LifeVest Trends Validation Protocol
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Approvals

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DOCUMENT REVISION HISTORY PAGE

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Title: LifeVest Trends Validation Protocol

Revision History Of Document

Rev	CO Number	Description of Change	Author	Effective Date
FI	-------	First Release	NRB	9/23/13
A	3493	The walk test at the office/clinic was changed so that there is only one clinic walk test per patient. Odd numbered subjects will do the human-instructed walk test. Even numbered subjects will perform the machine instructed walk test. Line 5.3.3 was redundant and was removed to avoid confusion at the site. Objective 3.1 was further clarified to avoid confusion.	NRB	12/19/13
B	0101	The walk test at home was modified to switch the paths taken by Even vs. Odd patients. Line 4.1.2 was rearranged to avoid confusion. Obtaining Informed Consent was moved from 5.1 (Pre-Study Assessment) to 5.2 (Initial Visit) for accuracy. Line 5.3.1 was removed as patient diaries are no longer collected by the site. Added details to the patient diary instructions in 5.2.4. Maximum number of sites was increased from 10 to 20. The definition of an adverse event was further clarified in Section 11.	NRB	7/20/15

PROTOCOL SUMMARY

Objectives

To conduct a multi-center validation study of heart failure patients wearing the LifeVest wearable cardioverter defibrillator (WCD) modified to collect data (Trends) in order to evaluate data accuracy and patient interactions with the device.

Study Population

Participants will be heart failure patients with an ejection fraction ≤ 35% who have been prescribed a LifeVest WCD.

Intervention

A LifeVest WCD modified to collect data (Trends). These devices will be commercially available and CE marked.

Study Design

This will be a multi-center prospective observational study.

Study Size

The study will enroll a minimum of 150 and a maximum of 250 subjects. A minimum of five and a maximum of twenty centers will be used for enrollment.

1. INTRODUCTION

ZOLL has released (CE marked) its latest software version of the LifeVest 4000, modified for the collection of data relevant to the heart failure patient population. Like all wearable defibrillators, this version also monitors for VT/VF, notifies the patient if VT/VF occurs and instructs them to press response buttons. If the patient is unresponsive to the alarms, the LifeVest delivers defibrillation therapy. Versions of the LifeVest have been used commercially in the United States and Europe since 2002, with over 100,000 patients having worn the device. There are many published articles regarding clinical performance of the LifeVest (Appendix A). The LifeVest general use and performance data are published regularly on the commercial website www.zoll.com.

This software version has modifications that include but are not limited to:

- Body position data collection
- Activity data collection
- The ability to perform a health survey
- The ability to guide patients through a walk test

2. DEVICE DESCRIPTION

A complete description of the operation and management of the LifeVest is given in the Operator Manual (20B0048).

2.1 Description of Heart Trends modification for heart failure monitoring

2.1.1 **Body Position**: This metric uses the accelerometer in the LifeVest belt node to measure body position trends. It is reported as a percent time of day at lying flat, reclined (and at what degree), or standing. This may be used to indicate body position during sleep. Fluid buildup in the lungs often causes patients to add pillows or sleep in a reclining chair to alleviate their symptoms. Changing body angle during sleep is an established indicator of worsening heart failure.

2.1.2 **Body Orientation:** This metric uses the accelerometer in the LifeVest belt node to measure sleeping position. It is reported as a percent time of day at lying supine, prone, left or right.

2.1.3 **Activity Trends**: The patient activity metric uses the accelerometer in the belt node to measure patient movement. It is reported as hours active per day and total number of steps taken.

Decreases in activity may represent an increase in heart failure symptoms, while an increase in activity may represent positive effects of the patient's medical treatment.

2.1.4 **Heart Rate Trends**: The heart rate (HR) metric uses the existing HR software to provide a moving average of HR. It is reported as minimum, maximum, and 5 minute averages. This information may be useful in heart failure diagnostics, as high resting HR has been associated with increased mortality, and effective therapy generally lowers HR.

