Indication of Wearable Defibrillator (lifevest)

Ashraf El-Shalakany, MD, PhD, FACC, FHRS, FSCAI
Director Arrhythmia & Interventional Cardiology Clinic, Coral Springs FL

Case study

48 yo LAM had recent ant MI s/p LAD stenting with Ef of 30%. He was dc home with medical therapy. Two weeks later, he sustained VF arrest at home with a long delay to CPR. the stent was patent on repeat cardiac cath but pt suffered significant anoxic encephalopathy.

80 yo male with recently dx NIDCM CHF and non sus VT which was not inducible for VT. Send home with lifevest. He received a shock two weeks later for VF and he received ICD at that time.
**Patient’s Changing Condition**

**Multiple Considerations To Balance**

- The risk of sudden cardiac death post-MI is the highest in the first 30 days\(^1,2\)
  - Post-MI patients with heart failure are at 4-6 times greater risk of sudden cardiac death in the first 30 days after MI
- Patient condition can improve from the benefits of optimized medical therapy\(^3\)
  - Significant improvements in EF are observed over the initial 8-10 weeks post-MI
  - REFINE Study average relative improvement in EF was 18% at 8-10 weeks

---

**VALIANT Trial**

**High Early Risk of SCA**

Post-MI patients with heart failure are at 4-6 times greater risk of SCA in the first 30 days post-MI\(^1\)

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

---


The CADILLAC Trial
High Early Mortality Post-PCI

Wealth of Evidence Supports Post-PCI Risk

*60% of mortality due to SCD*


CathPCI-NCDR®

11%
13%
12%

Post-PCI, AMI
EF <30%, Post-PCI, AMI
EF <30%, Post-PCI, Age >65 yo

Mortality Predictors
LVEF, Age
Renal insufficiency
Multi-vessel
Killip Class I/II
Anemia
TIMI flow

LVEF, Age
Diabetes Mellitus, Female gender

LVEF, Age
Renal insufficiency
Multi-vessel

McDonough et al. "Prevention of Sudden Cardiac Death Post Percutaneous Coronary Intervention to Older Males. Results From the National Cardiovascular Data Registry National Cardiovascular Data Registry." Circulation. 2017; 137; 1751–1761.
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

Medical Therapy Optimization
Opportunity for SCD Risk Protection

- LifeVest provides SCD protection during medical therapy optimization while a patient's risk is changing
Understanding the Risk
LV Systolic Dysfunction and SCD Risk

SCD accounted for ~50% (35-64%) of total mortality

- EF was the single most important risk factor for SCD

Cleveland Clinic Post-PCI Registry
Conclusions

- Patients with LVEF ≤35% have higher early compared to late mortality after coronary revascularization
- Post-PCI patients with EF ≤35% who were prescribed the WCD had:
  - 85% lower 90-day total mortality (2%) compared to a matched cohort of patients not prescribed the WCD (13%)
- WCD use associated with significant reduction in total mortality in patients with EF ≤35% following PCI
  - 57% lower risk of death (p<0.0001) over a mean follow-up of over 3 years in the total post-PCI cohort
  - Following the end of WCD use, a persistent survival benefit was observed out to 3 years

References:
**Cleveland Clinic Post-PCI Registry**

*LifeVest use associated with improved survival*

- Post-PCI low EF (≤35%) patients prescribed LifeVest had an 85% lower 90-day mortality (2%) compared to a matched cohort of patients not prescribed LifeVest (13%)
- WCD use associated with a 57% lower risk of death (p<0.0001) over a mean follow-up of over 3 years in the total post-PCI cohort

---

**FDA Indications for Use**

- The LifeVest System is indicated for patients* who are at risk for sudden cardiac arrest and are not candidates for or who refuse an implantable defibrillator.

*Patients under 18 years of age must have a chest circumference of 26 inches (66 centimeters) or greater, and a weight of 18.75 kilograms (41.3 pounds) or greater.
**LifeVest System**

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

- **Self-Gelling Defibrillation Electrodes**

- **Response Buttons**
  - May be used by patients to delay treatments

- **Monitor**
  - 150 joules biphasic
  - Stores ECG, activity, heart rate, etc.

---

**LifeVest Patient Example**

- Patient wears the LifeVest system for continuous monitoring.
1. Arrhythmia detected, activating vibration alert (continues throughout sequence).
2. Siren alerts begin (continues throughout sequence).
3. Siren alerts get louder.
5. Gel release.
7. Treatment shock.

