Sudden Cardiac Death in Heart Failure:
What do we need to know in 2018?

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Disclosures

Consultant for Zoll LifeVest.
One of the most common causes of death in developed countries:

<table>
<thead>
<tr>
<th></th>
<th>Incidence (cases/year)</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worldwide</td>
<td>3,000,000(^1)</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>U.S.</td>
<td>450,000(^2)</td>
<td>5%</td>
</tr>
<tr>
<td>W. Europe</td>
<td>400,000(^3)</td>
<td>&lt;5%</td>
</tr>
</tbody>
</table>

High recurrence rate


Leading cause of Death in the US

SCA is a leading cause of death in the U.S., second to all cancers combined.
**Disease States Associated with SCD**

1) Atherosclerotic CAD
2) Dilated Cardiomyopathy: 10% of SCD cases in adults.
3) Hypertrophic Cardiomyopathy: 2/1,000 young adults. 48% of SCD in athletes ≤ 35yo.
4) Valvular Heart Disease
5) Congenital Heart Disease: Four conditions associated with increased post-op risk of SCD (Tetrology of Fallot, transposition of the great vessels, Aortic Stenosis, pulmonary vascular obstruction).
6) Wolff-Parkinson-White Syndrome: Risk of SCD 1/1000 Mechanism: Afib with 1:1 conduction down accessory pathway leading to VF.
7) Arrhythmogenic Right Ventricular dysplasia.
8) Congenital long QT syndromes/Brugada/CPVT

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**Background for the current role of ICDs in cardiac patient management**

- Sudden cardiac death (SCD) accounts for ≈400,000 American deaths/year (0.1% in the general population). Single most common cause of death in the USA.
- Roughly two-thirds of Sudden Cardiac Arrest (SCA) deaths occur out-of-hospital.
- The survival rate in the U.S. for out-of-hospital cardiac arrest: 9.5%.
- Survivors who ultimately leave the hospital without significant neurologic deficit: 3%
- In-hospital SCA survival rate: 23.9%
The vast majority of the 400,000 SCA deaths are due to VT or VF.

SCA is the first manifestation of heart disease in 44% of men and 53% of women who die suddenly.

At autopsy healed infarctions are present in >50% (may be as high as 75%) of SCA victims.

Sustained MMVT associated with myocardial scar/old MI is the most common clinical VT.
- Mechanism: scar related reentry.
- Multiple triggers: neuroendocrine, drugs, electrolyte imbalances, sympathetic/parasympathetic tone.

Ischemic events tend to be the trigger for VF.
Prophylactic Implantable Cardioverter-Defibrillator Therapy in Patients With Left Ventricular Systolic Dysfunction: A Pooled Analysis of 10 Primary Prevention Trials

Death from all causes in all available primary prevention trials.

<table>
<thead>
<tr>
<th>Study or Sub-category</th>
<th>Treatment n</th>
<th>Control n</th>
<th>RR (random) 95% CI</th>
<th>Weight</th>
<th>RR (random) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMBULS</td>
<td>6/41</td>
<td>7/52</td>
<td>2.76 (0.97, 2.42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABO Pechak</td>
<td>10/146</td>
<td>15/414</td>
<td>12.79 (1.09, 2.42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAT</td>
<td>13/50</td>
<td>17/54</td>
<td>1.33 (0.80, 1.86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMPANION</td>
<td>105/595</td>
<td>131/617</td>
<td>13.19 (0.86, 1.66)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEPITE</td>
<td>20/229</td>
<td>40/229</td>
<td>0.96 (0.70, 1.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DMINA T</td>
<td>62/232</td>
<td>78/242</td>
<td>1.10 (0.89, 1.39)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MADIT I</td>
<td>12/45</td>
<td>27/101</td>
<td>1.12 (0.86, 1.49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MADIT II</td>
<td>105/742</td>
<td>77/470</td>
<td>12.72 (6.76, 0.92)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MUST</td>
<td>6/151</td>
<td>20/377</td>
<td>14.62 (6.76, 0.64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCIO HFIT</td>
<td>182/829</td>
<td>244/847</td>
<td>14.62 (6.76, 0.64)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total (95% CI): 212/970 (9723) 193/970 (9723)

Test for heterogeneity: CHI² = 28.67, df = 9, (P = 0.0005), P < 0.001

Test for overall effect: Z = 5.00 (P = 0.000)

Clinical Course of MI and Heart Failure

Sudden Death in Heart Failure
Key Randomized Post-MI Antiarrhythmic Drug Trials for Prevention of SCD

