



# Wearable cardioverter defibrillators: dead on arrival or chance of survival?

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Sudden cardiac death affects over 300,000 individuals annually in the United States (1-4), and it comprises 40–50% of total cardiovascular disease-related deaths (3). The wearable cardioverter defibrillator (WCD) gained FDA approval in 2002 (5) and is a guideline-directed therapy intended to reduce the risk of sudden cardiac death from death from ventricular tachyarrhythmias, including ventricular fibrillation (VF) or ventricular tachycardia (VT) (2,6). However, it is well-documented that ideal use of the WCD (trade name LifeVest<sup>®</sup>) is constrained by size and weight of the device as well as development of a rash (7-9). The recent groundbreaking research released by the VEST Trial investigators has cast further doubt on the validity of the device by failing to demonstrate a significantly lower rate of death from tachyarrhythmias among WCD users (10). Also considering that premature discontinuation rates are as high as 30% (11), this begs the question: Is the WCD dead on arrival, or does it have a chance of survival with some modifications?

The LifeVest (2,7,12) comes in a single size for both men and women, weighing 1.5 kg (13). It is comprised of a rechargeable external battery pack and cardiac monitor as well as a fabric vest-like garment with electrode-embedded pads that are worn directly touching the skin of the back. The front of the vest is an adjustable band worn horizontally below the breasts that are connected to the back by two vertical straps worn over the lateral aspects of the breasts. The device continuously monitors a patient's cardiac rhythm (5) and can defibrillate a patient up to five times at 150 Joules each when a ventricular tachyarrhythmia is detected (7). If conscious patients hear the device beeping,

indicating an imminent shock, they may abort the sequence by pushing two buttons simultaneously (3,7).

The most pressing issue is addressing the size and weight of the device. In an era when batteries are becoming smaller and obesity rates are climbing, it would make sense to modify the device to better suit its target audience. Obese patients can have trouble fitting into the device without appropriate fitting (2). Furthermore, patients with excess fat around the chest are more likely to have electrocardiographic artifact compared to patients of a normal or even overweight body mass index (12). This leads to inappropriate alarming, which may wake patients up from sleep or cause public embarrassment, contributing to premature discontinuation (14,15). In fact, one study by Lackermair *et al.* reported that 48% of the 109 studied patients reported sleep disturbance with increased alarms contributing to higher levels of anxiety about shock therapy ( $P=0.03$ ) (15). While studies have suggested no decreased WCD use in obese patients (12), much of the overall premature discontinuation of the WCD is related to discomfort (8). Thus, it is imperative to address the size of the device.

Next, rash is another reason cited for premature discontinuation (7,8). Feldman *et al.* noted that a full 6% of patients ( $n=17$ ) developed a hypersensitivity reaction to the device (8). Erath *et al.* documented in two patients a proven nickel hypersensitivity that was refractory to topical therapy; this allergy forced discontinuation of the WCD (14). The possibility of simple atopic dermatitis, development of folliculitis, or miliaria from sweat trapped between the device's pads and the skin can decrease comfort. While

the device manual shows how to wash the fabric portion of the device, other components cannot contact water and are harder to clean. This hampers the optimal cleanliness of the WCD. Addressing the device's breathability and its propensity of causing a rash can improve patient comfort.

There are many ways to address the design concerns of the WCD. First, instead of using a bulky monitor/battery pack, the monitor can be downsized to either an app on the patient's smartphone or to a smartphone-sized wireless- and Bluetooth-enabled device that is kept discreetly in a pocket or handbag. This device would then port data to the company's servers. Next, the battery pack should be made more compact. While a battery the size of an implantable cardioverter defibrillator is unlikely, given that the electric current must penetrate flesh to get to the heart, it can likely at least be made wireless. To prevent users from forgetting to carry it, it can have a unique alarm that sounds when a user is out of range. Ideally, it would also be small enough to carry in a pocket or a handbag. With the two previous components being wireless, the electrodes and pads could be single-use and flexible with pores to make them more breathable. They could be affixed on the skin in a similar location to either automated external defibrillator pads or on the patient's back, as with the current WCDs. For easier application to the back, a tool may need to be provided to help a patient reach the correct location. These three changes would also reduce the risk of nickel hypersensitivity and rash development, and hypoallergenic adhesive can further reduce adverse effects. This updated device would be more easily worn under clothes and applied to bulkier areas of the body with a decreased risk of electrocardiographic noise.

Currently, WCDs only target ventricular tachyarrhythmias, and they have no role in non-VT/VF rhythms, such as bradyarrhythmias (6). Bradyarrhythmias are a documented cause of death among patients wearing WCDs (14). With the device's current battery capacity, transcutaneous pacing could be an added function to bridge patients until they arrive at an emergency department for further care. In fact, the device may be totally overhauled to become an in-hospital pacing device.

It remains to be determined the effect of the VEST trial on the role of the WCD in current guidelines. Although the VEST trial demonstrates decreased all-cause mortality, WCD therapy failed to reduce the primary endpoint of arrhythmic death in the first 90 days post-myocardial infarction (10). As with previous studies, there was significant premature discontinuation that increased with time (10). The major limitations of the VEST trial

include its intention-to-treat analysis, wherein those who discontinued the device are still considered part of the WCD group; a full 75% of deaths in the treatment group were among device-non-adherent patients (10). This fosters the argument that with device modification and increased adherence to therapy, perhaps results may have been different.

As it stands, the WCD has Class IIb standing for primary prevention in recent post-myocardial infarction patients with ischemic heart disease and a left ventricular ejection fraction (LVEF) below 40% as well as for secondary prevention in newly diagnosed nonischemic cardiomyopathy patients with class II-III heart failure and an LVEF below 35%. There are device modifications that can improve function and use of the device and perhaps even expand its market and functionality, warranting reconsideration of its validity. Without changes, however, the LifeVest may just be dead on arrival.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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