

The wearable cardioverter-defibrillator is not needed for most high-risk patients



Advay G. Bhatt, MD, FHRS, Suneet Mittal, MD, FHRS

From the Snyder Center for Comprehensive Atrial Fibrillation at Valley Health System, Ridgewood, New Jersey.

The wearable cardioverter-defibrillator (WCD) was first evaluated in 1998¹ and this system (LifeVest; ZOLL Medical Corporation, Pittsburgh, PA) received FDA approval in 2001. The limited basis for approval was 2 multicenter prospective observational studies (totaling only 289 patients) assessing defibrillation efficacy where the number of patients receiving appropriate and inappropriate shocks was equivalent and adherence to guideline-directed medical therapy was poor by current standards.² To date, this still remains the only commercially available system in the world.

The WCD system is composed of 4 components: (1) a garment facilitating positioning of an electrode belt, (2) the electrode belt that incorporates 4 sensing (2 electrocardiograph channels) and 3 defibrillation nonadhesive electrodes, (3) charger, and (4) the monitor pack (Figure 1).^{3,4} The latter houses the rechargeable battery, the patient response button, and a touch screen that allows the patient to capture and transmit information about their rhythm, engage in a 6-minute hall walk test, and enter information to ascertain quality-of-life (QoL) indices. Arrhythmia detection is technically challenging, as the 4 dry sensing electrodes are prone to skin motion artifact or loss of contact; this necessitates sophisticated compensatory algorithms to minimize false alarms and inappropriate therapy. After accounting for artifact, arrhythmia detection incorporates rate, stability, and template matching. There are 2 programmable zones with a customizable detection time and shock energy, but optimal device programming is not yet defined and is left to the discretion of the prescribing physician. A patient response system facilitates inhibition of therapies for hemodynamically stable tachyarrhythmias.

In 2012, at the time Zoll was acquired by Asahi-Kasei, sales of the LifeVest had grown from \$6 million in 2006 to \$111 million and the WCD had been used by 50,000 patients.⁵ By 2018, when nearly 300,000 patients had used the WCD worldwide, sales of the LifeVest were estimated

to have increased to \$700–\$800 million.⁶ This raises questions about the appropriate patient population for this therapy and the clinical data to support ongoing use in these patients.

Based on 10 observational studies through December 2013, an American Heart Association Science Advisory was published to provide clinical guidance on the role of a WCD.⁷ The 4 patient populations identified (Figure 2) can be divided into 2 distinct cohorts. Of note, each of the cohorts received a Level of Evidence designation of “C,” suggesting that “very limited populations [were] evaluated” and “only consensus opinion of experts, case studies or standard of care” existed for the basis of the recommendations.

At the time these recommendations were written, no randomized clinical trial of the WCD had been performed. Thus, the highest class of recommendation was IIa, which was given to 2 niche patient populations:

- (1) Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in implantable cardioverter-defibrillator (ICD) care, such as infection;
- (2) Use of WCDs is reasonable as a bridge to more definitive therapy, such as cardiac transplantation.

We concede there is little reason to debate the utility of a WCD in these populations. However, it is highly unlikely that these patients represent the bulk of those receiving a WCD. In 2010, the aggregate experience in the United States with the WCD was reported for patients treated between 2002 and 2006.⁸ At that time, less than one-quarter of patients received a WCD for 1 of these 2 categories. In a more contemporary registry, only 8000 patients were identified between 2002 and 2014 who were prescribed a WCD after undergoing ICD explantation for infection.⁹

The area that merits the greatest discussion is the use of the WCD in patients who are in the “waiting period” for placement of an ICD. These are covered by the following 2 indications, each of which received only a class IIb recommendation:

- (1) Use of WCDs may be reasonable when there is concern about a heightened risk of sudden cardiac death (SCD) that may resolve over time or with treatment of left ventricular dysfunction; for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary

KEYWORDS High-risk patients; Non-compliance; Primary prevention; Sudden cardiac death; Wearable cardioverter-defibrillator (Heart Rhythm 0² 2020;1:230–233)

Address reprint requests and correspondence: Dr Suneet Mittal, Director, Electrophysiology, Valley Health System, 970 Linwood Ave, Paramus, NJ 07652. E-mail address: mittsu@valleyhealth.com.