Post-MI trials have shown limited clinical utility for antiarrhythmic drug therapy for either primary or secondary prevention of arrhythmic death in patients with baseline moderate to severe LV dysfunction post-MI EF < 40%.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Drug</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAST 1</td>
<td>Flecainide/encainide/moricizine</td>
<td>Harm</td>
</tr>
<tr>
<td>CAST 2</td>
<td>Moricizine</td>
<td>Harm</td>
</tr>
<tr>
<td>SWORD</td>
<td>d-Sotalol</td>
<td>Harm</td>
</tr>
<tr>
<td>Julian</td>
<td>d-J-Solalol</td>
<td></td>
</tr>
<tr>
<td>EMIAT</td>
<td>Neutral</td>
<td>Amiodarone</td>
</tr>
<tr>
<td>CAMIAT</td>
<td>Amiodarone (no EF criteria)</td>
<td>Neutral</td>
</tr>
<tr>
<td>DIAMOND</td>
<td>Neutral</td>
<td>Dofetilide</td>
</tr>
<tr>
<td>ALIVE</td>
<td>Neutral</td>
<td>Azimiide</td>
</tr>
<tr>
<td>b-blockers</td>
<td>Propranolol,metoprolol, others.</td>
<td>Benefit</td>
</tr>
</tbody>
</table>

Guidelines for Waiting Period for ICD LV Dysfunction Primary Prevention

<table>
<thead>
<tr>
<th>Condition</th>
<th>2017 ACCF/AHA/HRS</th>
<th>2015 ESC Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post MI EF &lt;35%</td>
<td>Greater 40 days EF &lt;35%</td>
<td>6-12 weeks Class I level of evidence A</td>
</tr>
<tr>
<td></td>
<td>Class I level of evidence A</td>
<td>6-12 weeks Class I level of evidence C</td>
</tr>
<tr>
<td>Post CAD revascularization</td>
<td>Greater 3 months</td>
<td>Greater 3 months</td>
</tr>
<tr>
<td>Nonischemic cardiomyopathy</td>
<td>Greater 3-6 months CMS 9 months</td>
<td>Greater 3 months EF &lt;35% Class II-III Survival &gt;1 year</td>
</tr>
</tbody>
</table>
Medical Therapy Optimization Required
Prior To Managing Long-Term Arrhythmic Risk

- Medical optimization and stabilization can take 3 months or more.
  - Beta blocker doses effective in HF are generally achieved in 8 to 12 weeks and do not impart any mortality benefit until at least 3 months.

![Graphs showing mortality and survival rates for different therapies](image)

Understanding the Risk
LV Systolic Dysfunction and SCD Risk

- SCD accounted for \( \sim 50\% \) (35-64\%) of total mortality.
  - EF was the single most important risk factor for SCD.
Medical Therapy Optimization Required

HF Patient Improvement

- A HF patient’s cardiac function can improve from the benefits of optimized medical therapy
  - IMAC-2 study showed a mean LVEF increase of 17% in newly diagnosed cardiomyopathy patients¹
  - REFINE Study average relative improvement in EF was 18% at 8-10 weeks²

![Time course of LVEF improvement with β-blocker use²](image)

¹ McNamara D et al., Clinical and Demographic Predictors of Outcomes in Recently Diagnosed Cardiomyopathy. JACC 2016;68(11):1150-9.

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Medical Therapy Optimization

Opportunity for SCD Risk Protection

- Rates of medication usage in patients discharged from hospital with HF have improved but continue to not meet guidelines
  - Prescription rates are 70%, 60% and 35% for ACE inhibitors, β-blockers and aldosterone antagonists, respectively.¹

- When medications used in HF are prescribed, they do not achieve doses shown to improve mortality²
  - The percentage of patients that achieve optimal doses of heart failure medications is low.

![Patients at Target Dose (%) from OPTIMIZE-HF (n=48,612)²](image)

¹ Adams K., et al., Characteristics and outcomes of patients hospitalized for heart failure in the United States: rationale, design, and preliminary observations from the first 100,000 cases in the ADHERE registry. American Heart Journal. 2005;149:209–16.
Preventing SCD with Medications

Non – Evidence-Based ICD Implants (n=21,145)

- MI within 40 days before ICD implantation (23%)
- CABG surgery within 3 months before ICD implantation (3%)
- NYHA class IV symptoms (12%)
- Newly diagnosed heart failure at the time of ICD implantation (62%)

Early AICD Implant in Heart Failure

**CAD/MI**

**DINAMIT** 2004 (N=674)
MI (6 to 40 days), EF <35%, HR >80 bpm, No NSVT, 72 Ant MI, 2/3 revascularization, 32-month f/u, No difference in total mortality

**NONISCHEMIC CARDIOMYOPATHY**

**IRIS** (Immediate Risk Stratification Improves Survival) 2009 N=898
MI (5 to 31 days), EF <40%, HR >90bmp or NSVT 30-month f/u No difference in mortality
Estimates of the cumulative risk of death from arrhythmia (A) and nonarrhythmic (B) causes.


