Use of the Wearable Cardioverter Defibrillator as a Bridge to Implantable Cardioverter Defibrillator

Jonathan Weinstock, MD

KEYWORDS

• Sudden cardiac death • Wearable defibrillator • Cardiomyopathy • Ventricular arrhythmias

KEY POINTS

- The wearable cardioverter defibrillator has been shown to be effective in terminating ventricular arrhythmias in patients at risk for sudden cardiac death.
- There are numerous scenarios in which implant of a permanent implantable cardioverter defibrillator is temporarily contraindicated or not advisable and a wearable cardioverter defibrillator may be beneficial.
- There are no prospective randomized studies published that provide conclusive guidance toward the use of the wearable cardioverter defibrillator, and thus, patient management needs to be individualized based on the available data.

INTRODUCTION

The advent of the implantable cardioverter defibrillator (ICD) has revolutionized the primary and secondary prevention of sudden cardiac death (SCD). However, several potential situations exist in which the implantation of an ICD, either transvenous or subcutaneous, at a given point in time is not advisable or indicated for other reasons. The wearable cardioverter defibrillator (WCD) provides a potential temporary alternative to ICD implantation in such situations. This review summarizes the technical aspects of the WCD, efficacy, and potential indications for use as a bridge to an ICD.

THE WEARABLE CARDIOVERTER DEFIBRILLATOR

The WCD was approved for clinical use by the US Food and Drug Administration in 2001.[1] At the time of this writing, the device is produced by a single manufacturer (LifeVest; Zoll Medical Corporation, Chelmsford, MA, USA). Its application requires no surgical procedure, and unlike implanted ICD technology, requires significant participation from the patient. The device consists of a garment and a battery pack. The garment is customized to fit the individual patient's body habitus and contains 4 electrodes for cardiac rhythm sensing and 3 defibrillation pads arranged in a posterior to apical configuration. The battery pack functions as the monitor and defibrillator, is connected to the garment, and is carried with a shoulder strap or via a holster at the waist. The patient is provided with a battery charger and a modem. The WCD has the ability to store and transmit data remotely to a secure Internet portal, including electrocardiogram (ECG) recordings of events leading to

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Department of Medicine, Division of Cardiology, Tufts University School of Medicine, Cardiac Arrhythmia Center, Tufts Medical Center, 800 Washington Street, Boston, MA 02118, USA
E-mail address: Jweinstock1@tuftsmedicalcenter.org

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shocks, nonsustained arrhythmias above the rate cutoff, asystolic events, patient-initiated recordings, and patient compliance.

Rate cutoff parameters for ventricular tachycardia (VT) and ventricular fibrillation (VF) can be programmed as can the shock energy (between 75 and 150 J) for each shock. The VT zone can be programmed to between 120 and 250 bpm, up to the floor of the VF zone. The default parameters are 150 to 200 bpm for VT, greater than 200 bpm for VF, and 150 J per shock. The device can deliver a maximum of 5 shocks per episode. The garment requires replacement after an episode is treated. The WCD cannot provide any pacing.[2]

Once the WCD detects an arrhythmia above the prescribed rate cutoff, morphology analysis compares it with a template of the patient's baseline rhythm as well as other filters to attempt to exclude external interference. If the device algorithms confirm a ventricular arrhythmia, a series of patient responsiveness alerts are initiated, which include an audible alarm, vibration of elements of the garment, and a message on the monitor pack. A conscious patient has the ability to depress 2 buttons on the monitor simultaneously, which will abort the shock. If the shock is not aborted, gel is automatically applied by the device to the defibrillation pads, and a shock or shocks are delivered. Detection within the VT zone results in a synchronized shock, as opposed to the VF zone, which triggers an unsynchronized shock. The elapsed time from arrhythmia onset to shock delivery is approximately 45 to 50 seconds. That time consists of detection criteria of 5 to 10 seconds, arrhythmia confirmation of 10 seconds, and 25 seconds of the arrhythmia alarm mechanism, during which the patient can manually abort the shock.[3]

SENSING AND SHOCK EFFICACY

The sensing algorithm of the WCD has been reported to result in a high sensitivity (90%–100%) and specificity (98%–99%). The rate of inappropriate shocks in clinical studies has been low (0.5%–2% per month).[3–5] Data regarding efficacy of the WCD are comparable to implanted ICDs and are derived from induced VF and from clinical studies. Twenty-two episodes of VF induced during electrophysiology study were successfully terminated with either a 70- or a 100-J biphasic shock from a WCD in 12 patients, providing a wide safety margin up to 150 J from the device.[6] In a study of 8453 patient prescribed a WCD after myocardial infarction (MI), a total of 146 arrhythmia events occurred in 133 patients, with a successful conversion rate of 82%. The short-term survival rate in those patients who received a shock was 91%.[5] In a registry of 2000 patients prescribed a WCD, a total of 30 appropriate shocks in 22 patients were delivered, all of which were successful in terminating VT or VF. Of note, in that same registry, therapies for 90 true arrhythmic events in 22 patients were manually aborted by the patient.[4]

PATIENT COMPLIANCE

A key element in the potential efficacy of the WCD is patient adherence. Directions accompanying device use are to wear it at all times, other than during bathing. Factors limiting the use of the device most commonly relate to patient discomfort and limitation on lifestyle. In 2 large nonrandomized series of patients using a WCD, median daily use was 21.7 and 22.5 hours, respectively.[4,5] In published studies, 14% to 25% of patients stopped using the WCD prematurely mostly because of comfort issues.[5,6]

WEARABLE CARDIOVERTER DEFIBRILLATOR CLINICAL STUDIES

It is important to note that at this time there are no published randomized data to guide the use of the WCD. As such, patient care decisions are based on data from nonrandomized prospective studies or retrospective analyses of patients wearing the WCD.

The first major study to address the clinical use of the WCD was the Wearable Defibrillator Investigative Trial and Bridge to ICD in Patients at Risk of Arrhythmic Death (WEARIT/BIROAD) study.[7] The publication was the combined results of 2 separate investigations. The WEARIT study enrolled patients with a left ventricular ejection fraction (LVEF) of less than 30% and New York Heart Association (NYHA) class III to IV congestive heart failure (CHF) symptoms who were not eligible for an ICD based on indications at that time. The BIROAD study enrolled patients for 4 months with several factors deemed to be high risk, including patients who had experienced a recent MI with VT/VF within 48 hours, LVEF of less than 30% more than 3 days after an MI, or cardiac arrest more than 48 hours after the MI, but otherwise not a candidate for an ICD. Other inclusion criteria included a ventricular arrhythmia within 48 hours after coronary artery bypass graft (CABG), LVEF of less than 30% at least 3 days after CABG, cardiac arrest or syncope at least 48 hours after CABG, but not able to have an ICD implanted, ICD candidates at home who were not expected to receive an ICD for 4 months, or patients who had refused ICD implantation. A total of 289 patients were enrolled