KEY FINDINGS

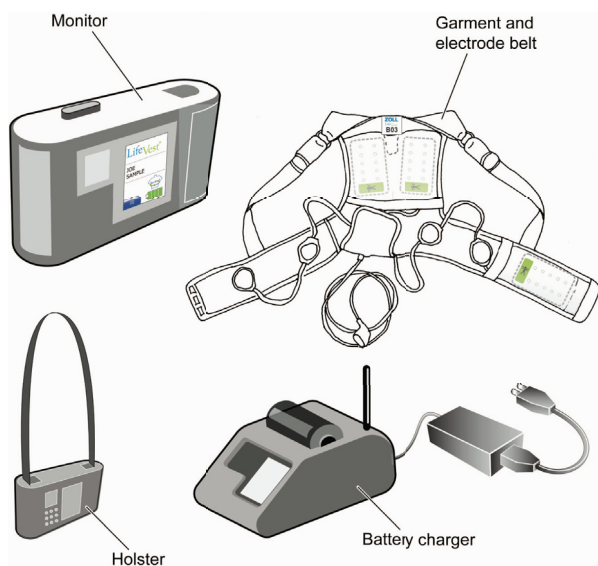
- Since FDA approval nearly 20 years ago, only a single wearable cardioverter-defibrillator (WCD) is commercially available in the world.
- The use of the WCD seems justified “as a bridge” in certain niche conditions such as infection or pre cardiac transplant; randomized clinical trials in these patient populations are not practical.
- The single randomized clinical trial ever performed with this technology failed to meet its primary endpoint; the routine use of the WCD for prevention of sudden death in patients perceived to be at high risk cannot be justified.
- A third of patients are simply unable to use the WCD; thus, significant improvements to the system are urgently needed to make it practical for routine clinical use.

cardiomyopathy (tachycardia-medicated, thyroid-mediated, etc) in which the underlying cause is potentially treatable.

- (2) 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 myocardial infarction (MI).

The clinical experience with the WCD has been well summarized in a recent meta-analysis of 28 studies (21 retrospective and 6 prospective) from January 2001 through March 2018 comprising 33,242 patients.¹⁰ There was significant heterogeneity based on number of patients enrolled (24 to more than 8000); gender mix; primary vs secondary prevention and ischemic vs nonischemic cardiomyopathy indications; duration of use (16–394 days), and daily use compliance (14.1–23.7 hours per day). The pooled incidence of appropriate vs inappropriate WCD treatment was 5 per 100 persons over 3 months (95% confidence interval [CI]: 3.0–6.0; *P* < .001) and 2 per 100 persons over 3 months (95% CI: 2.0–4.0; *P* < .001), respectively. The overall mortality was 0.7 per 100 persons over 3 months (95% CI: 0.3–1.7). There was no difference in outcome based on indication for the WCD. Subsequent referral for ICD implant ranged from 4.4% to 59%.

The Vest Prevention of Early Sudden Death Trial (VEST) trial is the first and only multicenter randomized controlled trial to investigate the role and benefit of a WCD as an adjunct to optimal guideline-directed medical therapy early following MI (left ventricular ejection fraction ≤35%) with 3 months of subsequent follow-up.¹¹ A total of 2302 patients predominantly in the United States and Poland were included and an intention-to-treat analysis did not demonstrate a difference in the primary endpoint of arrhythmic mortality (1.6% in the WCD arm vs 2.4% in the control arm, *P* = .18). Total mortality was lower in the WCD arm (3.1% vs 4.9%, uncorrected *P* = .04; corrected *P* value ranged from .046 to .45 depending on methodology).



