When to Implant an ICD and Which One

Brad Suprenant DO, FACC, FACOI
## Major Implantable Cardioverter-Defibrillator Trials for Secondary Prevention of Sudden Cardiac Death

<table>
<thead>
<tr>
<th>Trial</th>
<th>Year</th>
<th>Patients (n)</th>
<th>Inclusion Criterion: LVEF</th>
<th>Additional Study Features</th>
<th>Hazard Ratio*</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVID</td>
<td>1997</td>
<td>1016</td>
<td>≤ 40%</td>
<td>Prior cardiac Arrest, or Unstable VT</td>
<td>0.62</td>
<td>(0.43-0.82)</td>
<td>p&lt;0.02</td>
</tr>
<tr>
<td>CASH†</td>
<td>2000</td>
<td>191</td>
<td>Mean ≤ 45% ±18 at baseline</td>
<td>Prior cardiac arrest</td>
<td>0.766</td>
<td>‡</td>
<td>p=0.08</td>
</tr>
<tr>
<td>CIDS</td>
<td>2000</td>
<td>659</td>
<td>≤ 35%</td>
<td>Prior cardiac Arrest, Unstable VT, or Syncope</td>
<td>0.82</td>
<td>(0.60-1.1)</td>
<td>NS</td>
</tr>
</tbody>
</table>
## Major Implantable Cardioverter-Defibrillator Trials for Primary Prevention of Sudden Cardiac Death

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<tbody>
<tr>
<td>MADIT I</td>
<td>1996</td>
<td>196</td>
<td>&lt; 35%</td>
<td>NSVT and EP+</td>
<td>0.46</td>
<td>(0.26-0.82)</td>
<td>p=0.009</td>
</tr>
<tr>
<td>MADIT II</td>
<td>2002</td>
<td>1232</td>
<td>&lt; 30%</td>
<td>Prior MI</td>
<td>0.69</td>
<td>(0.51-0.93)</td>
<td>p=0.016</td>
</tr>
<tr>
<td>CABG-Patch</td>
<td>1997</td>
<td>900</td>
<td>&lt; 36%</td>
<td>+SAECG and CABG</td>
<td>1.07</td>
<td>(0.81-1.42)</td>
<td>p=0.64</td>
</tr>
<tr>
<td>DEFINITE</td>
<td>2004</td>
<td>485</td>
<td>&lt; 36%</td>
<td>NICM, PVCs or NSVT</td>
<td>0.65</td>
<td>(0.40-1.06)</td>
<td>p=0.08</td>
</tr>
<tr>
<td>DINAMIT</td>
<td>2004</td>
<td>674</td>
<td>≤ 35%</td>
<td>6-40 days post-MI and Impaired HRV</td>
<td>1.08</td>
<td>(0.76-1.55)</td>
<td>p=0.66</td>
</tr>
<tr>
<td>SCD-HeFT</td>
<td>2006</td>
<td>1676</td>
<td>≤ 35%</td>
<td>Prior MI or NICM</td>
<td>0.77</td>
<td>(0.62-0.96)</td>
<td>p=0.007</td>
</tr>
</tbody>
</table>
Guidelines

Current ACC/AHA/HRS guidelines for ICD and CRT implant from 2008
ICD

• Class I

  – VT/VF survivors with irreversible etiology
  – sustained VT with structural heart disease
  – syncope + VT/VF at EPS
  – NYHA II-III, LV EF<35%
  – NYHA I, post-MI, LV EF<30%
  – NSVT, post-MI, LV EF<40%, VT/VF at EPS
ICD

- Class IIa
  - syncope, LV dysfunction, non-ischemic DCM
  - Sustained VT
  - HCM with major risk factors
  - ARVD with major risk factors
  - LQTS with syncope while on BB therapy
  - transplant bridge
  - Brugada syndrome with syncope or VT
  - Catecholaminergic polymorphic VT with syncope
ICD

- Class IIb
  - NYHA I, LV EF<35%
  - LQTS and SCD risk factors
  - idiopathic syncope and advanced SHD
  - familial CMP
  - LV noncompaction
ICD

• Class III
  – expected survival less than 1 year (other cause)
  – incessant VT/VF
  – significant psychiatric illness
  – NYHA IV without transplant or CRT indication
  – idiopathic syncope with no inducible VT/VF and SHD
  – VT/VF amenable with ablation
  – VT/VF with reversible cause
Notable Changes in 2008 ACC/AHA/HRS Guidelines

1. ICD recommendations are combined into a single list because of overlap between primary and secondary indications.

2. Primary prevention ICD indications in nonischemic cardiomyopathy are clarified using data from SCD-HeFT (i.e., ischemic and nonischemic cardiomyopathies and LVEF ≤35%, NYHA II-III) for support.

