The Problem: Sudden Cardiac Arrest

- In people diagnosed with HF, sudden cardiac arrest occurs at 6-9 times the rate of the general population and can be mitigated by ICD implantation or recovery of the EF. Which one is needed takes time to discern.
- Genetic arrhythmia syndromes often present with syncope and can be difficult to diagnose, which takes time.
- In patients suffering aborted sudden death ICD’s can be transiently contraindicated and time is needed to allow safe implantation
  - Active infection
  - Neurologic insult with unclear outcome
  - Underlying malignancy with unclear outcome
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

Post-MI

The risk of SCD post-MI is the highest in the first 30 days
- Post-MI patients with heart failure are at 4-6 times greater risk of SCD in the first 30 days after MI
- 83% of SCA occurred after hospital discharge.
- 74% of those resuscitated in the first 30 days were alive at 1 year

1 Solomon SD, et al. Sudden Death in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both. NEJM 2005; 352: 2581-2588.
The Wearable Cardiac Defibrillator

FDA Labeling:

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

How It Works:

• Default 150 bpm for VT and 200 bpm for VF
• Discrimination for Afib and SVT up to 200 bpm
• If criteria met it will alarm and give opportunity to suspend treatment or emit gel and deliver therapy.
• Can deliver up to five 150J biphasic shocks if necessary.
• Can deliver this repetitively for up to 20 treatments
• Comes with two batteries and the fully charged battery changed every day.
• Lifevestpatient.com
Diagnostics Downloaded

- Tailor alerts & notifications to be notified for events, such as:
  - Treatments
  - Patient Recorded ECG
  - Detected arrhythmia where no treatment was given

- ECG recordings automatically recorded by the LifeVest or manually captured by the patient provide additional information that can be used to decide future care paths.

WEARIT-II Registry: Prospective Registry Of Patients Using WCD

- N= 2,000 patients enrolled in the US
- Data collection: August 2011 – February 2014

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICM</td>
<td>805 pts</td>
<td>40.3%</td>
</tr>
<tr>
<td>NICM</td>
<td>927 pts</td>
<td>46.4%</td>
</tr>
<tr>
<td>Cong/Inherited</td>
<td>268 pts</td>
<td>13.4%</td>
</tr>
</tbody>
</table>

Kutyifa, et al. 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). Circulation 2015; DOI: 10.1161/CIRCULATIONAHA.115.015677 [epub ahead of print].
WEARIT-II
Arrhythmic Events

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

<table>
<thead>
<tr>
<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>4 (2.1%)</td>
<td>120 (2.9)</td>
</tr>
<tr>
<td>WCD Therapy for VT/VF</td>
<td>22 (1.1%)</td>
<td>30 (1.36)</td>
</tr>
<tr>
<td>Non-sustained VT</td>
<td>2 (1.4%)</td>
<td>164 (5.9)</td>
</tr>
<tr>
<td>Atrial arrhythmias/SVT</td>
<td>7 (3.6%)</td>
<td>561 (7.8)</td>
</tr>
<tr>
<td>Asystole</td>
<td>6 (0.3%)</td>
<td>9 (1.5)</td>
</tr>
</tbody>
</table>

7.4% or 1/14

Outcomes Following LifeVest Use
WEARIT-II Registry

• Results in the HF population
  – 41%: LVEF improved and patients did not need an ICD
  – 42%: LVEF did not improve >35% and patients received an ICD

* Treated VT/VF and sustained VT’s that spontaneously terminated during the use of the response button or during the extended detection time
In Whom Do We Need To Consider Lifevest?

**OSU Experience**

- In 2015 the LifeVest was placed on 271 patients with 10 patients successfully treated by the LifeVest (3.6% compared to 2.1% nationwide).

- Of the 271 patients approx. 150 patients got an AICD (56% compared to 45% nationwide)

- 30 patients that had arrhythmia requiring either ablation or medical therapy
When To Use Implantable Loop Recorders

Indications for use

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia
Syncope

- 7814 participants followed for an average of 17 years, 822 reported syncope
  - In one-third of participants, a cause for syncope could not be assigned
  - Risk of death was increased by 31% among all participants with syncope
  - Risk of death was doubled among participants with cardiac syncope
  - Neurologic syncope (CVA, TIA, seizure) also associated with three-fold risk of stroke