Valiant Trial
High Early Risk for SCD

Post-MI patients with heart failure are at 4-6 times greater risk of SCA in the first 30 days post-MI:

- 83% of SCA occurred after hospital discharge.
- 74% of those resuscitated in the first 30 days were alive at 1 year

Predictors of Sudden Death: VALIANT

1. Higher baseline heart rate
   (HR 1.2 per 10 bpm)

2. Impaired baseline creatinine clearance
   (HR 0.82 per 10 ml/min)

3. EF < 30%

4. QRS duration


Wealth of Evidence Supports Post-PCI Risk

<table>
<thead>
<tr>
<th>The CADILLAC Trial(^1) (n=2082)</th>
<th>Cleveland Clinic Registry(^2)</th>
<th>CathPCI-NCDR(^3) (n=343,466)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 day mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11% (60% SCD)</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>Post-PCI, AMI</td>
<td>EF ≤35%, Post-PCI, AMI</td>
<td>EF &lt;30%, Post-PCI, Age &gt;65 yo</td>
</tr>
</tbody>
</table>

Mortality Predictors

- LVEF, Age
- Renal insufficiency
- Multi-vessel
- Killip Class II/III
- Anemia
- TIMI flow

- LVEF, Age
- Diabetes Mellitus
- Female gender

- LVEF, Age
- Renal insufficiency
- Multi-vessel


\(^3\) Weintraub et al. Prediction of Long-Term Mortality After Percutaneous Coronary Intervention in Older Adults: Results From the National Cardiovascular Data Registry. Circulation 2012;125:1501-1510.
### Early AICD Implant in Heart Failure

#### CAD/MI

**DINAMIT 2004 (N=674)**
- MI (6 to 40 days), EF <35%, HR >80 bpm, No NSVT, 72 Ant MT, 2/3 revascularization, 32-month f/u, No difference in total mortality

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- MI (5 to 31 days), EF <40%, HR >90bpm or NSVT, 30-month f/u, No difference in mortality

#### NONISCHEMIC CARDIOMYOPATHY

**The Cardiomyopathy Trial (CAT) 2002 (N=104)**
- HF <9 months, No difference in all-cause mortality, Trial stopped at one year, No NSVT

**DEFINITE (n=458)**
- HF duration 2.8 years
- EF 28 %, NSVT or >10 pvc's per hour on holter
- Non significant reduction death from any cause p=0.08
Death from Arrhythmia Among Patients who Received Standard Therapy and Patients who Received an ICD

B Sudden Death from Arrhythmia

<table>
<thead>
<tr>
<th>Survival (yr)</th>
<th>Standard therapy</th>
<th>ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>P=0.006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No. at Risk
- Standard-therapy group: 229, 210, 131, 67, 32
- ICD group: 229, 218, 140, 77, 41


Death From Any Cause by Duration of HF, (Inclusion Criteria: NSVT on telemetry or greater than 10 PVC’s/Hr on holter monitoring

A. NIDCM duration 3 mo. or less

<table>
<thead>
<tr>
<th>Probability of Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD</td>
</tr>
<tr>
<td>Standard therapy</td>
</tr>
</tbody>
</table>

P = .049

B. NIDCM duration more than 3 mo.

<table>
<thead>
<tr>
<th>Probability of Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD</td>
</tr>
<tr>
<td>Standard therapy</td>
</tr>
</tbody>
</table>

P = .483

Noninvasive Arrhythmia Risk Stratification in Idiopathic Dilated Cardiomyopathy

Results of the Marburg Cardiomyopathy Study

Wolfram Grimm, MD; Michael Christ, MD; Jennifer Bach, MD; Hans-Helge Müller, PhD; Bernhard Maisch, MD

Background—Arrhythmia risk stratification with regard to prophylactic implantable cardioverter-defibrillator therapy is a completely unsolved issue in idiopathic dilated cardiomyopathy (IDC).