3. Indications for ICD therapy in inherited arrhythmia syndromes and selected nonischemic cardiomyopathies are listed.

4. MADIT II indication (i.e., ischemic cardiomyopathy and LVEF ≤30%, NYHA I) is now Class I, elevated from Class IIA.

5. EF criteria for primary prevention ICD indications are based on entry criteria for trials on which the recommendations are based.
Notable Changes in 2008 ACC/AHA/HRS Guidelines

6. The need for optimization of medical therapy before CRT implantation is emphasized.

7. Independent risk assessment preceding ICD implantation is emphasized, including consideration of patient preference.

8. Optimization of pacemaker programming to minimize unneeded RV pacing is encouraged.

9. A section has been added that addresses ICD and pacemaker programming at end of life.

10. Emphasized primary SCD prevention ICD recommendations apply only to patients receiving optimal medical therapy and reasonable expectation of survival with good functional capacity for >1 year.
Key Timing Issues from Guidelines

• Ensure proper time periods since diagnosis or treatment
  – Must be > 40 day since MI
  – Must be > 3 months since revascularization
  – Must be > 3 months since diagnosis of CHF
  • On optimal HF medical treatment
CRT

• Class I
  – LV EF<35%, QRS>120ms, NYHA III-IV, SR

• Class Ila
  – LV EF<35%, QRS>120ms, NYHA III-IV, AF
  – LV EF<35%, NYHA III-IV, VP dependent

• Class IIb
  – LV EF<35%, NYHA I-II, VP% high

• Class III
  – reduced LV EF only
  – limited life expectancy (non-cardiac)
Trials have Proven CRT Safety and Efficacy

ACC/AHA/HRS Class I Indication:
OPT, EF ≤ 35%, QRS ≥ 120ms, and NYHA Class III-IV*

- MIRACLE NEJM; 2002
- CONTAK-CD JACC; 2003
- MIRACLE ICD JAMA; 2003
- COMPANION NEJM; 2004
- CARE-HF NEJM; 2005
- RHYTHM ICD Heart Rhythm; 2005

Total enrolled patients = nearly 4,000!

*Level of Evidence:"A"
The Role of CRT in Earlier Stages of Heart Failure

Recent CRT trials have examined the effect of CRT in patients with asymptomatic and mild heart failure (NYHA Classes I and II).

These include:
- MADIT-CRT\(^1\)
- REVERSE\(^2\)
- RAFT\(^3\)


Similar Results for CRT in Patients with Mild Symptoms

Death or Heart Failure Hospitalization
Hazard Ratio with 95% CI

- REVERSE: Hazard Ratio = 0.49, p = 0.004
- RAFT NYHA II: Hazard Ratio = 0.73, p = 0.001
- MADIT CRT: Hazard Ratio = 0.66, P < 0.001

CRT-D Better

In the expanded indication patient population, CRT-D:

• Reduces mortality
• Reduces heart failure hospitalization
• Improves cardiac function
NCDR ICD Registry

• The National Cardiovascular Data Registry for ICDs
  – CMS mandated
  – 78% of centers report on all ICD implants not just the ones covered by CMS
Methods

• Patients were classified as receiving a non-evidence-based implant if they had:
  • MI within 40 days
  • CABG within 90 days
  • CHF NYHA Class IV without CRT
  • CHF diagnosed within 90 days

Al Khatib et al., JAMA 2011;305(1):43-49
‘Non-Evidence-Based’ ICD Implantations

- NCDR ICD registry based study [Al Khatib et al., JAMA 2011;305(1):43-49]
  - 22.5% of primary prevention implants were ‘non-evidence-based’
    - higher risk of in-hospital mortality/post-procedural complications
    - substantial hospital variation (0-60%)
    - Not reducing over time

- Provocative and controversial issue
  - Arguments: Data limitations, criteria interpretations, clinical appropriateness, semantics, etc.