2.1.5 **Walk Test:** A six-minute walk test (6MWT) is a valuable tool used by physicians to measure subject's functional capacity. It is intended to be performed in an

outpatient setting by having subjects walk a premeasured path as long and fast as they can within a 6-minute timeframe. The distance walked in relationship to the length of time is used to make a determination regarding improvement or decline in functional capacity. A similar test has been added to the LifeVest, but is patient-initiated, and is conducted in the patient's home. The program reports HR and step count during the test, as well as the recovery period. The LifeVest can also calculate the distance covered by the patient if an average stride length is entered.

2.1.6 **Health Survey:** The health survey is a short questionnaire that is administered via the LifeVest Monitor. It can be conducted daily or weekly, and the physician can customize which questions should be asked.

2.2 Documents referenced

Wearable Defibrillator Operator's Manual: 20B0048
(to be referred to as "Operator Manual")

Wearable Defibrillator Patient Manual: 20B0047
(to be referred to as "Patient Manual")

Sample Consent Form: 90D0120-ICD

Case Report Forms: 90D0120-CRF

Patient Diary: 20C0238 (German) or 20C0240 (English)

3. OBJECTIVES

The primary objectives are to document the precision of the HF metrics measurements, and to demonstrate that they are comparable to results from other traditional methods of measurement. The specific primary objectives are:

3.1 To observe the relationship of the step count and distance measure of the LifeVest walk test as performed by patients with heart failure by comparison to distance measure of the medically supervised six-minute walk test, and

3.2 To observe the accuracy of daily heart rate, activities, and body position in patients with heart failure by comparison to patient dairies of activity and sleeping position.

Secondary objectives are to observe patient interactions with the Trends user interface. The specific secondary objectives are:

3.3 To observe compliance with answering questions regarding health through a wearable defibrillator, and

3.4 To observe compliance with instructions given through a wearable defibrillator in the performance of a Walk Test, and

Further secondary objectives are to observe patient interactions with the wearable defibrillator itself. The specific tertiary objectives are:

3.5 To observe compliance with wearable defibrillator use during the study period, and

3.6 To observe patient-device interactions during a ventricular arrhythmia, if any should occur during the study period.

4. SUBJECT SELECTION CRITERIA

The population for this study will be patients with heart failure who are being cared for in an outpatient environment.

4.1 All of the following inclusion criteria must be met:

4.1.1 Patients must have symptomatic heart failure (i.e., NYHA class II or higher).

4.1.2 Patients must have evidence of dilated cardiomyopathy or a prior MI.

4.1.3 Patients must have an ejection fraction of 35% or less at the start of WCD use.

4.1.4 Patients must be anticipated to need a WCD for three months or more.

4.1.5 Patients must be ≥18 years of age (over the legal age of providing consent).

4.2 None of the following exclusion criteria are permitted:

4.2.1 Patients who have an implantable cardioverter defibrillator (ICD), recently had an ICD removed, or are planning to receive an ICD within the next three months.

4.2.2 Patients who need an assistive device for ambulation (wheelchair, walker or cane).

4.2.3 Patients who have a unipolar pacemaker.

4.2.4 Patients who have physical or mental conditions that prevent them from interacting with or wearing the device.

4.2.5 Patients who have physical or mental conditions that prevent them from completing a diary or six minutes of walking.

4.2.6 Patients who have an advanced directive prohibiting resuscitation.

4.2.7 Patients who are pregnant.

5. PROCEDURE

Upon LifeVest prescription, the prescribing physician/research coordinator will determine whether the patient is eligible for the study.

5.1 Pre-study Assessment

The subject's eligibility to enter the study will be determined during the pre-study assessment. The pre-study assessment will include:

- Reviewing the subject's medical history and symptoms to determine whether the inclusion and exclusion criteria are met.
- Discussing the risks and benefits of the study with the patient.

5.2 Initial Visit (0 to 2 weeks of WCD use)

- Obtain informed consent.

5.2.1 WCD Setup

The monitor will be programmed in accordance with the instructions in the Operator Manual. The following settings will be used:

5.2.1.1 The Walk Test at home will be programmed to occur weekly.

5.2.1.2 The Heart Health Survey will be programmed to occur daily.

5.2.2 Walk Test at office/clinic (monthly)

This portion will be done under the supervision of the research coordinator during each visit, including the Initial Visit. Follow the instructions in section 5.6.