Component	Current State	Associated Issues
Garment	Needs to be washed every few days	Electrode belt needs to be removed and re-inserted each time
	Available in two sizes	Challenges in obese patients and females with large breasts
Electrode belt	Needs to be inserted at start and each time garment is cleaned	Time consuming and potentially error prone process; possible to insert shock electrodes incorrectly
Charger	Recharges the battery	Takes 16 hours to charge; each battery lasts just a day
	Communicates wirelessly with the monitor and transmits ECG data	Requires patient to be tethered to a bedside charger; may compromise ability to transmit ECG data in a timely manner
Monitor touchscreen	Help messages; Error messages; Health surveys; 6-minute walk	Patients required to respond to critical messages, including those indicating severe device malfunction; Suboptimal user interface; would be easier if tethered to a patient's smartphone; Multiple symbol-based messages; may not be immediately intuitive to patients
Monitor based alarms	Vibration; gong; and siren alerts	Possibility for confusion; Lack specificity (etiology remains unclear and optimal programming remains undefined) and thus potential for "alarm fatigue"

Figure 1 Components of the wearable cardioverter-defibrillator, the current state, and associated system related issues. ECG = electrocardiogram. (Image showing components of system courtesy of LifeVest [ZOLL Medical Corporation, Pittsburgh, PA].)