- Department of Justice audits [Steinberg and Mittal, JACC 2012;59:1270-1274]
Conclusions

- A substantial number of ICDs are being implanted in patients who were either excluded from the major clinical trials of primary prevention ICDs or proven not to benefit from ICD therapy in other trials.

- Such patients are not only sicker than patients receiving an evidence-based-device, but they are at a higher risk of in-hospital death and any post-procedure complication.
Conclusions

• More efforts should focus on enhancing adherence to evidence-based practice.
Patient Case Study 1

- Following a 67 year old female with non-ischemic cardiomyopathy, Class II HF, and a LVEF of 30%. Diagnosed with HF 2 years ago and continues to be mildly symptomatic despite optimized medical therapy. No history of SCA or sustained VT.
- Should an ICD be considered for this patient?
Patient Case Study 1

• Yes
  – Primary prevention of VT/VF

• Which type of ICD?
  – Single Chamber
  – Dual Chamber
  – Triple Chamber (CRT-D)

• Does Patient have LBBB with QRS > 130ms?
Patient Case Study 1

• If no LBBB with QRS > 130ms
  – Dual chamber if bradycardia pacing indication
  – Single chamber otherwise

• If yes to LBBB with QRS > 130ms
  – Consider CRT-D

• New evidence of benefit in these patients with CRT-D
  – FDA approved use*
    – Guidelines written prior to this

*Medtronic and Boston Scientific have FDA approved labeling for use of their Bi-V ICDs in these patients.
Patient Case Study 2

• 55 year old male with ESRD successfully resuscitated from SCA. Non-ischemic DCM with LVEF=38%, NYHA Class II systolic/diastolic HF with sinus rate 90 bpm and QRS duration=100msec.

Implant ICD?
Which one?
Patient Case Study 3

• 65 year old male in sinus rhythm with three vessel CAD, moderate-severe AS, and LVEF=20%. Post-op patient develops CHB that requires a PPM.

Implant AVPPM ?
Implant CRT-P ?
Implant CRT-D ?
Sub-Q ICD
Thank You

Questions?
Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial

- 1520 patients with NYHA Class III or IV HF, ischemic cardiomyopathy (ICM) or nonischemic cardiomyopathy (NICM) and QRS of at least 120 ms
- Randomized 1:2:2 to optimal pharmacological therapy (OPT) alone or in combination with cardiac resynchronization therapy with either a pacemaker (CRT-P) or pacemaker-defibrillator (CRT-D)
- Both device arms significantly ↓ combined risk of all-cause hospitalization and all-cause mortality by ~20% compared with OPT
- CRT-D ↓ mortality by 36% compared with OPT (p=0.003)
- Insufficient evidence to conclude that CRT-P inferior to CRT-D

Multicenter Automatic Defibrillator Implantation Trial II (MADIT II)

- 1232 patients ≥ 1 month post-MI and LVEF ≤ 30%
- Randomized to ICD (n=742) or medical therapy (n=490)
- No spontaneous or induced arrhythmia required for enrollment
- 6% absolute and 31% relative risk ↓ in all-cause mortality with ICD therapy (p=0.016)

Sudden Death in Heart Failure (SCD-HeFT) Trial

- 2521 patients with NYHA Class II or III HF, ICM, or NICM and LVEF ≤ 35%
- Randomized to
  1) conventional rx for HF + placebo;
  2) conventional rx + amiodarone; or
  3) conventional rx + conservatively programmed shock-only single lead ICD
- No survival benefit for amiodarone
- 23% ↓ in overall mortality with ICD therapy
- Absolute ↓ in mortality of 7.2% after 5 y in the overall population

Defibrillator in Acute Myocardial Infarction (DINAMIT) Trial

- 674 patients 6 to 40 days post-MI with LVEF ≤ 35% and impaired cardiac autonomic function
- Randomized to ICD therapy (n=332) or no ICD therapy (n=342)
- Arrhythmic death ↓ in ICD group, but ↑ in nonarrhythmic death (6.1% per year vs. 3.5% per year, HR 1.75 (95% CI 1.11 to 2.76; p=0.016)
- No difference in total mortality

Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Trial

- 458 patients with NYHA Class I to III, NICM, LVEF ≤ 36% and premature ventricular contractions (> 10/h) or NSVT
- Randomized to standard medical rx alone or in combination with single-chamber ICD
- Strong trend toward ↓ all-cause mortality with ICD therapy, although not statistically significant (p=0.08)

Achieving Cardiac Resynchronization

- Improved Contraction Pattern
  - Organized ventricular activation sequence
Achieving Cardiac Resynchronization

- Optimized AV Interval
  - Reduced mitral regurgitation $^{1,2,3}$

1 Nishimura et al.
2 Etienne et al.
3 Brecker et al.
### Overview of Primary Prevention Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADIT</td>
<td>54% reduction in mortality with ICD</td>
</tr>
<tr>
<td>MUSTT</td>
<td>55-60% reduction in mortality with ICD</td>
</tr>
<tr>
<td>MADIT II</td>
<td>31% reduction in mortality with ICD</td>
</tr>
<tr>
<td>DEFINITE</td>
<td>Mortality benefit 5.7% at 2 years with ICD</td>
</tr>
<tr>
<td>SCDHeFT</td>
<td>23% reduction in mortality with ICD</td>
</tr>
</tbody>
</table>
SCD and ICD Summary

• SCD – THE leading cause of death in the US
• ICDs superior to optimal medical mgmt alone as demonstrated in multiple clinical trials
• Patients at risk need to be identified before they have SCD
  –KNOW YOUR PATIENT’S EF !!!!
• ICDs are cost-effective and underutilized
• ICD therapy can be painless
• The mortality risk of NOT having an ICD far outweighs the risk of device failure
SCD-HeFT Versus Other Landmark Device Trials in Heart Failure

<table>
<thead>
<tr>
<th>HF Etiology</th>
<th>Ischemic: 100%</th>
<th>Ischemic: 59% Non-ischemic: 41%</th>
<th>Non-ischemic: 100%</th>
<th>Ischemic: 52% Non-ischemic: 48%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class</td>
<td>I/II/III (35%/35%/30%)</td>
<td>III/IV (87%/13%)</td>
<td>I/II/III (20%/60%/20%)</td>
<td>II/III (71%/29%)</td>
</tr>
<tr>
<td>LVEF</td>
<td>≤ 30%</td>
<td>≤ 35%</td>
<td>≤ 35%</td>
<td>≤ 35%</td>
</tr>
<tr>
<td>No. Pts</td>
<td>1232</td>
<td>1520</td>
<td>458</td>
<td>2521</td>
</tr>
<tr>
<td>Follow-Up</td>
<td>20 months</td>
<td>12 months</td>
<td>24 months</td>
<td>45 months</td>
</tr>
<tr>
<td>Hazard Ratio</td>
<td>0.69</td>
<td>0.64</td>
<td>0.66</td>
<td>0.77</td>
</tr>
</tbody>
</table>
# CRT Trials in Early Stage Heart Failure

<table>
<thead>
<tr>
<th></th>
<th>MADIT-CRT&lt;sup&gt;1&lt;/sup&gt;</th>
<th>REVERSE&lt;sup&gt;2&lt;/sup&gt;</th>
<th>RAFT&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NYHA Class</strong></td>
<td>NYHA I, II ischemics; NYHA II, non-ischemics</td>
<td>Stable NYHA Class I with current ACC/AHA stage C or NYHA class II HF</td>
<td>NYHA II</td>
</tr>
<tr>
<td><strong>QRS Duration</strong></td>
<td>130 ms</td>
<td>120 ms</td>
<td>Intrinsic 120 ms Paced 200 ms</td>
</tr>
<tr>
<td><strong>LVEF</strong></td>
<td>30%</td>
<td>40%</td>
<td>30%</td>
</tr>
<tr>
<td><strong>LVEDD</strong></td>
<td>NA</td>
<td>55 mm (or LVEDD index 2.8 cm/m²)</td>
<td>60 mm</td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td>Stable HF OPT</td>
<td>Stable HF OPT</td>
<td>Stable HF OPT</td>
</tr>
<tr>
<td><strong>Primary Endpoint</strong></td>
<td>Objective combined endpoint of all-cause mortality or heart failure event, whichever occurs first</td>
<td>HF clinical composite response that includes all cause-mortality, HF hospitalizations, NYHA class and patient global assessment</td>
<td>HF composite score including all-cause mortality and HF hospitalization</td>
</tr>
<tr>
<td><strong>Randomization</strong></td>
<td>CRT-D: ICD (3:2)</td>
<td>CRT ON: CRT OFF (2:1)</td>
<td>CRT-D: ICD (1:1)</td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td>1820</td>
<td>683 enrolled, 610 randomized</td>
<td>1800</td>
</tr>
<tr>
<td><strong>Centers</strong></td>
<td>110</td>
<td>~73</td>
<td>~25</td>
</tr>
<tr>
<td><strong>Geography</strong></td>
<td>US, Europe, Israel, Canada</td>
<td>US, Canada, Europe</td>
<td>Canada, Australia, Europe</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Completed</td>
<td>Completed</td>
<td>Enrollment completed; trial continues</td>
</tr>
</tbody>
</table>