5.2.3 Instructions for Walk Test at home (weekly)

5.2.3.1 Subjects will receive a WCD notification once per week to do a Walk Test.

5.2.3.2 It is important for subjects to wear the WCD for the complete duration of the Walk Test

5.2.3.3 Before and after, they will be asked to answer a question about shortness of breath and another about fatigue. They should pick the answer from the WCD screen that most closely describes how they feel at that moment.

5.2.3.4 Subjects should walk at a comfortable pace.

5.2.3.4.1 Odd numbered subjects: Advise odd-numbered subjects to walk in a straight line, turning back at each end, such as walking back and forth in a hallway or narrow room.

5.2.3.4.2 Even numbered subjects: Advise even-numbered subjects to walk in a circle or oval, such as walking a track, or walk in a square or rectangle, such as walking around a room.

5.2.3.5 Subjects should stop walking when the voice prompt says “stop walking”.

5.2.3.6 During the walk test, it is OK for subjects to stop and rest at any time. The subject should continue walking after resting if they feel able.

5.2.3.7 Subjects should do the Walk Test in the same place each week.

5.2.3.8 Remind subjects that these instructions can also be found in the Patient Manual.

5.2.4 Instructions for Subject Diary (daily, for 28 days)

Subjects will be given four diaries comprising 7 days each and asked to write in them in the morning and the evening. The subjects will be asked to return the completed diaries at the end of each week in the pre-paid envelopes provided.

In the morning, subjects should, at a minimum, record the following:

5.2.4.1.1 How well they slept on a scale of 1 (very restless) to 5 (very well).

5.2.4.1.2 Location of sleep, either chair or bed.

5.2.4.1.3 Number of pillows used.

5.2.4.1.4 The position assumed when first lying down.

5.2.4.1.5 The position they found themselves when awakened.

5.2.4.1.6 If they got out of bed at night (include approximate time and duration).

5.2.4.2 In the evening, subjects should, at a minimum, record the following:

5.2.4.2.1 How active they were during the day on a scale of 1 (seldom active) to 5 (very active).

5.2.4.2.2 Any activities they can remember during the day and the approximate time (examples: "I went shopping from 3:30 to 5:00PM" or "I watched my grandchildren from 10 AM to 2 PM").

5.2.4.2.3 If they slept during the day (include approximate time and duration, as well as whether it was on a chair or bed).

5.2.4.2.4 If the WCD prompted the performance of a Walk Test and the subject did not do it, the reason why should be recorded.

5.2.5 Instructions for Heart Health Survey (daily)

Subjects will answer questions daily concerning their health. These questions will appear on the screen of the WCD. The questions should be answered honestly.

5.2.6 Schedule a return visit for the subject in approximately four weeks.

5.2.7 Complete the Initial Case Report Form.

5.3 Follow-up Visit 1 (4 to 6 weeks of WCD use)

5.3.1 Perform a Walk Test following the instructions in section 5.6.

5.3.2 Complete the Follow-up Visit Case Report Form.

5.3.3 Schedule a return visit for the subject in approximately four weeks.

5.4 Follow-up Visit 2 (8 to 10 weeks of WCD use)

5.4.1 Perform a Walk Test following the instructions in section 5.6.

5.4.2 Complete the Follow-up Visit Case Report Form.

5.4.3 Schedule a return visit for the subject in approximately four weeks.

5.5 Follow-up Visit 3 (12 to 14 weeks of WCD use)

5.5.1 Perform a Walk Test following the instructions in section 5.6.

5.5.2 Complete the Follow-up Visit Case Report Form.

5.5.3 Thank the patient for their participation.

5.6 Walk Test at office/clinic

5.6.1 Odd numbered subjects: While the subject is wearing the WCD, the Walk Test should be performed in the office/clinic using the American Thoracic Society guidelines. Record the data using the Walk Test Case Report Form.

5.6.2 Even numbered subjects: Program the WCD to start a Walk Test. The subject should perform the WCD Walk Test using the same walking space as the odd numbered subjects. Record the data using the Walk Test Case Report Form.

5.7 Adverse Event Case Report Form

5.7.1 If a subject or person associated with the subject reports or otherwise indicates an adverse event occurred due to the performance of the study, an Adverse Event Form must be completed.