Soteriades et al. NEJM 2002; 347: 878

Syncope: Diagnostic Methods & Yield

<table>
<thead>
<tr>
<th>Test/Procedure</th>
<th>Yield based on mean time to diagnosis of 5.1 months¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>History and Physical (including carotid sinus massage)</td>
<td>49-85% ¹, ²</td>
</tr>
<tr>
<td>ECG</td>
<td>2-11% ³</td>
</tr>
<tr>
<td>Electrophysiology Study without SHD*</td>
<td>11% ³</td>
</tr>
<tr>
<td>Electrophysiology Study with SHD</td>
<td>49% ³</td>
</tr>
<tr>
<td>Tilt Table Test (without SHD)</td>
<td>11-87% ⁴, ⁵</td>
</tr>
<tr>
<td>Ambulatory ECG Monitors:</td>
<td></td>
</tr>
<tr>
<td>- Holter</td>
<td>2% ⁷</td>
</tr>
<tr>
<td>- External Loop Recorder (2-3 weeks duration)</td>
<td>20% ⁷</td>
</tr>
<tr>
<td>-Insertable Loop Recorder (up to 18 months duration)</td>
<td>65-88% ⁶, ⁷</td>
</tr>
<tr>
<td>Neurological † (Head CT Scan, EEG, Carotid Doppler)</td>
<td>0-4% ⁴, ⁵, ⁶, ⁸, ⁹, ¹⁰</td>
</tr>
</tbody>
</table>

Symptom-Rhythm Correlation

Diagnosis of AF in stroke patient changes treatment protocol (currently aspirin)

1/3 of Ischemic Strokes are Cryptogenic

61% of patients who had both AF and a stroke did not know they had AF prior to their stroke
CRYPTOGENIC STROKE

Detection of AF allows for treatment with OAC therapy

More patients with AF detected at 12 months with ILR

Median number of days to AF detection over 12 months

Percent of patients prescribed OAC once AF was detected

Crystal-AF Study, NEJM

ILR AF monitoring
Duration-based performance metrics

Comparison of AF burden detected by ICM and Holter
Detailed AF Data

- Daily AF Burden
- Ventricular Rate During AF
- Day/Night HR
- Patient Activity
- Heart Rate Variability

AF MANAGEMENT
Optimize decisions pre- and post-ablation

PRE
- Document Baseline AF burden.
  - Provide objective data for follow-up comparisons (burden, symptoms).
- Case Planning
  - PVI when Paroxysmal AF is documented?
  - PVI + additional techniques if substrate ablation is needed (atrial flutter, rotor)
- Work Flow Planning
  - Triage patients on your waiting list (poor rate control, frequent Sx)

POST
- Monitor patients for up to 3 years.
- Optimize medical therapy.
  - Discontinue OAC or AARx?
- Re-ablate to disrupt progression over time.
Summary: Current Trends in Arrhythmia Monitoring

- Greater Use of Implantable Loop Recorders:
  - Diagnosis of Syncope
  - Management of Atrial Fibrillation
  - Evaluation of Cryptogenic Stroke

Insurance Coverage

- 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 (Coverage during the 3 to 9 month ICD waiting period).
  - NYHA class IV heart failure.
  - Terminal disease with life expectancy of less than 1 year.

- ICD indications when patient condition delays or prohibits ICD implantation
- ICD explantation
Syncope Diagnosis: Role of an ILR

AHA/ACC Scientific Statement on the Evaluation of Syncope:

“This approach (ILRs) is more likely to identify the mechanism of syncope than is a conventional approach that uses Holter or event monitors and EP testing and is cost-effective.”

ISSUE Study Implications

- HUT outcome was not predictive of vasodepressor vs. cardioinhibitory response
  - Bradycardia is common in spontaneous VVS - independent of HUT outcome
- Bradycardia is more prevalent in spontaneous events vs. HUT induced VVS
- Clinical Implication: Consider a strategy of ILR guided evaluation in positive TTT patients unresponsive to medication
ISSUE 2

Methods:
• 392 patients with suspected neurally-mediated syncope were enrolled
• 103 pts. had an ECG documented syncope, leading to therapy and a follow-up observational period

Results:
• A 92% relative reduction in syncope burden and 80% relative reduction in one-year recurrence rate with pacing and antiarrhythmic therapies guided by ILR findings

Methods:
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• 392 patients with suspected neurally-mediated syncope were enrolled
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Reveal LINQ SYSTEM ADVANTAGES

ECG data storage: 59 minutes total
Patient-activated: up to 30 minutes

Reveal LINQ™ Insertable Cardiac Monitoring System
Reveal LINQ™ Insertable Cardiac Monitor®

**Reveal LINQ SYSTEM ADVANTAGES**

**ECG data storage: 59 minutes total**
Automatically detected: 27 minutes

- Pause, Brady, Tachy
- AT/AF

2 minutes of longest AF episode stored since last interrogation in addition to the 27 minutes of automatically detected episodes.

*Reveal LINQ™ Insertable Cardiac Monitoring System*

---

**Reveal LINQ SYSTEM ADVANTAGES**

- **PROVEN ARRYTHMIA DETECTION.**
- **INFORMED CLINICAL DECISIONS.**

**99.4%**
Reveal LINQ is proven to find AF

Highest published AF detection accuracy on the market, at 99.4%, streamlines data review

**63%**
63% fewer false positives than shown in other ICM published data

**50+**
As the most clinically-validated ICM, with 50+ detection performance papers, Reveal LINQ is the reliable choice for arrhythmia management

*Reveal LINQ™ Insertable Cardiac Monitoring System*
**PROVEN ACCURACY**

- **AF FALSE POSITIVE COMPARISON**
  - Confirm-AF™: 40.9%
  - BioMonitor 2-AF™: 26.3%
  - Reveal LINQ™: 9.6%

*% of False Positives = (1 - Episode PPV). Episode PPV may vary (gross, patient average).