## Major ICD Trials

<table>
<thead>
<tr>
<th>Trial name, pub year</th>
<th>N</th>
<th>Hazard ratio</th>
<th>LYEF other features</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADIT-I 1996</td>
<td>196</td>
<td>0.46</td>
<td>0.35 or less, NSVT, EP positive</td>
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<tr>
<td>AVID 1997</td>
<td>1016</td>
<td>0.62</td>
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<td>1.07</td>
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<td>CIDS 2000</td>
<td>659</td>
<td>0.82</td>
<td>Aborted cardiac arrest or syncope</td>
</tr>
<tr>
<td>MADIT-II 2002</td>
<td>1232</td>
<td>0.69</td>
<td>0.30 or less prior MI</td>
</tr>
<tr>
<td>DEFINITE 2004</td>
<td>456</td>
<td>0.65</td>
<td>0.35 or less, NICM and PVCs or NSVT</td>
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<tr>
<td>DINAMIT 2004</td>
<td>674</td>
<td>1.08</td>
<td>0.35 or less, MI within 6-40 days and impaired cardiac autonomic function</td>
</tr>
<tr>
<td>SCD-HeFT 2005</td>
<td>1676</td>
<td>0.77</td>
<td>0.35 or less, LVD due to prior MI and NICM</td>
</tr>
</tbody>
</table>

ICD Indications

• **Primary Prevention (Pre Event)**
  - High risk familial/inherited condition (HCM/LQT)
  - Previous remote MI (>4 weeks to 40 days)
    - MADIT I: EF<35, NSVT, inducible sustained VT/VF
    - MADIT II: EF< 30%, no revascularization within 3 months
  - CHF
    - SCD-HeFT Class II-III EF< 35% any cause > 3 months duration
    - Companion Class III-IV CRT device QRS >120, EF<35%
ICD Indications

• **Secondary Prevention (post cardiac event)**
  - Cardiac arrest due to VT/VF not due to reversible cause
  - Spontaneous sustained VT not associated with MI or reversible cause
Implantable Cardioverter-Defibrillators and Prevention of Sudden Cardiac Death in Hypertrophic Cardiomyopathy

- Multicenter registry study of implanted ICDs in 506 unrelated patients with HCM @ high risk for SCD (family hx of SCD, [septal thickness ≥ 30 mm], NSVT, syncope)
- Mean patient age 42 years (SD=17) and 87% had no or only mildly limiting symptoms
- Appropriate ICD discharge rates were 11% per year for 2° prevention and 4% per year for 1° prevention
- For 1° prevention, 35% of patients with appropriate ICD interventions had undergone implantation for only 1 risk factor