Methods and Results—Arrhythmia risk stratification was performed prospectively in 343 patients with IDC, including analysis of left ventricular (LV) ejection fraction and size by echocardiography, signal-averaged ECG, arrhythmias on Holter ECG, QTc dispersion, heart rate variability, baroreflex sensitivity, and uninvestigated T-wave alternans. During 52±21 months of follow-up, major arrhythmic events, defined as sustained ventricular tachycardia, ventricular fibrillation, or sudden death, occurred in 46 patients (13%). On multivariate analysis, LV ejection fraction was the only significant arrhythmia risk predictor in patients with sinus rhythm, with a relative risk of 2.3 per 10% decrease of ejection fraction (95% CI, 1.5 to 3.3; P=0.0001). Nonsustained ventricular tachycardia on Holter was associated with a trend toward higher arrhythmia risk (RR, 1.7; 95% CI, 0.9 to 3.3; P=0.11), whereas β-blocker therapy was associated with a trend toward lower arrhythmia risk (RR, 0.6; 95% CI, 0.3 to 1.2; P=0.13). In patients with atrial fibrillation, multivariate Cox analysis also identified LV ejection fraction and absence of β-blocker therapy as the only significant arrhythmia risk predictors.

Conclusions—Reduced LV ejection fraction and lack of β-blocker therapy are important arrhythmia risk predictors in IDC, whereas signal-averaged ECG, baroreflex sensitivity, heart rate variability, and T-wave alternans do not seem to be helpful for arrhythmia risk stratification. These findings have important implications for the design of future studies evaluating prophylactic implantable cardioverter-defibrillator therapy in IDC. (Circulation. 2003;108:2083-2091.)

Key Words: arrhythmia • cardiomyopathy • defibrillation

Association of Fibrosis With Mortality and Sudden Cardiac Death in Patients With Nonischemic Dilated Cardiomyopathy

6.2 Nonischemic Cardiomyopathy

### Predictors of Sudden Death New onset Cardiomyopathy Post MI

1. Higher baseline heart rate
2. Impaired baseline creatinine clearance
3. EF< 30 percent
4. QRS duration
5. Elevated BUN

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**Recommendations for Patients With NICM**

<table>
<thead>
<tr>
<th>CR</th>
<th>LOE</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>B-NR</td>
<td>1. In patients with suspected NICM from myocardial infiltrative processes, cardiac MRI with late gadolinium enhancement is useful for diagnosis (1-3).</td>
</tr>
<tr>
<td>IIa</td>
<td>B-NR</td>
<td>2. In patients with suspected NICM, cardiac MRI with late gadolinium enhancement can be useful for assessing risk of SCA/SCD (1-3).</td>
</tr>
<tr>
<td>IIa</td>
<td>C-EO</td>
<td>3. In patients with NICM who develop conduction disease or LV dysfunction at less than 40 years of age, or who have a family history of NICM or SCD in a first-degree relative (&lt;50 years of age), genetic counseling and genetic testing are reasonable to detect a heritable disease that may clarify prognosis and facilitate cascade screening of relatives (4, 5).</td>
</tr>
</tbody>
</table>

Risk Stratification for Primary Implantation of a Cardioverter-Defibrillator in Patients with Ischemic Left Ventricular Dysfunction


<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>HR</th>
<th>95% Confidence Interval</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA functional class &gt;II</td>
<td>1.87</td>
<td>1.23-2.86</td>
<td>0.004</td>
</tr>
<tr>
<td>Atrial fibrillation‡</td>
<td>1.67</td>
<td>1.06-2.62</td>
<td>0.034</td>
</tr>
<tr>
<td>QRS &gt;120 ms</td>
<td>1.65</td>
<td>1.08-2.51</td>
<td>0.020</td>
</tr>
<tr>
<td>Age &gt;70 yrs</td>
<td>1.57</td>
<td>1.02-2.41</td>
<td>0.042</td>
</tr>
<tr>
<td>BUN &gt;26 mg/dl (and &lt;50 mg/dl)</td>
<td>1.56</td>
<td>1.00-2.42</td>
<td>0.048</td>
</tr>
</tbody>
</table>

*Analysis was conducted in 445 patients allocated to the conventional group; 23 VHR patients are omitted, as well as 22 patients with missing information on one or more of the 5 risk factors.
‡Model was derived from a best subsets regression analysis (penalizing by 3.84 for each factor included) that was carried out for the 12 risk factors in Table 3. †Defined in Table 1.
Abbreviations as in Tables 1 and 3.