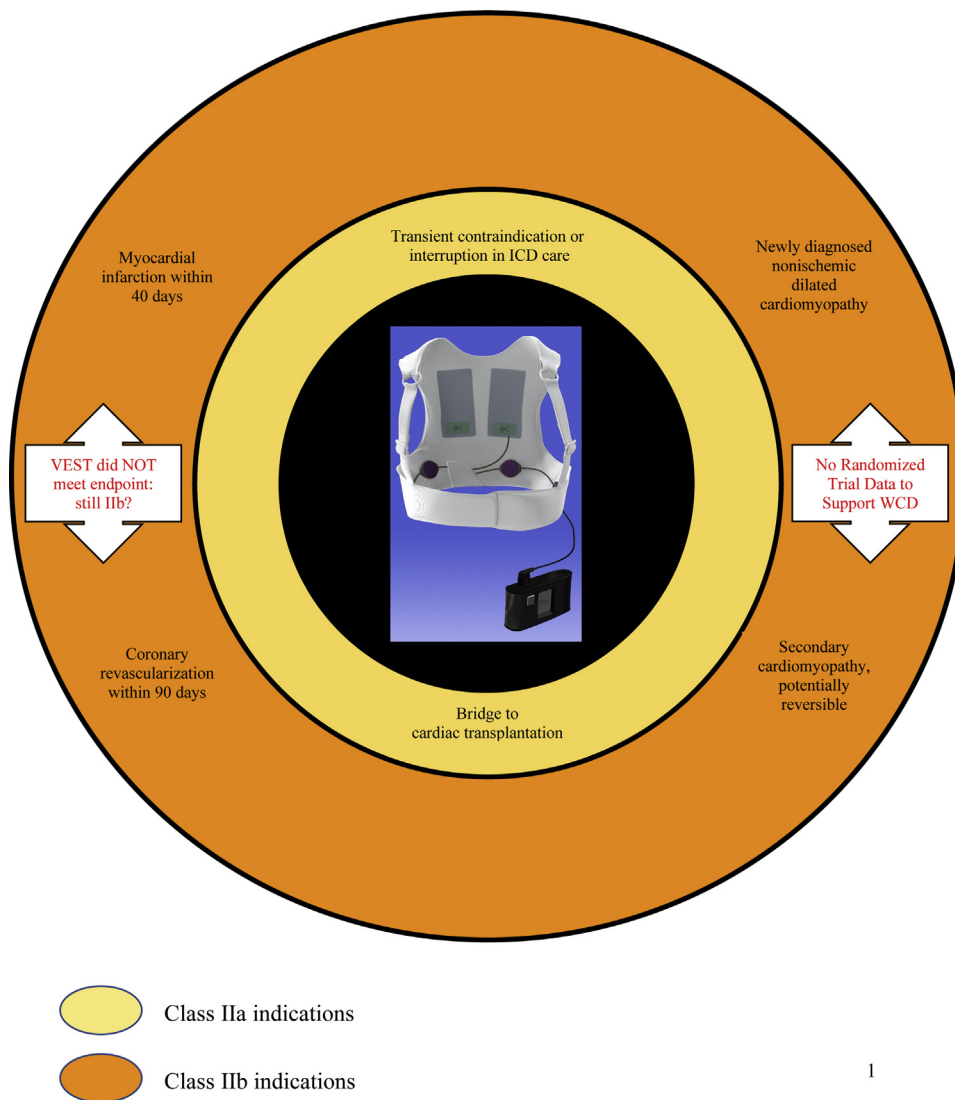


Figure 2 Current state of the wearable cardioverter-defibrillator (WCD). There is only 1 commercially available system in the world (center image). The inner (yellow) circle shows the 2 currently accepted class IIa indications for WCD use. The larger outer (orange) circle shows the 2 currently accepted class IIb indications for WCD use; undoubtedly, most WCD prescriptions are written for these indications. Unfortunately, randomized clinical trial data in these patients either is lacking or has failed to show the benefit of the WCD. ICD = implantable cardioverter-defibrillator. (Center image courtesy of LifeVest [ZOLL Medical Corporation, Pittsburgh, PA].)

Appropriate shocks were observed in 1.3% and inappropriate shocks in 0.6% of patients; thus, a third of all shocks delivered were inappropriate. No information was provided in the primary manuscript about the rate or rhythm that triggered appropriate or inappropriate ICD shocks. There was no difference in the subsequent need for or timing of ICD implant in the 2 arms. Thus, we no longer offer the WCD at our institution in the VEST patient population.

A major issue with the available version of the WCD is the rate of compliance with daily use. In VEST, (1) 2.8% of patients never used the device after randomization; (2) on any given day, the proportion of patients using the device decreased from 81% at randomization to 41% at 90 days; (3) nearly a third of patients wore it for 0 hours; and (4) only 25% of patients were even wearing the device at the time of their death. Thirty percent of participants stopped wearing the WCD within 1 month of randomization, 43%

within 2 months, and 80% before the end of the planned 90-day follow-up period.¹² In a subsequent “on-treatment” analysis, the WCD was associated with a significant reduction in total mortality (hazard ratio 0.25; CI: 0.13, 0.48; $P < .001$), arrhythmic death (hazard ratio 0.38, CI: 0.17, 0.86; $P = .02$), and nonsudden death (hazard ratio 0.09, CI: 0.02, 0.39; $P = .001$). Thus, how should we interpret the results of VEST?

A fundamental requirement of the WCD is that the patient needs to use it as much as possible. The current version of the WCD could not be used by a third of patients; in this context, the VEST randomized trial failed to meet its primary endpoint. Disappointingly, most deaths occurred when the patient was not using the WCD. These data suggest that in its current form, the only commercially available device is not ideally suited for routine clinical use.

In our opinion, significant improvements in the form factor are needed to ensure near-100% compliance and to eliminate the important issues that plague the current device. In VEST, 80% of patients had stopped using the WCD before the 3-month follow-up period. Even when patients do use the device, it has to be removed when a patient takes a shower; at least 1 patient in VEST died during this time. Toward this end, a patch-based WCD is currently in development that can be used while the patient showers and sleeps.¹³ This may also help address the 2-fold increased likelihood of a patient reporting a rash in the WCD arm of VEST. Our review of the FDA MAUDE database further supports this concern, as there are reports of discontinuation owing to pruritis, sores, blisters, bleeding wounds, and skin infection.

The second issue is the high rate of device alarms, triggered when the algorithm determines that a treatable arrhythmia or asystole is present, experienced by patients. The chance that a participant would have at least 1 arrhythmia alarm during 24 hours of wear time was 10.8% (95% CI: 9.8, 11.9).¹¹ Overall, an arrhythmia alarm occurred in 72% of participants and nearly 10% of patients experienced more than 100 alarms over the 90-day period. Since only 20 appropriate ICD shocks were delivered in the entire study, it stands to reason the arrhythmia detection is simply not specific enough for clinical use; it is likely this is an important contributing factor in the decline in WCD use over time. The etiology for this high rate of alarms (eg, sensing issues, nonsustained ventricular arrhythmias, supraventricular arrhythmias, etc) needs to be elucidated. Finally, the current system suffers from several additional issues that would need to be addressed in a more idealized system (Figure 1).