**CLINICAL RIGOR**

- **EVIDENCE SUPERIORITY.**
  - With an evidence portfolio of 500+ published clinical articles and abstracts\(^1\)

- **REAL-WORLD IMPACT.**
  - Across Cryptogenic Stroke, Syncope, and Atrial Fibrillation patient populations\(^8-10\)

- **Published in multiple premier journals,** including *Heart Rhythm, The New England Journal of Medicine* and *JACC* \(^8,9,11\)

Reveal LINQ™ Insertable Cardiac Monitoring System
**Clinical rigor**

**CRYPTOGENIC STROKE**

Real-world practice with Reveal LINQ ICM
Superiority of Reveal LINQ system to detect AF in cryptogenic Stroke patients

- 72% of AF patients would be missed if monitoring ends at 30 days

Everyday use of Reveal LINQ confirms findings in landmark CRYSTAL AF study (NEJM).

**CLINICAL RIGOR**

**SYNCOPE**

40% of the population will experience syncope
Cardiac syncope doubles the risk of death

- **MORTALITY**
  - Cardiac condition doubles the risk of death and increases the 6-month mortality rate by 10%

- **MAGNITUDE**
  - 3-5% of all ER visits
  - 1-3% of all hospitalizations

- **UNDIAGNOSED**
  - 50% of all patients leave the hospital without a diagnosis

- **FRUSTRATION**
  - 13 different tests during diagnosis period
  - Syncope patient visits 3 specialists on average
CLINICAL RIGOR

SYNCOPE

Limited yield of many diagnostic tests
Diagnostic yield of non implantable diagnostic tests is less than 50%

![Graph showing diagnostic yields for various tests]

CLINICAL RIGOR

SYNCOPE GUIDELINES, *European Heart Journal* 2009
Recommendations for the use of ICM monitoring

Guidelines for the diagnosis and management of syncope (version 2009)
The Task Force for the Diagnosis and Management of Syncope of the European Society of Cardiology (ESC)
Developed in collaboration with European Heart Rhythm Association (EHRA), Heart Failure Association (HFA), and Heart Rhythm Society (HRS)

Monitoring Choice by Frequency of Symptoms:

- **Daily**
  - 24 h Holter, in-hospital telemetric monitoring
  - 48-72 h Holter, in-hospital telemetric monitoring
  - 7 days Holter or external loop recorder
  - 14-30 days external loop recorder
  - Implantable loop recorder

- **Every 2-3 days**
- **Every week**
- **Every month**
- **Less than once per month**

Monitoring Choice by Patient Risk:

...
**SUSPECTED AF MONITORING**

Continuous monitoring can reveal AF

- Symptoms are not a good indicator for presence of AF\(^{30-34}\).
- Continuous monitoring with ICMs can identify AF in patients at high risk\(^{35,36}\).

<table>
<thead>
<tr>
<th>Study</th>
<th>Method of Monitoring</th>
<th>% Asymptomatic AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page et al. 1994(^{30})</td>
<td>External monitors: 1 day/week (5×)</td>
<td>92.3% of episodes</td>
</tr>
<tr>
<td>Strickberger et al. 2005(^{31})</td>
<td>Implantable Pacemakers</td>
<td>94% of episodes</td>
</tr>
<tr>
<td>Quirino et al. 2009(^{32})</td>
<td>Implantable Pacemakers</td>
<td>81% of episodes</td>
</tr>
<tr>
<td>Orlov et al. 2007(^{33})</td>
<td>Implantable Pacemakers</td>
<td>94.7% of episodes</td>
</tr>
<tr>
<td>Verma et al. 2013(^{34})</td>
<td>Implantable Loop Recorders</td>
<td>79% of episodes</td>
</tr>
</tbody>
</table>

22% of a patient population at high risk was found to have > 5min of AF within 12 months\(^{36}\).

**Advanced monitoring**

- Streamlined insertion workflow
- Actionable reports
  - Supported by an enhanced Medtronic CareLink Network
  - Industry’s highest diagnostic yields, with actionable reports\(^{30,34}\).

**Simplified patient management**

- Resources to support clinic efficiency and data review
- New Medtronic Academy Learning Plan
- New Patient Education Resources
Advanced monitoring

Simplify device management with the NEW Reveal LINQ Mobile Manager, an innovative app-based programming system.