5.8 Shock Event Case Report Form

If any subject receives a shock while using the WCD, a Shock Event Case Report Form must be completed. The data for the form may be acquired by phone or chart review, and does not require an additional subject visit.

6. EVALUATION OF RESULTS

Comparisons will be made between six minute walk as performed using the standard method with medical supervision, the Walk Test prompted by the WCD in the same (clinical) environment, and the Walk Test prompted by the WCD outside the clinic. Distance will be used to compare the standard method with the WCD method performed within the same environment. Step count will be used to compare WCD methods. Odd and even numbered subjects will have outpatient WCD results analyzed separately and combined. Paired or independent t-test methods will be used as appropriate.

Patient Diaries will be qualitatively compared to the position, orientation, and activity metrics recorded by the WCD, as well as to the results of the Health Survey.

Health Survey results will be qualitatively and quantitatively correlated (Pearson or Spearman as appropriate) to the position, orientation, and activity metrics recorded by the WCD. Health Survey results will also be compared to the position, orientation, and activity metrics recorded by the WCD.

Heart Rate metrics will be evaluated by comparison (t-test) with a random and non-random sampling of ECG data recorded by the WCD. At a minimum, one random sample per week will be compared to the Heart Rate metrics.

All data will be analyzed and reviewed for intervariable trends and correlations.

7. RISKS AND BENEFITS

Since subjects are selected from patients already wearing a WCD for medical reasons, the risks of the study relate entirely to the performance of the Walk Test and the data collection involved.

Some subjects may not be accustomed to walking for six minutes at a time. The extra exercise may result in sore muscles. A few subjects may experience cardiac ischemia while walking. Subjects are advised not to perform the Walk Test or stop the test if they feel any cardiac symptoms. If the patient does not adhere to these directives, it is possible that a myocardial infarction may occur, with pain, hospitalization or even death as a result.

Although subjects will not receive direct personal or health benefits from taking part in this study, the study may be helpful to future patients by providing information about using certain features of WCDs.

8. SUBJECT CONSENT AND CONFIDENTIALITY

Each subject will be informed of the purpose of the investigation as well as the potential risks and benefits prior to their enrollment in the study. The subject must freely sign the Informed Consent Form prior to subject enrollment.

Each subject will receive a unique subject identification number. The subject's name and identity will be known to the Investigator and ZOLL (the "Sponsor") but will be kept confidential. Authorized personnel from the ethics committee and regulatory authorities may have access to original subject records.

9. STUDY SIZE

A minimum of 150 subjects and a maximum of 250 will be enrolled using five to twenty clinical centers.

10. FORMS AND DATA HANDLING

As with any study, accurate and timely completion of documentation is essential for the successful completion of the trial. The Investigator will be responsible for obtaining and maintaining Informed Consent Forms and Case Report Forms (90D0120-CRF). A copy of the signed Informed Consent Form will be given to every subject. A copy of each Case Report Form will be sent to the Sponsor, with the originals maintained by the Investigator.

11. ADVERSE EVENTS

If a subject or person associated with the subject reports or otherwise indicates an adverse event occurred due to the performance of the study, specifically while performing the Walk Test or Health Survey, an Adverse Event Form must be filled out.

Serious adverse events should be reported to ZOLL immediately. The reviewing ethics committee must also be notified within 10 working days.

Muscle soreness or other activity-related symptoms due to the performance of a Walk Test are anticipated to occur in some subjects.

All questions, complaints, or concerns regarding anything other than the performance of the Walk Test or completing the Heath Survey should be referred to customer support. These are not to be reported as adverse events.

12. DATA ANALYSIS PLANS

Data from all patients enrolled in the study that wear the WCD will be considered and/or analyzed and may be correlated with arrhythmias and other events recorded by the institution's monitoring system and patient charts. The data stored in the monitor includes:

- Automatically stored ECG recordings (including true arrhythmias and false arrhythmia declarations).
- Manually stored ECG recordings.
- Duration of time that the WCD was worn.
- Noise, arrhythmia, and other internal event flags.

