amplifier

Special Note: ICD continues to monitor QRS signal during the Vent. Refractory Period to identify peak amplitude of this signal.

Sensing the intrinsic deflection

Initiation of Ventricular Refractory Period
Patient received a shock while operating a arch welding equipment
Electromagnetic Interference

Cautery

- Can be sensed by an ICD and cause:
  - Oversensing
  - False detection of an arrhythmia
  - Therapy for falsely detected arrhythmia
  - False episode recordings

- Can occur in acute and chronic systems

- May require suspension of detection/therapy in ICD to prevent inappropriate behavior
Common Sources of EMI

- **Surgical/Therapeutic equipment**
  - Electrocautery
  - Transthoracic defibrillation
  - Extracorporeal shock-wave lithotripsy
  - Therapeutic radiation
  - RF Ablation
  - TENS units
  - Heat Diathermy
  - MRI
Common Sources of EMI

- **High Intensity Electromagnetic Fields**
  - TV/Radio transmitting towers (>100,000 volts)
  - Power plants/ power lines
  - Large generators

- **Heavy Electrical Equipment**
  - Chain saw
  - Arc welding equipment
  - Electric steel furnaces

- **Industrial Magnets**
Patient received a shock while playing basketball without warning
Recorded Episodes

Episode Text

![Medtronic Programming Screen](image)
Case 10

Patient had a dual chamber ICD 1 year ago, has multiple shocks without warning postoperative after shoulder surgery, EGM as below
Inappropriate ICD shocks

- 30% Shocks are inappropriate
- 70% due to sinus tachycardia and AF
- 30% due to lead or system failure
- Inappropriate shocks should be prevented if devices is programmed carefully, appropriately and custom for each patient
SVT Discriminators:

- Prevent detection of tachyarrhythmias caused by the presence of an SVT/AF
- Prevent inappropriate, unnecessary therapy due to rapid SVT/AF conduction
- Are present in some form in most ICDs
<table>
<thead>
<tr>
<th></th>
<th>Medtronic (P-R Logic)</th>
<th>St Jude (MD + A/V)</th>
<th>Biotronik (SMART)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudden Onset</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Rate Stability</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Electrograms</td>
<td>_</td>
<td>+</td>
<td>-</td>
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<tr>
<td>AV events</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>AV relationship</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>
• Discriminate based on:
  - 1. Waveform morphology
    • EGM Width (single chamber)
    • Wavelet/Morphology
  - 2. Onset of arrhythmia
  - 3. Stability of arrhythmia
  - 4. Relationship between P- and R-waves
    (dual chamber / requires an atrial lead)
- Measures and stores the QRS characteristics of a normal sinus beat
- Identifies SVT vs. VT based on the QRS changes that occur in most VTs
• Identifies start and end points of a sensed QRS complex
• Uses 2 parameters to measure QRS:
  - Slew Width
  - Slew Threshold
SVT Discriminators

EGM Width

SVT

Width Threshold

As determined by programmed value.

VT

Narrow

Wide
SVT Discriminators - Single chamber

- Records and stores a template of a normal QRS wave
- Compares stored template with a QRS occurring within the detection zone
- Withholds detection if 3 of last 8 QRS complexes match the stored template
  - Detects VT/FVT/VF if 6 out of 8 do not match
- Applies to initial detection only
SVT Discriminators

Wavelet

- Template

% difference compared against: Match Threshold Value
**Match Threshold Programming**

- **Lower %**
  - More likely to withhold appropriately; less likely to detect true VT

- **Higher %**
  - Less likely to appropriately withhold; more likely to detect true VT
Based on the premise that most VTs are characterized by a sudden onset,

Evaluates the acceleration of the ventricular rate.

Discriminates between:
- Gradual rate increase
- Abrupt rate increase

Determines VT present if rate increase is abrupt
• **When On:**
  - Averages 4 beats and compares with an average of previous 4 (multiplied by programmed Onset Percentage)

• **Onset met if recent average is less than previous**
- Onset Percentage = 81%

530ms X 81% = 430ms

430ms ≠ 460ms = Onset Not Met

* in Medtronic devices
SVT Discriminators

Stability

- Based on the premise that AF conducts irregularly to the ventricles (and VT is a stable, regular rhythm)
- Discriminates regular from irregular intervals within a detect zone
SVT Discriminators

Stability

- Activated when the VT counter = 3
- Requires Stability Interval Value
  - Set in Milliseconds (ms)
  - The programmed variation defining instability (ex. 50 ms)
- Considers rhythm unstable if:
  - When compared to any previous 3 intervals, an interval differs > Stability Interval
- Active during detection and re-detection
SVT Discriminators

Stability = 50 ms

VT Count Reaches 3

Varies >50 ms from previous 3

Unstable

* in Medtronic devices
SVT Discriminators

Most sophisticated P-R relationship

- Considers P and R relationship to discriminate SVT from VT
- **Dual Chamber** (requires an atrial and ventricular lead)
- Can be used in conjunction with other discriminators
SVT Discriminators

PR Logic™

• What it looks for:
  - Atrial Fibrillation / Flutter
  - Sinus Tachycardia
  - Other 1:1 SVTs (such as AVNRT)

• How it works:
  - Analyzes:
    • Pattern (P:R wave relationship)
    • AV Association
    • Rate
    • Regularity (R waves)