**NEW REVEAL LINQ MOBILE MANAGER**

**IT'S EASY TO GET STARTED**

**SUPPORTED TABLET**
Visit LINQMobileManager.com for the most up-to-date list of supported tablets.

**MEDTRONIC PATIENT CONNECTOR**

**WI-FI OR CELLULAR CONNECTION**

**DOWNLOAD APP ON SUPPORTED TABLET**

The Reveal LINQ Mobile Manager can only be used with the Reveal LINQ ICM and the Medtronic patient connector, available from Medtronic.

**Reveal LINQ™ Insertable Cardiac Monitoring System**

Advanced monitoring

**Easy-to-use, clinically actionable reports**

The information you need when you need it, supported by an enhanced CareLink Network.

**Comprehensive**

- Get the full picture with diagnostic trends on simplified reports.

**Customizable**

- Optional CareAlert™ notifications with auto-generated reports.

95% of physicians found the Reveal LINQ reports easy to use and clinically actionable.

96.7% of patients say it is very easy to use the MyCareLink Patient Monitor to transmit data to the CareLink Network.

**Reveal LINQ™ Insertable Cardiac Monitoring System**
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 medical therapy optimization]

LifeVest by the Numbers

- 98% first shock success rate
- 92% shocked event survival (conscious ER arrival or stayed at home)
- Most (73%) treated within 60 seconds (remaining delayed from response button use or VT programming)
LifeVest Offers Protection From SCD
Time To Recovery and Assess Long-Term Risk

‒ Allows physician to assess long-term arrhythmic risk at the end of the Medicare ICD waiting period (40 days post-MI and 90 days post-PTCA/post-CABG).
‒ Patients return to the prescribing or referring physician at the term of their LifeVest prescription for follow-up to determine if:
  1) LifeVest usage should be extended,
  2) Long-term arrhythmic risk requires ICD implantation, or
  3) Cardiac recovery has mitigated arrhythmic risk, and ongoing follow-up with optimized medical therapy is appropriate.

WCD allows time to develop long-term risk management strategies

Figure 1. Risk stratification for ICD therapy: The role of the WCD (Klein et al. Eur Heart J 2013;34:2230-2242)
Conclusions

• Post-MI patients with heart failure are at 4-6 times greater risk of SCD in the first 30 days after MI
• OMT optimization takes time and is different for every patient
• The AHA (endorsed by the HRS) recommends the WCD as a Class IIb indication for a broad range of patients
• SCD screening tools can help to identify those patients at the highest risk
• The LifeVest is an effective tool to protect HF patients with low EF during medication titration while long-term risk is being determined
2016 AHA Science Advisory
Wearable Cardioverter Defibrillator Therapy for the Prevention of Sudden Cardiac Death

- WCDs can serve as temporary means of preventing arrhythmic death without the need for bystander response to cardiac arrest.
- WCD use may be appropriate in clinical circumstances associated with transient increased arrhythmic risk.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Class</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection.</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation.</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction; for example, in ischemic heart disease with recent revascularization, newly diagnosed non-ischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI.</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>WCDs should not be used when non-arrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive &gt;6 mo.</td>
<td>III: No benefit</td>
<td>C</td>
</tr>
</tbody>
</table>
LifeVest Patient Example
Remote Patient Data Management with the Wearable Cardioverter Defibrillator

Agenda

- WEARIT II Registry
- Overview of the LifeVest Network and LifeVest Trends
- Clinical Case Studies – Remote Patient Management in Action
Remote Patient Data Management with the LifeVest Network

• Information about Clinical Events in the earliest period after a cardiac event
• Automatic Event Recordings
  – Shock Treatment
    • VT/VF detection
  – Arrhythmia Detected but Not Treated
    • Sustained VT/VF that terminated prior to treatment
    • Non-sustained VT/VF
  – Asystole
    • Asystole
    • Bradycardia that meets asystole criteria

LifeVest Network: Customized Reports
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

Trends
Features – Health Survey

Clinicians can select up to 12 preset Health Survey questions for patients to answer on a daily or weekly basis
Trends Features – Health Survey

Survey Answers by Individual Day

Users can review patient survey responses by day

Trend of Survey Answers by Question

Or view trending data of patient survey responses for each question over time

Trends Features – Health Survey

Patients can respond to clinician selected Health Survey questions directly on the LifeVest monitor. Patient survey responses are transmitted with patient downloads.

How many pillows did you sleep on last night?

Use the arrow buttons to select your answer.

2 pillows

Confirm your answer

OK
Trends Features – Trends Reports

Users can create custom reports to include any of the Trends features.