High Risk Features for Sudden Death in New Onset Nonischemic Cardiomyopathy

- Greater than 10 PVC/hr on Holter
- Confirmed sarcoid heart disease, giant cell myocarditis, noncompaction cardiomyopathy
- LBBB, greater QRS duration
- (increased LVEDD,)
- Myocardial fibrosis
Clinical Course of MI and Heart Failure

LifeVest System

ECG Electrodes
- Dry & non-adhesive
- 4 electrodes providing 2 channels of monitoring

Self-Gelling Defibrillation Electrodes

Response Buttons

Monitor
- 150 joules biphasic
- Stores ECG, daily use, etc.
Alarm Sequence

1. Arrhythmia detected, activating vibration alert (continues throughout sequence).
2. Siren alerts begin (continues throughout sequence).
3. Siren alerts get louder.
4. Patient audible prompt: "Electrical shock possible."
5. Gel release
7. Treatment shock.

Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients: Data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry)

Valentina Kutyifa, Arthur J. Moss, Helmut Klein, Yitschak Biton, Scott McNitt, Bonnie MacKechnie, Wojciech Zareba and Ilan Goldenberg

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WEARIT-II Registry
{MADIT-RIT -3 app shock per 100 pt years}

Table 1. Baseline Clinical Characteristics of Patients by Disease Etiology.

<table>
<thead>
<tr>
<th></th>
<th>Total patient population</th>
<th>Ischemic cardiomyopathy (1)</th>
<th>Non-ischemic cardiomyopathy (2)</th>
<th>Congenital/inherited (3)</th>
<th>p-value for comparison 1-2-3 continuous measures</th>
<th>p-value for comparison 1-2-3 categorical measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>2000</td>
<td>805</td>
<td>927</td>
<td>268</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>62 (16)</td>
<td>65 (14)</td>
<td>59 (18)</td>
<td>59 (15)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>EF, %</td>
<td>25 (10)</td>
<td>26 (15)</td>
<td>20 (15)</td>
<td>23 (15)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>1040 (52)</td>
<td>388 (48)</td>
<td>483 (52)</td>
<td>169 (63)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Renal disease</td>
<td>162 (8)</td>
<td>79 (10)</td>
<td>54 (6)</td>
<td>29 (11)</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Diabetic</td>
<td>551 (28)</td>
<td>280 (35)</td>
<td>190 (20)</td>
<td>81 (30)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>557 (28)</td>
<td>242 (30)</td>
<td>211 (23)</td>
<td>104 (39)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Prior SCA</td>
<td>370 (9)</td>
<td>85 (11)</td>
<td>67 (7)</td>
<td>18 (7)</td>
<td>0.023</td>
<td></td>
</tr>
<tr>
<td>Syncope</td>
<td>586 (17)</td>
<td>182 (23)</td>
<td>116 (13)</td>
<td>50 (19)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>ACE-I/ARBs</td>
<td>1482 (74)</td>
<td>604 (75)</td>
<td>697 (75)</td>
<td>181 (68)</td>
<td>0.031</td>
<td></td>
</tr>
<tr>
<td>Amiodarone</td>
<td>259 (13)</td>
<td>113 (14)</td>
<td>107 (12)</td>
<td>39 (15)</td>
<td>0.014</td>
<td></td>
</tr>
</tbody>
</table>

* ABBREVIATIONS: EF = ejection fraction, SCA = sudden cardiac arrest, ACE = ACE-inhibitor, ARB = Angiotensin receptor blocker


WEARIT-II: Arrhythmia Events

<table>
<thead>
<tr>
<th></th>
<th>Patients, n (%)</th>
<th>Events (Mean Events/Patient) (Range)*</th>
<th>Event Rate Per 100 Patient-Years†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any sustained VT/VF‡</td>
<td>41 (2.1)</td>
<td>120 (2.9) (1–18)</td>
<td>22</td>
</tr>
<tr>
<td>WCD therapy for VT/VF</td>
<td>22 (1.1)</td>
<td>30 (1.4) (1–8)</td>
<td>5</td>
</tr>
<tr>
<td>Sustained VT, no therapy</td>
<td>22 (1.1)</td>
<td>90 (4.1) (1–18)</td>
<td>16</td>
</tr>
<tr>
<td>Nonsustained VT</td>
<td>28 (1.4)</td>
<td>164 (5.9) (1–48)</td>
<td>30</td>
</tr>
<tr>
<td>Atrial arrhythmias/SVT</td>
<td>72 (3.6)</td>
<td>561 (7.8) (1–136)</td>
<td>101</td>
</tr>
<tr>
<td>Asystole</td>
<td>6 (0.3)</td>
<td>9 (1.5) (1–3)</td>
<td>2</td>
</tr>
<tr>
<td>Inappropriate therapy</td>
<td>10 (0.5)</td>
<td>11 (1.1) (1–2)</td>
<td>2</td>
</tr>
</tbody>
</table>