There is little reason to debate the utility of a WCD in the setting of an infection or bridge to cardiac transplant; however, the systematic and universal use of a WCD as a primary-prevention SCD risk reduction strategy following either MI associated with ventricular dysfunction or newly diagnosed nonischemic cardiomyopathy is not adequately supported by currently available data. Overall, the increasing utilization of WCD in clinical practice is due to the over-assumption of benefit without adequate consideration of risk. As such, prescriptions may be driven not by data but rather by fear and emotion, which are very difficult to overcome. The number of possible lives saved appears to be small and potentially occurs at the expense of emotional distress, reduced QoL, and economic burden.¹⁴ Data on QoL and

resource utilization were prospectively captured by the VEST investigators; we eagerly await the availability of these results. We urge the prescribing community to pursue further randomized clinical trials and for industry to pursue much-needed device enhancements.

Funding sources

The authors have no funding sources to disclose.

Disclosures

The authors have no conflicts of interest to disclose.

References

1. Auricchio A, Klein H, Geller CJ, Reek S, Heilman MS, Szymkiewicz SJ. Clinical efficacy of the wearable cardioverter-defibrillator in acutely terminating episodes of ventricular fibrillation. *Am J Cardiol* 1998;81:1253–1256.
2. Feldman AM, Klein H, Tchou P, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BROAD. *Pacing Clin Electrophysiol* 2004;27:4–9.
3. Sandhu U, Rajyaguru C, Cheung CC, Morin DP, Lee BK. The wearable cardioverter-defibrillator vest: indications and ongoing questions. *Prog Cardiovasc Dis* 2019;62:256–264.
4. Cheung CC, Olgin JE, Lee BK. Wearable cardioverter-defibrillators: a review of evidence and indications. *Trends Cardiovasc Med*. <https://doi.org/10.1016/j.tcm.2020.03.002>. 2020.03.12.
5. Asahi Kasei Corporation. Acquisition of ZOLL Medical Corporation. Available at <https://www.asahi-kasei.com/ir/library/presentation/pdf/120312eng.pdf>. Accessed May 30, 2020.
6. Asahi Kasei Corporation. Medium-term Management Initiative (FY 2016–2018) Progress and Outlook. Available at <https://www.asahi-kasei.com/ir/library/initiative/pdf/e180529en.pdf>. Accessed May 30, 2020.
7. Piccini JP Sr, Allen LA, Kudenchuk PJ, Page RL, Patel MR, Turakhia MP. Wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death: a science advisory from the American Heart Association. *Circulation* 2016;133:1715–1727.
8. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol* 2010;56:194–203.
9. Ellenbogen KA, Koneru JN, Sharma PS, Deshpande S, Wan C, Szymkiewicz. Benefit of the wearable cardioverter-defibrillator after implantable-cardioverter defibrillator explant: results from the national registry. *JACC Clin Electrophysiol* 2017;3:243–250.
10. Masri A, Altibi AM, Erqou S, et al. Wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death: a systematic review and meta-analysis. *JACC Clin Electrophysiol* 2019;5:152–161.
11. Olgin JE, Pletcher MJ, Vittinghoff E, et al. Wearable cardioverter-defibrillator after myocardial infarction. *N Engl J Med* 2018;379:1205–1215.
12. Olgin JE, Lee BK, Vittinghoff E, et al. Impact of wearable cardioverter-defibrillator compliance on outcomes in the VEST trial: as-treated and per-protocol analyses. *J Cardiovasc Electrophysiol* 2020;31:1009–1018.
13. Element Science. Jewel Wearable Defibrillator. Available at <https://www.elementscience.com/product/>. Accessed May 30, 2020.
14. Lackermair K, Schuhmann CG, Kubieniec M, et al. Impairment of quality of life among patients with wearable cardioverter defibrillator therapy (LifeVest®): a preliminary study. *Biomed Res Int* 2018;2018:6028494.