Conclusions

- In the WEARIT II Registry, 1 in 14 patients were diagnosed with an arrhythmia requiring intervention while wearing the LifeVest.
- In addition to protection from SCD, the LifeVest captures valuable data about the patient’s broader cardiac function and health status that offers meaningful clinical value during the early period following a cardiac event when a patient’s condition is changing.
Case Studies
Remote Patient Data Management

Case 1: Syncope
Patient Experiences Unexplained Syncope

- A conscious 64-year-old female presented to the ER after suffering a syncope event that resulted in minor injuries. Lab work and CT scan of head were normal.
- History:
  - 2.5 months post large anterior STEMI.
  - LAD had 100% de novo stenosis requiring DES placement. Following intervention, there was 0% stenosis with TIMI grade 3 flow.
  - Discharge LVEF = 30%.
- Pharmacy:
  - Patient is euvoletic; continue carvedilol, spironolactone, lisinopril, add sublingual nitroglycerin prn
- Recent hospitalization noted continued low LVEF = 30% with dilated cardiomyopathy.
  - Suspected Ventricular Tachycardia (VT) cause for syncope
- Electrophysiology (EP) consult resulted in patient discharge with the LifeVest wearable defibrillator for protection from SCD

Patient History and Plan
LifeVest Network Configuration

- LifeVest Network Configuration
  - Red (high-level) alert for treatments
  - Orange (mid-level) alert for asystole event
  - Orange (mid-level) alert for patient initiated ECG recording.

- The LifeVest detection algorithm is programmed to declare asystole when the heart rate falls below 10 beats per minute (bpm) for 16 seconds and automatically records the event, with 120 seconds of onset.

- Patients can perform manual recordings by pressing the response buttons for three seconds, which records the previous 30 seconds plus the next 15 seconds.
Results

- ECG review by the EP revealed bradycardia at rate below 20 bpm with increasing R-R intervals. **In-office follow-up by the EP resulted in permanent pacemaker implant.**

- One (1) day post-discharge, the LifeVest captured 2 patient-initiated recordings and 5 asystole events with no tachyarrhythmia detections or shocks.

- The asystole events occurred while the patient was sleeping.

Identification of Bradycardia through Remote Patient Monitoring

- The clinic regularly reviews notifications and patient recordings on the LifeVest Network.

- Upon review of the ECG recordings in the LifeVest Network, it was determined that the patient experienced several bradycardia events, identified by the LifeVest as asystole events, that required additional in-office work up.

- In this case, information captured by the LifeVest directly impacted the patient’s care path.
Case 2: Atrial Fibrillation

Patient Experiences Atrial Fibrillation

Patient Baseline

Patient ECG downloaded and viewed on LifeVest Network
History and Plan

- 68 year-old man with no known past medical history was admitted to the ER due to a one week history of shortness of breath and chest discomfort
- Chest x-ray showed cardiomegaly; labs indicated mildly elevated BNP
- Enzymes were negative for acute MI
- 2D echogram:
  - LVEF = 20%
  - Global hypokinesis of left ventricle
  - Mild mitral valve regurgitation
- Pharmacy:
  - Patient was Dx with Lasix 20 mg QD, carvedilol 1.5625 mg BID, low salt diet, and a plan to follow up with a cardiologist in 3-5 days.
- Upon follow-up, patient complained of continued non-exertional chest “tightening” lasting 30-45 minutes.
- Cardiologist prescribed the LifeVest wearable defibrillator for protection from SCD.

LifeVest Network Configuration

- LifeVest Network Configuration
  - Orange (mid-level) alert for a sole event
  - Orange (mid-level) alert for at least 2 patient-initiated recordings per day, detected but not treated events
- The LifeVest allows patients to manually record ECG strips by pressing the response buttons for three seconds.
correct carvedilol spelling
Bernard Komoroski, 11/5/2015

font color
Bernard Komoroski, 11/5/2015
Results

- Seven (7) days after being fit with the LifeVest, the patient manually captured several ECG recordings by pressing the response buttons on the LifeVest.
- Review of the recordings showed irregular R-to-R intervals and were determined to be atrial fibrillation.
- The patient was contacted over the phone and a medication regimen was initiated. The patient was referred for a consult with an Electrophysiologist.

Identification of Afib through Remote Patient Monitoring

- Newly-diagnosed heart failure patient with an LVEF = 20% was prescribed the LifeVest for primary prevention of SCD.
- NP regularly reviews the LifeVest Network Dashboard, and noted that the LifeVest captured two automatic recordings and a patient-initiated recording.
- When abnormalities are noted in the patient’s alert profile, information is shared with a physician for additional review. In this case, the patient manually recorded an ECG that, upon review by the physician, showed irregular R-R intervals indicating atrial fibrillation.
- In addition to manual ECG recording, the LifeVest will also automatically detect supraventricular tachycardias when there is conduction to the ventricles at a rate above the programmed detection rate.
Current Trends: Development of Subcutaneous Sensors for Disease Management