CRT Shown to Slow HF Progression in Mild or Moderate/Severe HF

<table>
<thead>
<tr>
<th>Study</th>
<th>Mortality</th>
<th>HF or CV Hospitalizations</th>
<th>Cardiac Function/Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARE-HF&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>COMPANION&lt;sup&gt;3&lt;/sup&gt;</td>
<td>+</td>
<td>+</td>
<td>Not collected</td>
</tr>
<tr>
<td>MIRACLE&lt;sup&gt;4&lt;/sup&gt;</td>
<td></td>
<td>Not powered for mortality or hospitalization</td>
<td>+</td>
</tr>
<tr>
<td>MIRACLE ICD&lt;sup&gt;5&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>Not powered</td>
</tr>
<tr>
<td>REVERSE&lt;sup&gt;6&lt;/sup&gt;</td>
<td>Not powered</td>
<td>+*</td>
<td>+</td>
</tr>
<tr>
<td>RAFT&lt;sup&gt;7&lt;/sup&gt;</td>
<td>+</td>
<td>+</td>
<td>Not collected</td>
</tr>
<tr>
<td>MADIT CRT&lt;sup&gt;8&lt;/sup&gt;</td>
<td>+*</td>
<td>+</td>
<td>+*</td>
</tr>
</tbody>
</table>


* Post-hoc analysis.
Consistent Benefit of CRT for Patients with LBBB within Study Cohorts*

Death or Heart Failure Hospitalization/Event

LBBB:
- REVERSE: 0.48
- RAFT Class II: 0.63
- MADIT-CRT: 0.43

Non-LBBB:
- REVERSE: 0.53
- RAFT Class II: 1.10
- MADIT-CRT: 1.32

Odds Ratio with 95% CI

CRT-D Better

Death or Heart Failure Hospitalization/Event

* Post-hoc analysis for all 3 trials.

MADIT-CRT: Cognis 100-D Physician’s Technical Manual, Boston Scientific, Inc.
More than a Decade of Experience
With CRT in Mild Heart Failure

- Mortality benefit
- Reduced HF hospitalizations
- Mortality benefit in LBBB population*
- Reduced HF hospitalizations
- Improved cardiac function*

2003: CONTAK CD
6 mos; n = 263
- Improved cardiac function

2004: MICD II
6 mos; n = 186
- Improved CCR
- Improved cardiac function

2008: REVERSE
12 mos, n = 610;
24 mos, n = 262
- Reduced HF hospitalizations*
- Improved CCR*
- Improved cardiac function

2009: MADIT CRT
Average 29 mos, n = 1,820
- Mortality benefit
- Reduced HF hospitalizations
- Improved CCR*
- Improved cardiac function*

2010: RAFT
Average 40 mos, n = 1,438
- Mortality benefit
- Reduced HF hospitalizations

* Post-hoc analysis.
**Figure Legend:**

[Graph showing distribution of non-evidence-based ICD implantations in the United States]
## Results

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Non-evidence-based ICD implant (N=25,145)</th>
<th>Evidence-based ICD implant (N=86,562)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (25th, 75th %), y</td>
<td>67.0 (57.0, 75.0)</td>
<td>66.0 (57.0, 75.0)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Male gender, No. (%)</td>
<td>18,965 (75.4)</td>
<td>64,464 (74.5)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, No. (%)</td>
<td>19,463 (77.5)</td>
<td>66,730 (77.2)</td>
<td></td>
</tr>
<tr>
<td>Black, No. (%)</td>
<td>3,955 (15.7)</td>
<td>15,186 (17.6)</td>
<td></td>
</tr>
<tr>
<td>Other, No. (%)</td>
<td>1,695 (6.7)</td>
<td>4,550 (5.3)</td>
<td></td>
</tr>
<tr>
<td>Hispanic ethnicity, No. (%)</td>
<td>1,702 (6.8)</td>
<td>4,893 (5.7)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Primary insurance payer</td>
<td></td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Government, No. (%)</td>
<td>16,589 (66.0)</td>
<td>57,209 (66.1)</td>
<td></td>
</tr>
<tr>
<td>Commercial, No. (%)</td>
<td>5,260 (20.9)</td>
<td>19,033 (22.0)</td>
<td></td>
</tr>
<tr>
<td>HMO, No. (%)</td>
<td>2,060 (8.2)</td>
<td>7,604 (8.8)</td>
<td></td>
</tr>
<tr>
<td>Other, No. (%)</td>
<td>1,236 (4.9)</td>
<td>2,716 (3.1)</td>
<td></td>
</tr>
<tr>
<td>History of HF, No. (%)</td>
<td>23,092 (91.8)</td>
<td>75,700 (87.5)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Time since initial HF diagnosis</td>
<td></td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>&lt; 3 months, No. (%)</td>
<td>15,604 (67.6)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3 to 9 months, No. (%)</td>
<td>1,558 (6.7)</td>
<td>15,770 (20.8)</td>
<td></td>
</tr>
<tr>
<td>&gt; 9 months, No. (%)</td>
<td>5,930 (25.7)</td>
<td>59,930 (79.2)</td>
<td></td>
</tr>
<tr>
<td>NYHA class</td>
<td></td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>I, No. (%)</td>
<td>1,684 (6.7)</td>
<td>7,490 (8.7)</td>
<td></td>
</tr>
<tr>
<td>II, No. (%)</td>
<td>10,824 (43.0)</td>
<td>47,183 (54.5)</td>
<td></td>
</tr>
<tr>
<td>III, No. (%)</td>
<td>9,615 (38.2)</td>
<td>31,889 (36.8)</td>
<td></td>
</tr>
<tr>
<td>IV, No. (%)</td>
<td>3,022 (12.0)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Al Khatib et al., JAMA 2011;305(1):43-49
Temporal Changes in Non-evidence-based ICD Implants