* in Medtronic devices
- Distinguishes SVTs by analyzing P and R-wave:
  - Pattern: number and position of atrial events relative to ventricular events
• Distinguishes SVTs by analyzing P and R-wave:
  - Pattern - number and position of atrial events relative to ventricular events
  - Rate
  - Regularity
Example: Sinus Tachycardia
Example: Atrial Fibrillation
• Algorithm used to identify AF:
  - Increments by 1 when 2 or more atrial events occur within one V-V interval
  - Decreased by 1 when 1 atrial event occurs within one V-V interval
Example: AVNRT (Other 1:1 SVTs)
PR Logic™

Programmable Boundaries

- Zone adjustment for patient specific SVTs

Diagram showing programmable boundaries with percentages and zones.
PR Logic™ Programming

*Medtronic Programming Screen
VT appropriate treatment
AF classified as AF
Positive Predictive Value: 88.4%
  • probability the arrhythmia is VT
  • % of appropriate delivered therapy

Sensitivity: 100%
  • probability VT received correct therapy

Specificity: 99.6%
  • probability therapy was correctly withheld for SVT
Episode of tachycardia

AV Nodal Reentrant Tachycardia (SVT)

Ventricular Tachycardia

Change in VEGM morphology

AV dissociation
ATP therapy terminates monomorphic VT

Termination of VT allows AVNRT to again conduct to the ventricle
Episode 974

Termination of VT

Atrium
AV Node
Ventricle
Remote Home Monitoring with Early Detection - the standard of Care in device management

1. Device status

2. Lead monitoring

3. Early detection of atrial arrhythmias
Home Monitoring with Early Detection provides constant surveillance of device and lead integrity. Wireless transmission by Home Monitoring takes place automatically without patient intervention. The following case study illustrates the rapid notification of potential lead problems and differentiation between benign and potentially harmful situations.
Patient Profile

- 67 y.o. male with idiopathic dilated cardiomyopathy (LVEF 25%)

- History of ventricular tachycardiac and atrial fibrillation

- Implanted with Biotrionik Kronos LV-T ICD with Sprint Fidelis (MDT 6949) lead 15 months earlier

- Patient lives 2 hours from clinic, regular office visit was hardship for patient. Home Monitoring was implemented for patient.
- January 21, 2008 a report was generated indicating aborted shocks

- Report documented 3 VF episodes resulting in 1 therapy delivery

- Aborted therapies and shocks raised concerns about lead integrity

- Patient’s Fidelis was under advisory but it was decided at the time to monitor and not replace the lead

- It was crucial to verify the reason for aborted shocks

- IEGMs were automatically transmitted wirelessly and available online for review
IEGM and Pacing Impedance Alert:

|-------|-----------------------------------|------|-------------|

![Graph showing ECG and pacing impedance](image)
Impedance Trend:
- Report showed an alert that the Ventricular Lead was 1164 Ohms (a drastic increase from 500 ohm baseline)

- IEGM revealed that the episode was generated due to noise artifacts rather than true VF

- Ventricular lead impedance trend was also downloaded and an abrupt change was noticed which coincided with lead noise and false positive VF report

- Communication of clinical evaluation occurred without patient awareness of any problems
DIAGNOSTIC RESOURCES
• Patient
• X-rays
• Device Data
  - EGM/Marker Channels
  - Telemetered Data
    • ICD Observations
    • Patient Information
    • Diagnostics
    • Battery/Capacitor/Lead Integrity
  - Recorded Episodes
  - Settings
Patient Alert™ Heard?

*Medtronic Programming Screen* in some Medtronic devices
• Valuable Device Data:
  - EGM/Marker Channels
  - Telemetered Data
    • ICD Observations
    • Patient Information
    • Diagnostics
    • Batter/Capacitor/Lead Integrity
Non-Invasive Solutions

- Reprogramming to correct
  - Over/Undersensing
  - Loss of Capture
  - Inappropriate Detection/Therapy
  - Ineffective Therapy
  - Long Charge Time
  - Optimization of Parameters

- Remove provoking EMI source
  - Electrocautery
  - Heavy Machinery
  - Electric Therapy
Invasive Solutions for:

- End of Life Battery (EOL)
  - Elective Replacement/ERI
- Loss of capture/sensing due to:
  - Lead Dislodgement
  - Lead Failure
- Inadequate DFT
- Poor Lead Connection
- Perforation
- Endocarditis
- Infection
- Faulty Device
4-Step Troubleshooting Strategy

Step 1: Define the Problem
- Patient Information
- Diagnostic Retrieval

Step 2: List the Potential Causes
- Lead Issues
- Device Issues
- Other Issues

Step 3: Determine the Cause(s)
- Diagnostic Testing & Analysis

Step 4: Correct the Problem
- Non-Invasive vs. Invasive
The more puzzle pieces we can assemble, the easier it will be to see the answer.....

1) VF Episode EGM: "Looks like noise"
2) Potential Causes: Connector Issue, EMI, Lead Sliced @ Implant
3) Reproducible (Manipulated ICD in the pocket. Oversensing seen.)

4) Solution: Invasive procedure. (Probably set screw)
   #1 Loose set-screw. #2 Inspect lead for nicks.
Even if the troubleshooting seems troublesome...

JUST HANG IN THERE!