Example Event ECG
WEARIT-II
Study Purpose

➢ To provide **prospective data on:**
  ▪ The safety and efficacy of the LifeVest Wearable Cardioverter Defibrillator (WCD) in a real world setting
    • Characterize the patients prescribed with WCD
    • Assess the risk for sustained ventricular tachyarrhythmic events among at-risk patients during WCD use by disease etiology
    • Identify the rate of ejection fraction improvement and the need for ICD implantation at the end of WCD use
  ▪ **One-year outcomes of patients prescribed the WCD**

WEARIT-II
Registry Design & Follow-Up

LifeVest prescription in the US
  ➢ Informed consent
  ➢ Acquisition of baseline clinical data
  ➢ Wearing time: 3 months
  ➢ Clinical and arrhythmic event acquisition
  ➢ WCD return: end of use evaluation

One-Year follow-up questionnaire
WEARIT-II
Study Population

- A prospective registry of 2,000 patients prescribed the LifeVest
- Data management: University of Rochester
- Ejection Fraction (median) = 25%

WEARIT-II
Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All Patients N=2000</th>
<th>Ischemic N=805</th>
<th>Non-ischemic N=927</th>
<th>Cong/Inherited N=268</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (median)</td>
<td>62</td>
<td>65</td>
<td>59</td>
<td>59</td>
</tr>
<tr>
<td>Female</td>
<td>30%</td>
<td>23%</td>
<td>36%</td>
<td>30%*</td>
</tr>
<tr>
<td>EF (median)</td>
<td>25%</td>
<td>30%</td>
<td>25%</td>
<td>25%*</td>
</tr>
<tr>
<td>HF symptoms</td>
<td>52%</td>
<td>48%</td>
<td>52%</td>
<td>63%*</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28%</td>
<td>35%</td>
<td>21%</td>
<td>30%*</td>
</tr>
<tr>
<td>Prior ACA</td>
<td>9%</td>
<td>11%</td>
<td>7%</td>
<td>7%</td>
</tr>
</tbody>
</table>

*p-value < 0.05 ischemic, non-ischemic, congenital/inherited, †p-value < 0.05 ischemic, non-ischemic
Data are reported by patients using a baseline evaluation form.
WEARIT-II
Arrhythmic Events

- 1 in 14 patients diagnosed with an arrhythmia requiring intervention while wearing the LifeVest

<table>
<thead>
<tr>
<th></th>
<th>Patients (%)</th>
<th>Events (events/pt)</th>
<th>Event Rate Per 100 Pt-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Sustained VT/VF</td>
<td>41 (2.1%)</td>
<td>120 (2.9)</td>
<td>22</td>
</tr>
<tr>
<td>WCD Therapy for VT/VF</td>
<td>22 (1.1%)</td>
<td>30 (1.38)</td>
<td>5</td>
</tr>
<tr>
<td>Non-sustained VT</td>
<td>28 (1.4%)</td>
<td>164 (5.9)</td>
<td>30</td>
</tr>
<tr>
<td>Atrial arrhythmias/SVT</td>
<td>72 (3.6%)</td>
<td>561 (7.8)</td>
<td>101</td>
</tr>
<tr>
<td>Asystole</td>
<td>6 (0.3%)</td>
<td>9 (1.5)</td>
<td>2</td>
</tr>
</tbody>
</table>

*Treated VT/VF and sustained VT’s that spontaneously terminated during the use of the response button or during the extended detection time

WEARIT-II
Treatment Rate

- The treatment rate with the LifeVest was high at 5 events per 100 patient-years.
  - ICD treatment rate in MADIT-RIT\(^1\) was 3 events per 100 patient-years

---

WEARIT-II
Low Occurrence of Inappropriate Therapies

<table>
<thead>
<tr>
<th>Type</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=2000</td>
</tr>
<tr>
<td>Inappropriate Treatment, n (%)</td>
<td>10 (0.5%)</td>
</tr>
<tr>
<td>Death, n (%) with the WCD</td>
<td>3 (0.2%)*</td>
</tr>
</tbody>
</table>

* LifeVest detected asystole at the time of death in all 3 patients
No death related to unsuccessful termination of VT/VF

WEARIT-II
Outcomes Following WCD Use

➢ At the end of LifeVest Use
- 41% of patients demonstrated improved LVEF did not need an ICD
- 42% of patients had an LVEF that did not improve and received an ICD

End of Use Reasons

%- Patients

- Received ICD
- EF Improved

42% 41%
Total
WEARIT-II
One-Year All-Cause Mortality

- One-Year survival following use of the LifeVest across all patients was high at 96%.

WEARIT-II
All-Cause Mortality by Disease Etiology

- No meaningful difference in one-year survival between patients with ischemic and non-ischemic cardiomyopathy.
**WEARIT-II**  
All-Cause Mortality after VT/VF event

- One-year survival for patients who experienced VT/VF during use of the LifeVest was high at 92%.

---

**WEARIT-II**  
Conclusions

The LifeVest can be used as part of a strategy for managing patients at risk of sudden cardiac death.

- High one-year survival rate
- Risk assessment tool to identify patients at higher risk for SCD who need subsequent ICD implantation
- Very low rate of inappropriate therapies
- Safe, no death related to LifeVest
PREDICTS Study

2400 pts randomized post MI with EF <= 35% for lifevest vs regular care.
Primary outcome SCD occurrence in the first three months post MI.

Study results will be announced in the late breaking trials at ACC this March.

LifeVest

- Primary prevention (EF<=35% and MI, NICM or other DCM) including:
  - After recent MI (Coverage during the 40 day ICD waiting period)
  - Before and after CABG or PTCA (Coverage during the 90 day ICD waiting period)
  - Listed for cardiac transplant
  - Recently diagnosed nonischemic cardiomyopathy
    Terminal disease with life expectancy of less than 1 year

- ICD indications when patient condition delays or prohibits ICD implantation
- ICD explantation