The Role of the Wearable Cardioverter-Defibrillator In Contemporary Clinical Practice

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ABSTRACT. The implantable cardioverter-defibrillator (ICD) has been shown to improve survival in patients at high risk for sudden cardiac arrest (SCA). However, there remain situations in which an ICD may be inappropriate: the high risk for SCA is temporary, there is need for interruption of implanted ICD therapy (e.g. for infection), there is temporary inability to implant an ICD, there is bridge period to heart transplant, or there is refusal of an indicated ICD. In these situations a wearable cardioverter-defibrillator (WCD) can be used to protect against SCA during the bridging period. We review the potential role of the WCD in clinical practice and summarize the published studies detailing the use of the WCD.

KEYWORDS. Wearable cardioverter defibrillator, sudden cardiac arrest risk, ventricular arrhythmias, implantable cardioverter defibrillator.

Introduction

Sudden cardiac arrest (SCA) remains a major public health concern with an estimated 300,000–450,000 cases annually in the United States.1–3 Most SCAs are due to ventricular tachycardia (VT) or ventricular fibrillation (VF), and both of these arrhythmias can be successfully treated with defibrillation, especially if recognized and treated within seconds of onset.4 The implantable cardioverter-defibrillator (ICD) has been shown to improve overall survival in several populations at high risk for SCA. However, there are situations in which an ICD may be inappropriate or needs to be deferred. The wearable cardioverter-defibrillator (WCD) (LifeVest, ZOLL Lifecor Corporation, Pittsburgh, PA) is a US Food and Drug Administration (FDA) approved external device capable of automatic ventricular tachyarrhythmia detection and defibrillation. Approved for patients who are at risk for sudden cardiac death but are unable or unwilling to have an ICD, the WCD may provide protection in patients at risk for sudden cardiac death due to ventricular tachyarrhythmias but who are not or not yet candidates for protection using an ICD.

Description of the WCD

The device is composed of four dry, non-adhesive capacitive tantalum oxide monitoring electrodes, three defibrillation electrodes incorporated into a lightweight chest strap assembly, and a defibrillation unit carried on a waist belt (Figure 1). The monitoring electrodes are positioned circumferentially around the chest, held in place by tension from an elastic belt, and provide two surface electrocardiogram (ECG) leads. The defibrillation electrodes are positioned in a vest assembly for apex-posterior defibrillation.

WCD detection algorithm

Arrhythmia detection is programmed using rate criteria. The tachycardia detection rate is programmable for VF between 120 and 250 beats/minute and VF shock delay can be programmed from 25 to 55 seconds. The VT detection rate is programmable between 120 bpm to the VF setting. The default VT and VF detection rates are 150 and 200 bpm, respectively. The WCD detection algorithm uses heart rate, template matching, and persistence...
The heart rate is determined independently from 2 leads and incorporates a driven ground, analog and digital filters to reduce noise, falloff detection for each electrode, and review of each lead for loss of skin contact, noise and interference, including presence of high frequency signals and clipping. The signal is also compared to a morphology template recorded during device setup. This template matching algorithm uses a vectorcardiographic analysis that helps to distinguish VT from supraventricular tachycardia (SVT) when both leads appear to be on the skin without evidence of noise. If only one lead is usable, then template matching is not used, and rate, rate stability and persistence are used. The algorithm uses arrhythmia persistence (duration) rather than x of y beat criteria for detection of arrhythmia. In the absence of significant noise, the presence of an arrhythmia is signaled internally after 3 to 5 seconds, but the arrhythmia must persist another 10 secs before confirmation and declaration of an arrhythmia.

If an arrhythmia is detected, an escalating alarm sequence starts, including a vibration against the skin and audible tones. Although shocks may be transmitted to bystanders in physical contact with the patient being shocked by a WCD, a voice cautions bystanders to the impending shock. Patients are trained to hold a pair of response buttons during these alarms to avoid a shock while awake. Responding acts as a test of consciousness; if no response occurs, the device charges, extrudes gel from the defibrillation electrodes, and delivers up to five biphasic truncated exponential shocks of pre-programmable energy levels with a maximum output of 150 J. The WCD can also be used as an event monitor and has capabilities of symptom-triggered recording and trans-telephonic transmission of rhythm strips that can be made available to the patient’s treating physician for analysis. The WCD can be worn for years, although typically the device is used for weeks to months for temporary protection against SCA. The device may be removed for bathing, but no protection is afforded while the device is off, so it is advisable that caregivers or other persons be nearby during periods when the WCD is not worn.

Programming of the WCD

Although the VT detection rate can be programmed as low as 120 bpm, lower rates will usually need to be avoided to prevent inappropriate shocks and because antitachycardic pacing therapies are not available. Typical programming may be higher (e.g. 170–200 bpm) to avoid inappropriate shocks. VT shock delay may be programmed from 60 to 180 secs and additional shock delays to 30 secs are allowed at night. VT signals can allow R wave synchronized shock delivery, but if the R wave cannot be identified, unsynchronized shocks will be delivered. The shock energy is programmable from 75 to 150 joules. Up to 5 shocks per event may be programmed.