- Device actions during a treatment sequence; i.e., transthoracic impedance measurement, energy delivered and outcome.
- Patient device interactions, including patient use of the response buttons.

The stored data will be analyzed and correlated to data recorded through Case Report Forms. The data will also be analyzed to determine frequency of noise events, frequency of false arrhythmia events, and percentage of subject wear time. The results obtained will be compared with the results of commercial LifeVest use.

13. ADMINISTRATIVE RESPONSIBILITIES

ZOLL, the Sponsor, is responsible for study administration and providing devices and related materials for the study.

The Sponsor will designate one or more appropriately trained and qualified individuals to monitor the investigation. These individuals will conduct at least one pre-investigation on-site visit and one on-site visit during the investigation to verify the adherence to procedures specified in the protocol, and verify maintenance of required subject and data records. Monitoring activities will be conducted according to ZOLL's Monitoring of Clinical Studies Standard Operating Procedure (ZOLL 90D0013) and will be documented.

The Investigator is responsible for obtaining and maintaining ethics approval of the study protocol. The Investigator is responsible for obtaining patient consent, and maintaining Informed Consent Forms and Case Report Forms for each subject. The Investigator is responsible for maintaining records of study protocol deviations and amendments and all correspondence relating to the study. The Sponsor will provide an Investigator Notebook for this purpose. At the conclusion of the study, the Investigator will provide a report to the Sponsor and the ethics committee.

If the device malfunctions or fails to function as expected, the Investigator must report the incident to ZOLL immediately.

Patient identities will be kept confidential; however, ZOLL may provide study results to the USA's Food and Drug Administration (FDA) and other regulatory agencies.

Appendix A

Bibliography of LifeVest publications

Wearable Cardioverter Defibrillator publications in chronological order

1. Auricchio et al., "Clinical Efficacy of the Wearable Cardioverter-Defibrillator in Acutely Terminating Episodes of Ventricular Fibrillation," Am J Card, 1998, 81(10):1253-1256.

   Initial EP lab experience

2. Meltendorf et al., "The Wearable Defibrillator – a new Method to prevent Sudden Death," PACE, 2000; 23(4, part II):606.

   Abstract of single-center case series demonstrating safety and feasibility in post-MI and post-CABG. Three of 39 patients had VT/VF events corrected by the LifeVest.

3. Reek et al., "The Wearable Cardioverter Defibrillator (WCD®) for the prevention of sudden cardiac death – a single center experience," Z Kardiol, 2002; 91:1044–1052.

   An expanded post-MI and post-CABG single center case series demonstrating safety and feasibility.

4. Schott, "The Wearable Defibrillator," J Cardiovasc Nurs, 2002; 16(3):44-52.

   A review of LifeVest function and use from a nursing perspective.

5. Reek et al., "Clinical Efficacy of the Wearable Defibrillator in Acutely Terminating Episodes of Ventricular Fibrillation Using Biphasic Shocks," PACE, 2002, 25(4, part II):577.

   Abstract documenting the clinical efficacy of the LifeVest biphasic waveform.

6. Reek et al. "A wearable defibrillator for patients with an intermittent risk of arrhythmia," Dtsch Med Wochenschr, 2002; 127(41):2127-30.

   Review of wearable defibrillator function and use.

7. Capucci et al. "Cost-effective use of a new wearable cardioverter defibrillator to protect patients at risk of SCA," Europace, 2003, 4(suppl 1):A44-A45.

   Abstract analyzing cost of wearable defibrillators.

8. Gasparini et al. "A new wearable defibrillator: Initial single center experience," Europace, 2003, 4(suppl 1):A45.

   Abstract of a small, single-center case series.

9. Pignatelli et al. "Use of a new wearable cardioverter defibrillator to reduce the risk of sudden cardiac death," Europace, 2003, 4(suppl 1):A45-A46.

   Abstract of a small, single-center case series.

10. Suzzani P et al. "The lifecor lifevest™ wearable cardioverter defibrillator," Europace, 2003, 4(suppl 1):A46.

    Abstract reviewing LifeVest function and use.

11. Lang et al., "Morbidity and Mortality of UNOS Status 1B Cardiac Transplant Candidates at Home," J Heart Lung Transplant, 2003; 22:419-426.