LifeVest by the Numbers

- 98% first shock success rate
- 92% shocked event survival (conscious ER arrival or stayed at home)
- Average duration of use is 2 to 3 months
- Median daily use is 94% (22.6 hours/day)

WEARIT-II Registry

End of Use EF Improvement and ICD Implantation Rates by Disease Etiology

WEARIT-II Registry

Rate of First Arrhythmic Events in WCD Patients by Disease Etiology


Wearable Cardioverter-Defibrillator

Recommendations for Wearable Cardioverter-Defibrillator

References that support the recommendations are summarized in Online Data Supplement 56.

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ila</td>
<td>B-NR</td>
<td>1. In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD (1-4).</td>
</tr>
<tr>
<td>Ilb</td>
<td>B-NR</td>
<td>2. In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, wearable cardioverter-defibrillator may be reasonable (1-5).</td>
</tr>
</tbody>
</table>

Secondary and Primary Prevention of SCD in Patients With NICM

1. Patients with NICM
   - BECA survival sustained VT (spontaneous/inducible)
     - Yes
       - ICD candidate
       - Amiodarone (Class IIb)
     - No
       - Symptom concerning for VA
         - Yes
           - Atrial fibrillation
           - Yes
             - ICD (Class II)
             - EP study (Class IIa)
           - No
             - No
             - No
             - Yes
               - ICD (Class I)
               - EP study (Class IIa)
             - No
               - If positive
                 - If LVEF ≤35% and Class I-III HF
                   - ICD (Class Ib)
                   - If LVEF ≥35% and Class I-III HF
                     - WCD (Class IIb)
                     - Yes
                       - Reassess LVEF ≥35%

2. Symptoms concerning for VA
   - Class II-III HF and LVEF ≤35%
   - No
     - NICM due to LAMA mutation and CP risk factors
     - Yes
       - ICD candidate
       - High baseline HR
       - Impaired baseline crea
       - QRS duration
       - Nonsustained VT
       - BNP
       - Post MI <40 days
       - CAD revascularization <3 months
       - Nonischemic cardiomyopathy <3 months
       - Helpful
       - PVC frequency >10 PVC/hr
       - Sarcoid, myocarditis noncompact
       - QRS duration ↑
       - LVEDD
       - Myocardial fibrosis
   - Unhelpful
     - EP Testing
     - HRV
     - BRS
     - HRT
Case Study: Non-Ischemic Cardiomyopathy (UF 1/20/16)

- 38 y/o year old with new onset HF (D/C Toprol 150mg, ACE and lifevest)
- 1. Location of Event: The patient was on an ocean cruise NYHA class 2, in Honduras 2 months out from initial hospitalization.
- 2. Patient’s Neurological Status: The patient was sleeping. He had a great day
- 3. Event Witness and Interactions: Patient’s wife sees husband begin to gasp.
- 4. Shock with subsequent shock the following day. Does not tell cruise ship

Case Study: Non-Ischemic Cardiomyopathy
VT/VF Event 3/23 7:44am

[Graph and data]
All-cause mortality by VT/VF event on the WCD

Kutyifa V. et al. One-Year Follow-Up of the Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II Registry), presented as Late-Breaking Clinical Trial at CARDIOSTIM/EUROPACE 2016, June 10, 2016.

Trends
Features Overview

- **Heart Rate**
  - Avg daily heart rate
  - Avg heart rate in 5 min increments for each day

- **Activity**
  - Total steps per day
  - Steps in 5 min increments for each day

- **Body Position**
  - Overall body position (movement, upright, reclined, lying)
  - Body angle while reclined or lying
  - Body position while reclined or lying (prone, supine, left, right)

- **Health Survey**
  - Clinicians can select up to 12 questions for patients to answer on a daily or weekly basis
Case Study: Non-Ischemic Cardiomyopathy

Clinical Course of Heart Failure

Transition to Advanced Heart Failure:
- Oral therapies failing
- A time for many major decisions
- Consider MCS and/or transplantation, if eligible
- Consider evolution of care plan to one dominated by a palliative approach, which may involve formal hospice

*Circulation 2012, 125:1928-1952*