Recording capacity

The WCD stores ECGs from tachyarrhythmia events greater than a pre-programmed rate threshold with morphology that does not match a baseline template. The system defines such arrhythmias as ventricular arrhythmias. Buffering in the monitoring software captures 30 s of ECG signal prior to the determination of VT/VF and 15 s after the alarms stop. Asystole recordings are also triggered when ventricular rates drop below 20 bpm. Buffering in the monitoring software also stores 5 min of ECG data prior to asystole determinations. Current devices have an overall event ECG storage capacity of 75 min.

The WCD also records information about patient compliance, ECG signal quality, alarm history, and noise occurrence. Time/date stamps for device on/off switching, monitor connection to the electrodes, and electrode-to-skin contact are recorded. ECG and defibrillation electrode contact is determined by microampere AC signals similar to conventional monitoring.
systems. Compliance may be determined by assessing the time that the user had the device turned on, the belt connected, and at least one ECG lead contacting the skin.

Arrhythmia recordings from the WCD are available for physician review once stored data are transmitted via a modem to the manufacturer’s network. Treatments, patient compliance, ECG records, and system performance can be viewed using a secure password-protected website (https://wcdnet.lifecor.com/wcd/default.asp).

**Uses and potential indications**

Although the ICD has been shown to improve survival from SCA in high-risk patients, there remain situations in which an ICD may eventually prove to be inappropriate, or implantation may be too risky without evidence of survival benefit, or need to be delayed or become unnecessary when the arrhythmic substrate is temporary. The initial studies of ICD implantation for primary prevention of SCA excluded patients early after events, such as acute myocardial infarction (MI), coronary revascularization, or recent diagnosis of cardiomyopathy, and thus there has been controversy about the optimal timing of ICD implantation for primary prophylaxis against SCD in post myocardial infarction, post revascularization, and newly diagnosed cardiomyopathy patients. Although the SCD risk is elevated after MI in patients with left ventricular (LV) dysfunction or heart failure, ICD implantation for primary prevention of SCA is not currently indicated within 40 days after acute MI. ICD implantation may also need to be deferred in patients with cardiac thrombi, venous obstruction that precludes safe endovascular placement of ICD leads, infection, or surgical contraindications. In such situations a WCD may be an acceptable alternative approach or bridge therapy for prevention of sudden cardiac death. In summary, the WCD is indicated and should be considered for patients with a temporary high risk for SCD; for patients in need for interruption of implanted ICD therapy (e.g. for infection); and for patients where there is temporary inability to implant an ICD, bridge to heart transplant, or refusal of an indicated ICD. However, it should be noted that current approved devices do not have pacing capabilities and thus cannot provide therapy for bradycardic or asystolic events or antitachycardic pacing.

Circumstances in which the WCD may be useful and the published studies (Table 1) detailing the use of the device are outlined below.

**Effectiveness at detection and termination of VT/VF**

The efficacy of the WCD has been tested for induced VT/VF as well as in spontaneous events during clinical trials and after market release. The first published report of clinical use of first-generation WCDs in 1998 demonstrated successful termination of induced VT/VF in 9 of 10 patients in the catheterization laboratory with the first automatically delivered monophasic shock of 230 J. One patient had erroneously disconnected sensing electrodes, which prevented adequate VT detection. In a subsequent study with a newer generation of WCD, the device successfully detected and terminated VT/VF induced in the electrophysiology laboratory with 100% first shock success using 70–100 J biphasic shocks in a study of 22 episodes in 12 patients.

The Wearable Defibrillator Investigative Trial (WEARIT) and Bridge to ICD in Patients at Risk of Arrhythmic Death (BIROAD) studies were combined to form the WEARIT/BROAD trial, which is the only published prospective multicenter study that has evaluated the efficacy and safety of the device. A total of 289 patients used a WCD: 177 patients with symptomatic New York Heart Association (NYHA) functional class III or class IV heart failure with left ventricular ejection fraction (LVEF) <30% (WEARIT) and 112 patients at high risk for SCD after MI or coronary artery bypass graft (CABG) not receiving an ICD for up to 4 months (BIROAD). Over a mean use duration of approximately 3 months, six patients (2% of total patients) had arrhythmic events. There were six successful defibrillations in four patients out of eight attempts, giving a success rate of 75%. The two unsuccessful defibrillations occurred in patients with incorrectly placed therapy electrodes (e.g. defibrillating pads reversed and not directed to the skin), with one sudden death in a patient with reversed leads. Twelve deaths occurred during the study. Six were sudden deaths: five not wearing and one incorrectly wearing the device. Six inappropriate shock episodes occurred during 901 months of patient use (0.67% unnecessary shocks per month of use). Most patients tolerated the device, although 68 patients quit participating in the study due to comfort issues or adverse reactions. The results of the WEARIT/BROAD study suggest that a wearable defibrillator is beneficial in detecting and effectively treating ventricular tachyarhythmias in patients at high risk for sudden death who are not clear candidates for an ICD and may be useful as a bridge to transplantation or ICD in some patients. However, the sudden deaths in patients not wearing or incorrectly wearing the WCD highlighted the need for compliance and proper patient instruction for effective use of this device.