    Article on outpatient inotropic drug use for transplant patients. Both ICDs and wearable defibrillators were used. Compliance not favorable in this article and two patients died not wearing the LifeVest.

12. Reek et al., "Clinical Efficacy of a Wearable Defibrillator in Acutely Terminating Episodes of Ventricular Fibrillation Using Biphasic Shocks", PACE, 2003, 26:2016-2022.

    Documents the clinical efficacy of the LifeVest biphasic waveform.

13. Beauregard, "Personal Security: Clinical Applications of the Wearable Defibrillator," PACE, 2004; 27(1):2-3.

    Editorial comments on FDA approval study.

14. Feldman et al., "Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death: Results of WEARIT/BIROAD", PACE, 2004, 27:4-9.

    FDA approval study. Shows 75% resuscitation success, few inappropriate shocks. Compliance and length of use less than current stats (older versions of LifeVest).

15. Chung et al., "Robust Long-Term Cardiac Monitoring Using Dry, Non-adhesive Capacitive Electrodes," JACC, 2004; 43(5, suppl A):141A.

    Abstract showing low levels of signal disruption using capacitive electrodes.

16. Joseph et al., "Compliance and Effectiveness of the Wearable Defibrillator Vest," JACC, 2004; 43(5, suppl A):300A.

    Abstract showing commercial compliance and effectiveness. Better compliance, only 8 VT/VF events.

17. Meltendorf, "Using the Wearable Cardioverter Defibrillator- a strategy for bridging high risk patients after CABG," Heart Rhythm, 2005; 2(5, suppl):S32.

    Abstract reviewing 30 post-CABG patients. Two events. Only 9 of 30 needed ICD after three months of use.

18. Wase, "Wearable Defibrillators: A New Tool in the Management of Ventricular Tachycardia/Ventricular Fibrillation," EP Lab Digest, 2005; 12:22-24.

    Case report and review of LifeVest function and use.

19. Szymkiewicz et al., "Analysis of Sudden Cardiac Arrests During Wearable Defibrillator Use," Circulation, 2006; 114 (18, suppl II):II-349.

    Abstract reviewing commercial SCA events while the LifeVest was worn. Shows SCA was mostly VT/VF and high rate of successful resuscitation.

20. Gronda et al., "Heart Rhythm Considerations in Heart Transplant Candidates and Considerations for Ventricular Assist Devices: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates—2006," J Heart Lung Transplant, 2006; 25(9):1043-1056.

    LifeVest given class I recommendation for status 1B cardiac transplant candidates discharged home.

21. Losordo et al., "Intramyocardial Transplantation of Autologous $CD34^+$ Stem Cells for Intractable Angina: A Phase I/IIa Double-Blind, Randomized Controlled Trial," Circulation, 2007; 115:3165 - 3172.

    LifeVest used to protect during high-risk time after stem cell transplantation for angina.

22. Traub et al., "Sudden cardiac arrest aborted by a wearable cardioverter-defibrillator in newly diagnosed non-ischemic cardiomyopathy," Heart Rhythm, 2007; 4(5, suppl):S101.

    Abstract of SCA termination in NICM (case report).

23. Choudhuri et al., "Arrhythmic Events During the 40/90 days 'Cooling Off' Period: Clinical Utility of the Wearable Defibrillator," Circulation, 2007; 116: II_348.

    Abstract of case series using LifeVest before ICD to prevent unnecessary ICD use.

24. Wang et al., "Ventricular Fibrillation remains the Primary Presenting Rhythm: Results from the Wearable Cardioverter Defibrillator Human Study," Circulation, 2007; 116: II_934 - II_935.

    Abstract documenting VT/VF as first arrhythmia in SCA while wearing LifeVest.

25. Freeman et al., "Is Severe Post-shock Bradyarrhythmia In Patients Using Wearable Defibrillators Common or Serious?" Circulation, 2007; 116: II_931.

    Abstract documenting post-shock bradyarrhythmias are uncommon using LifeVest.

26. LaPage et al., "A Fatal Device-Device Interaction between a Wearable Automated Defibrillator and a Unipolar Ventricular Pacemaker," PACE, 2008; 31:912–915.