<table>
<thead>
<tr>
<th>Signal</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>• Medtronic</td>
</tr>
<tr>
<td></td>
<td>• St. Jude</td>
</tr>
<tr>
<td></td>
<td>• Transoma Medical</td>
</tr>
<tr>
<td></td>
<td>• AJ Medical</td>
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<tr>
<td>Arterial Pressure</td>
<td>• Transoma Medical</td>
</tr>
<tr>
<td>Gross Motor Activity</td>
<td>• Medtronic</td>
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<tr>
<td></td>
<td>• St. Jude</td>
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<tr>
<td></td>
<td>• Transoma Medical</td>
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<tr>
<td>Heart Sounds</td>
<td>• Boston Scientific</td>
</tr>
<tr>
<td>Respiration</td>
<td>• Apnexit</td>
</tr>
<tr>
<td></td>
<td>• Transoma Medical</td>
</tr>
</tbody>
</table>

Case 3: Bradycardia
Patient Experiences Bradycardia

History and Plan

- A 61-year-old woman presented to the ER with complaints of acute chest pain x2 hours radiating to the left side of chest that improved with nitroglycerin.
- Significant history of rheumatoid arthritis, hypertension, hyperlipidemia, and osteoporosis.
- No known surgical history.
- Cardiac enzymes and ECG were both negative for STEMI.
- ECG indicated RBBB.
- Cardiac echo:
  - Mild left ventricular hypertrophy
  - Mild mitral annular calcification
  - LVEF = 30%
- SPECT imaging showed lack of activity throughout the inferior wall extending into the inferolateral region. Cardiomegaly with large areas of infarction also noted.
- The patient was discharged with the LifeVest wearable defibrillator for protection from SCD.
LifeVest Network Configuration

- LifeVest Network Configuration
  - Orange (mid-level) alert for asystole events, at least 2 patient-initiated recordings per day, detected but not treated events
- The LifeVest detection algorithm is programmed to declare asystole when the heart rate falls below 10 beats per minute (bpm) for 16 seconds and automatically records the event, including 120 seconds of onset.

Results

- On day 29 post discharge, the LifeVest detected an asystole event and captured an ECG recording. Upon ECG review on the LifeVest Network, the event was determined to be bradycardia.
- The patient was contacted at home and instructed to seek immediate medical care in the ER.
- Cardiac catheterization and angiography showed apical and inferior hypokinesia of left ventricle with triple vessel disease involving left anterior descending (LAD) with its first diagonal branch (D1), left circumflex (LCx) with its first diagonal branch, and right coronary artery (RCA).
- Post-CABG, the patient’s LVEF remained ≤ 35% and the patient was discharged home with instructions to continue LifeVest use.
Identification of Bradycardia through Remote Patient Monitoring

- The patient was diagnosed with ischemic cardiomyopathy following a NSTEMI with a LVEF = 30% and prescribed the LifeVest for primary prevention of SCD.
- The nurse in this practice reviews the LifeVest Network dashboard weekly, monitoring the practice’s active LifeVest patients.
- The discovery of several bradycardia events in this case revealed a significant underlying ischemic disease requiring CABG, potentially avoiding significant future myocardial injury.
Case 4: Sustained VT
History and Plan

- A 70-year-old man presented to the hospital with cough, congestion, and shortness of breath.
- Patient was diagnosed with pneumonia and admitted to the ER.
- Significant history of chronic renal insufficiency, COPD, incomplete LBBB, systolic congestive heart failure, coronary artery disease status post 4-vessel CABG last year, type 2 diabetes, hypertension, and peripheral vascular disease.
- Cardiac echo:
  - Left atrium markedly dilated
  - Dilated inferior vena cava with poor inspiratory collapse consistent with elevated right atrial pressure
  - Mild concentric LV hypertrophy with impaired LVEF = 25%
- Pharmacy:
  - Lasix, potassium repletion, continue ACE, BB.
- The patient was discharged with the LifeVest wearable defibrillator for protection from SCD.

LifeVest Network Configuration

- LifeVest Network Configuration
  - Orange (mid-level) alert for events labeled as detected but not treated.
- The LifeVest will automatically record a patient’s ECG following the initiation of the treatment sequence. If the VT/VF terminates prior to a shock treatment, the ECG recording is downloaded to the LifeVest Network.
Slide 85

BK10  fixed misspelled hypertrophy
Bernard Komoroski, 11/5/2015

Slide 86

BK11  font color
Bernard Komoroski, 11/5/2015
Results

- Twelve (12) days after discharge, the patient experienced an episode of ventricular tachycardia (VT) at a rate of 240 bpm.
- The LifeVest appropriately detected the VT, and the treatment sequence was initiated. Treatment was delayed through proper patient use of the response buttons.
- The VT spontaneously terminated after 35 seconds.
- The patient was referred to an Electrophysiologist (EP) and a permanent implantable cardioverter defibrillator (ICD) was later implanted.