Al Khatib et al., JAMA 2011;305(1):43-49
Proportional Mortality Increase

- VEST study analysis
- NYHA Class II-IV patients
- 3,654 ECGs digitally scanned
- Age, creatinine, LVEF, heart rate, and QRS duration found to be independent predictors of mortality
- Relative risk of widest QRS group 5x greater than narrowest

Adapted from Gottipaty et al.
MADIT-CRT Results Summary

- In asymptomatic or mild heart failure patients on stable optimal heart failure pharmacologic therapy who have LBBB, wide QRS and LV dysfunction, CRT-D, as compared to ICD, was significantly associated with:
  
  - Acceptable safety profile
  
  - Primary endpoint showing a 57% reduction in the risk of a composite of all-cause mortality or heart failure events (p < 0.001). This was driven by:
    - 63% reduction in the risk of first heart failure events (p < 0.001)
    - 35% reduction in the risk of all cause mortality (p = 0.048)
  
  - Secondary endpoint showing a 43% reduction in the risk of recurrent heart failure events (p = 0.001)
Recent Findings

• Recent study looking at data from NCDR ICD Registry
  – Claimed 22.5% of primary prevention ICD implants were “non-evidence-based”
    • higher risk of in-hospital mortality/post-procedural complications
    • substantial hospital variation (0-60%)
    • Not reducing over time

Al Khatib et al., JAMA 2011;305(1):43-49
## In-Hospital Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Non-evidence-based ICD (N=25,145)</th>
<th>Evidence-based ICD (N=86,562)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.6%</td>
<td>0.2%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Any post-procedure complication</td>
<td>3.2%</td>
<td>2.4%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hematoma involving the ICD pocket</td>
<td>0.9%</td>
<td>0.7%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Device-related infection</td>
<td>0.04%</td>
<td>0.02%</td>
<td>0.06</td>
</tr>
<tr>
<td>Risk of cardiac tamponade and pneumothorax</td>
<td>0.06%</td>
<td>0.09%</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Al Khatib et al., JAMA 2011;305(1):43-49
Results

• The overall number of non-evidence-based ICD implants, as a proportion of all implants, decreased appreciably from 21.5% in 2006 to 18.9% in the first 6 months of 2009 (p<0.0001)

• The decrease was mostly due to a decline in ICD implants in patients within 40 days from an MI and patients with NYHA IV HF symptoms
ICD Evolution

- 1947 First human internal defibrillation
- 1956 First human external defibrillator
- 1969 First external canine prototype tested
- 1970 First implantable prototype (895g)
- 1975 First implantable defib in canines (250g)
- 1980 First human implant @ John Hopkins
- 1985 First ICD market released (350 units)
ICD Evolution

- 1991 Non thoracotomy lead systems
- 1995 Pectoral ICD systems
- 1997 ICD & DDD
- 1998 ICD & DR
- 1999 ICD & Atrial Defibrillation
- 2001 ICD & Resynchronization Therapy
Guideline Gaps

• Elderly > 80 y.o.

• ESRD on hemodialysis

• Female gender