    Case report of pacemaker-LifeVest interaction (despite operator manual warnings).

27. Abi−Samra et al., "Wearable Defibrillator: Effective Bridging Substitute for ICD Implants," Europace, 2008; 10: i160.

    Abstract describing case series with one successful resuscitation.

28. Mortada et al., "Sudden Cardiac Death" in: Jeremias A, Brown DL (eds). Cardiac Intensive Care, 2nd Edition, Elsevier, St. Louis (in press).

    Chapter contains description and picture of LifeVest.

29. Szymkiewicz, et al. "A Comparison of Compliance and Effectiveness of Wearable Defibrillators and Home AEDs in Out-of-Hospital Sudden Cardiac Arrest," Circulation, 2008; 118: S_1466.

    Abstract showing the superiority of the LifeVest to home AED.

30. Lewicke et al., "Exploring QT interval changes as a precursor to the onset of ventricular fibrillation/tachycardia," Journal of Electrocardiology, 2009; 42(4):374-9.

    Changes in QTc prior to a VT event in a variety of VT/VF patients were not significant.

31. Szymkiewicz, et al., "Incidence and causes of inappropriate defibrillation during wearable defibrillator use," Heart Rhythm, 2009; 6(5, suppl): S74.

    Abstract demonstrating the safety of LifeVest use.

32. Morrison et al., "Taking a vested interest in a wearable cardioverter defibrillator," Nursing, 2009; 39(6):30-2.

    Nursing perspective of LifeVest use.

33. Dillon et al., "An evaluation of the effectiveness of a wearable cardioverter defibrillator detection algorithm," Journal of Electrocardiology, 2009; (June, electronic ahead of print).

    The WCD detection algorithm has a low risk of inappropriate shocks.

34. Saltzberg et al., "Characteristics of Peripartum Cardiomyopathy Patients Using a Wearable Cardiac Defibrillator," Journal of Cardiac Fail, 2009; 15(6):S59.

    Abstract demonstrating wearable defibrillator use in peripartum patients.

35. Lee et al., "Role of wearable and automatic external defibrillators in improving survival in patients at risk for sudden cardiac death," Curr Treat Options Cardiovasc Med, 2009;11(5):360-5.

    Review of wearable defibrillator.

36. Klein et al., "Bridging a Temporary High Risk of Sudden Arrhythmic Death. Experience with the Wearable Cardioverter Defibrillator (WCD)," PACE, 2009 Nov 2 [Epub ahead of print]

    Detailed technical review, indication review, and reports results of European experience (350+ patients.

37. Prochnau, "Successful use of a wearable cardioverter-defibrillator in myocarditis with normal ejection fraction," Clin Res Cardiol, 2009 Nov 17. [Epub ahead of print]

    Case report of myocarditis use.

38. Zareba et al., "Sudden Cardiac Arrest in End-Stage Renal Disease: Successful Resuscitation With Wearable Cardiac Defibrillator", Circulation, Nov 2009; 120: S701 - S702.

Shows resuscitation success among dialysis patients.

39. Klein et al. "The Wearable Cardioverter Defibrillator: Bridge to the Implantable Defibrillator," Cardiac Electrophysiology Clinics, 2009; 1(1):129-46.

Detailed technical review, indication review, and some commercial experience.

40. Everitt et al., "Use of the Wearable External Cardiac Defibrillator in Children," PACE, 2010 Feb 23. [Epub ahead of print].

Small retrospective of pediatric commercial experience.

41. Chung et al. "Aggregate national experience with the wearable cardioverter-defibrillator vest: event rates, compliance and survival," JACC, 2010; 55(10 suppl 1):A10.

Abstract reviewing commercial experience through 2006.

42. Szymkiewicz et al. "Wearable defibrillator use prior to ICD implantation or evaluation," Heart Rhythm, 2010; 7(5 suppl):S54.

Abstract (also oral presentation) detailing use prior to ICD in 950 patients.

43. Zishiri, et al. "Appropriateness of ICD indications: insights from an analysis of mortality rates in patients using a wearable cardioverter-defibrillator," Heart Rhythm, 2010; 7(5 suppl):S122.

Abstract comparing "traditional" and "non-traditional" sudden death indications.

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