Identification of Sustained VT through Remote Monitoring

- The patient was diagnosed with a DCM and a LVEF = 25% and prescribed the LifeVest for primary prevention of SCD.
- The NP regularly reviews the LifeVest Network dashboard to monitor for new alerts for the practice’s current active patients.
- Upon dashboard review, a “detected but not treated” event was noted for the patient. Review of the ECG recordings revealed that the LifeVest had recorded a sustained VT event.
- Subsequent consult with an EP resulted in the implantation of an ICD.
Case 5: Sinus Tachycardia

History and Plan

- A 63-year-old male presented to the emergency department with severe chest pain and pressure.
- Significant history of hypertension, hyperlipidemia, chronic kidney disease and tobacco use.
- Coronary Angiography:
  - 80% ostial stenosis of the large first diagonal of the left anterior descending (LAD) artery.
  - 80% bifurcation lesion affecting both the LAD and the ostium of the diagonal branch.
  - Two (2) drug-eluting stents were placed.
- Pharmacy:
  - Patient was prescribed aspirin 81 mg QD, ticagrelor 90 mg BID, lisinopril 10 mg QD and metoprolol succinate 25 mg QD.
- The patient was discharged with the LifeVest wearable defibrillator for protection from SCD.
LifeVest Network Configuration

- LifeVest Network Configuration
  - Red (high-level) alert for notifications when the patient manually captured ECG recordings
  - Orange (mid-level) alert for events labeled as ‘detected but not treated’
- The LifeVest detection algorithm is programmed to initiate a treatment sequence and automatically record an ECG if it meets the programmed rate threshold (default setting of \( \geq 150 \) beats per minute (bpm)) and morphology criteria. Once a treatment sequence is initiated, treatments can be prevented by appropriate patient use of the response buttons. Symptomatic events can also be captured by the patient via a manual recording. Manual recordings are initiated by pressing and holding the response buttons for three seconds.
Results

- Two (2) weeks post-discharge, the LifeVest captured several ‘detected but not treated’ events. The ECG recordings of these events were transmitted to the LifeVest Network.
- Physician review of the ECG recordings revealed sinus tachycardia at rates between 150 and 170 bpm. The patient was then contacted to assess any symptoms, and reported that he “felt his heart racing.” To control the patient’s heart rate, the dose of metoprolol succinate was increased to 50 mg QD with plans for further up-titration as tolerated.
- In order to assess the intended effect, the physician instructed the patient to complete two manual ECG recordings on the LifeVest device by pressing the response buttons.
- Review of the manual ECG recordings revealed the patient’s heart rate returned to a normal sinus rhythm with a rate of 83 bpm.

Identification of Sinus Tachycardia through Remote Monitoring

- The clinic regularly reviews notifications and patient recordings on the LifeVest Network. Upon review of the ECG recordings, it was determined that the patient experienced several sinus tachycardia events that were detected by the LifeVest but did not result in a treatment shock.
- The cardiologist was able to remotely review the ECG recordings, make the necessary medication adjustments and confirm the intended results.
Conclusions

• LifeVest Network provides actionable information to clinicians to assist in making patient care decisions.
• The LifeVest protects patients at risk of Sudden Cardiac Death
• Remote Patient Management with the LifeVest Network goes beyond shock therapy for VT/VF, providing a more complete picture of a patient’s cardiac health.

Syncope: High Incidence and Likely to Increase

• 7814 participants followed for an average of 17 years, 822 reported syncope
• Estimated 10-year cumulative incidence of syncope was 6%
• The incidence rates increased with age, with a sharp rise at 70 years
• 22% of the study participants with syncope had a recurrence

Soteriades et al. NEJM 2002; 347: 878
Syncope

- ~40% of the population will have at least one syncopal event in their lifetime

- 10% of falls by elderly are believed due to syncope

- Major morbidity reported in 6% (e.g., fractures, motor vehicle accident)

- Minor injury reported in 29% (e.g., lacerations, bruises)

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Annual U.S. Emergency Dept. Visits

<table>
<thead>
<tr>
<th>Year</th>
<th>Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>600,000</td>
</tr>
<tr>
<td>2002</td>
<td>800,000</td>
</tr>
<tr>
<td>2003</td>
<td>1,000,000</td>
</tr>
<tr>
<td>2004</td>
<td>1,200,000</td>
</tr>
<tr>
<td>2005</td>
<td>1,200,000</td>
</tr>
<tr>
<td>2006</td>
<td>1,200,000</td>
</tr>
</tbody>
</table>

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Syncope QOL Impact

- Anxiety/Depression: 73% 
- Alter Daily Activities: 71% 
- Restricted Driving: 60% 
- Change Employment: 37%

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Types of External Arrhythmia Monitors

• **Electrocardiogram**: snapshot in time

• **Holter monitor**: 24 to 48 hours of continuous outpatient electrocardiographic (ECG) recording
  - Shortcoming: repeated monitoring if an arrhythmia not occur 24-48 hours
  - Processing can delay action on malignant arrhythmias

• **Event recorder**: stores 1 to 2 minutes of ECG as soon as the patient activates
  - Enables much longer period of monitoring
  - Misses asymptomatic arrhythmias and some symptomatic arrhythmias when pt fails to activate

• **Automatic-trigger loop monitors**: Records in continuous loop and automatically captures certain arrhythmias or can be manually activated during symptoms
  - Devices can capture detect several types of arrhythmias.
  - Typically worn for up to 30 days.
  - Download data to base station or phone

• **Real-time cardiac surveillance**: continuous outpatient ECG monitoring for periods ranging up to several weeks, if necessary.
  - Cardiac activity detected by 3 electrodes attached to a ~2 ounce pager-sized sensor/telephone transmitter
  - Continuously analyzes the heart rhythm data. If an arrhythmia detected, the monitor automatically transmits data to a central monitoring station for analysis/action
  - Any symptoms recorded by the patient are also transmitted.

---

Cumulative number of patients who sent an electrocardiogram from an event recorder by the number of days needed to record an electrocardiogram during palpitations

Prospective, randomized crossover comparison 48 hour holter to 30 day EVM

Twice as many symptomatic recordings from EVM as holter

19% of events recorded on EVM required intervention, none from the holter

MCOT Study

- Multicenter randomized controlled trial
- 266 pts with palpitations, presyncope, syncope and nondiagnostic Holter
- Randomized to 30 days of MCOT (Cardionet) or external loop (Loop Group).
- Results
  - Clinically significant arrhythmias
    - 55 (41%) pts in the MCOT Group
    - 19 (14%) patients in the Loop Group (p< 0.001).


RAST study
Randomized Assessment of Syncope Trial

- Results:
  - Primary strategy: diagnostic yield is 47% vs. 20%
  - Diagnosis overall: 19 vs. 55% (p=0.0014)
Ideal System for Long Term Cardiac Monitoring

- Subcutaneous placement, simple and fast to implant, excellent safety profile.
- Reliably provides information that can aid selection and titration of therapies
  - High sensitivity detector in ILR
  - Signal processing software to remove false positives and extract information at monitoring center
  - Human over-read at service center to assure information delivered to physician is clinically relevant
- Simple for the patient – requires little or no compliance
  - Long-range telemetry for automated data transfer
- Simple for the physician – maximizes practice efficiency, follow up requires minimal work load
  - Data download tailored to institution/practice

Sub-Q ILR’s: Evolution

- Reveal 1998
- Reveal Plus 2000
- Transoma Sleuth
- Reveal DX 2007
- Reveal XT, Sleuth AT, Confirm 2009

Reveal is developed to help diagnose unexplained syncope
Automatic detection added
Transoma: the first wireless and automated monitoring system
Longevity and ECG memory increased (to 3 yrs., 49.5 minutes), with episode logs, ICD sensing technology, MRI labeling, and remote monitoring added
AF detection and long-term trended diagnostics (the Cardiac Compass and AF Summary Reports) added
### Competing ILR’s

<table>
<thead>
<tr>
<th>Asystole</th>
<th>Bradycardia Detection Settings</th>
<th>Tachycardia Detection Settings</th>
<th>AF Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any single pause &gt;3.0 sec.</td>
<td>30, 40, 50 bpm</td>
<td>120 to 220 bpm, Off 4/4, 6/8, 8/8, 16/16, 32/32 beats</td>
<td>20 sec. ECG strips sent to Monitoring Center every 7.5 min. Analysis of ECG data and arrhythmia classification, by Certified Cardiac Techs at Monitoring Center</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>On board detection algorithm based on R to R variability</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Memory for ECG Data</th>
<th>ILR Battery Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>673 min. between automatic, wireless transmission to the Monitoring Center ILR: 43 min. PDM: 630 min.</td>
<td>18 to 30 months</td>
</tr>
<tr>
<td>49.5 minutes total between scheduled office visits Memory available on ILR only Download to Carelink</td>
<td>36 months</td>
</tr>
<tr>
<td>48 minutes total between scheduled office visits Memory available on ILR only Download to TTM</td>
<td>36 months</td>
</tr>
</tbody>
</table>

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### RUP Study: Importance of Wireless Download

Automatic detection mode in the REVEAL was activated, but no significant arrhythmias were recorded: because ILR memory “was always saturated by inappropriate activations.”

Importance of an Antenna

Loss of tissue contact from shape/form factor

Figure 3. Transient loss of signal felt to be due to loss of tissue-electrode contact within the device pocket. Loss of signal (***) with capillary retraction and repositioning of signal is seen during a morphological recording, which is detected automatically (A) as a pause.

Krahn et al. PACE 2006; 27: 657

Medicomp Arrhythmia Access

Patient Activated Report Page
The Value of Advanced Diagnostics

- Daily AF burden
- V-rate during AF
- Avg. day/night HR
- Patient activity
- Heart rate variability (HRV)
Value of Advanced Diagnostics

What is the AF burden?

How long do the episodes last?

When did the episodes start?

Note: All clinic, physician, and patient names and data in this document are fictitious.