In another study of 354 patients using the WCD in Germany, over a mean wear time of 106 days, 27 patients (7.6%) experienced 246 arrhythmic episodes while wearing the WCD. Of these, 228 were sustained VT/VF, eight non-sustained ventricular tachycardia (NSVT), and eight other arrhythmia detections (sinus tachycardia or other SVT, none leading to an inappropriate shock due to use of the response buttons). In this study 139 VT/VF or torsade de pointes episodes occurred in a female patient with type 2 long QT syndrome over a 7-year period; all but six terminated spontaneously while she withheld shocks, sometimes this occurred 60–80 s after onset of tachycardia and the patient was still conscious and able to push the response buttons. In the remaining patients, many were able to withhold therapy for VT with events
<table>
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<tr>
<td>Auricchio, et.al. (12)</td>
<td>1998</td>
<td>10</td>
<td>Clinical testing of device for treating induced VT/VF</td>
<td>N/A</td>
<td>9/10 (90%) (1 patient erroneously discontinued sensing electrode so VT could not be detected)</td>
<td>None</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reek, et.al. (13)</td>
<td>2003</td>
<td>12</td>
<td>Clinical testing of newer generation of WCD for treating induced VT/VF</td>
<td>N/A</td>
<td>22/22 (100%)</td>
<td>None</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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<td>Lang, et.al.(26)</td>
<td>2003</td>
<td>13</td>
<td>Status 1B on heart transplant list</td>
<td>0.8</td>
<td>No VT/VF events while wearing the WCD</td>
<td>1 died on inotropes while not wearing WCD</td>
<td>1 shock for atrial fibrillation</td>
<td>Not reported</td>
</tr>
<tr>
<td>Feldman, et.al. WEARIT/BIROAD (14)</td>
<td>2004</td>
<td>289</td>
<td>WEARIT NYHA FC III,IV HF BIROAD post MI/CABG</td>
<td>3.4 WEARIT 2.6 BIROAD</td>
<td>6/8 (75%) (2 failures due to electrode malplacement)</td>
<td>6 nonsudden 5 sudden (not wearing WCD) 1 sudden (reversed leads)</td>
<td>6 (0.67%/mo) 30% WEARIT 11% BIROAD</td>
<td></td>
</tr>
<tr>
<td>Klein, et.al.(11)</td>
<td>2010</td>
<td>354</td>
<td>Various: Early post MI (39%) Post CABG (25%) Risk stratification (18%) ICD explants (10 %) Pretransplant (6%) Delay/refusal of ICD (2%)</td>
<td>3.5</td>
<td>246 events in 27 pts (5 NSVT, 3 ST/SVT, 2 asystole (both died); 139 in 1 pt with LQTS, all but 6 terminated spontaneously while patient withheld shock; 1st shock success 95% in rest</td>
<td>16 - 2 with asystole, 1 due to misplaced electrodes</td>
<td>3 (0.8%) 11 (3.1%)</td>
<td></td>
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<tr>
<td>Chung, et. al.(16)</td>
<td>2010</td>
<td>3569</td>
<td>Various</td>
<td>1.75</td>
<td>79/80 (99%)</td>
<td>28 (4 recurrent VT/VF, 1 bystander prevention of therapy, 2 ECG disruption, 1 unipolar PM inhibition; 3 no WCD events recorded; 17 asystole)</td>
<td>67 (1.9%, 1.4%/mo)</td>
<td>N/A</td>
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last 15 s to 20 min before the tachycardias terminated. Treatment of VT/VF was needed for 21 VT/VF episodes in 11 other patients. In 20/21 VT/VF events the first shock was successful (95%). Two discharges for the same VT episode were necessary for one of the 21 VT/VF episodes.

In a US post-marketing study of 3569 patients, 80 sustained VT/VF events occurred in 59 patients (1.7% of the total).15,16 First shock success was 76/76 (100%) among unconscious patients and 79/80 (99%) for all patients. The single failure to convert VT/VF on the first attempt occurred when a conscious patient with sustained VT allowed himself to be shocked 10 min after using the response button and subsequently converted to sinus rhythm on pharmacologic therapy. Eight patients died after successful conversion of unconscious VT/VF with survival occurring in 89.5% of events. Of these, four died due to recurrent VT/VF after initial recovery and arrival of emergency personnel, one due to a bystander preventing therapy, two due to ECG signal disruption from a fall, and one due to inhibition of detection from a unipolar pacemaker. This study also reported that long-term survival in WCD patients was similar to a cohort of ICD patients. In summary, shock efficacy appeared to be similar to that of shocks reported with ICDs. However, some SCDs may still occur due to not wearing the device, bystander interference, ECG signal disruption, or unipolar pacing inhibiting detection. These results have again highlighted the importance of patient education and promotion of compliance in using the WCD.

Table 1: Continued

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<td>Dillon, et.al. (5)</td>
<td>2010</td>
<td>2105</td>
<td>Various Evaluation of effectiveness of arrhythmia detection algorithm in patients who wore device in 2006</td>
<td>1.2</td>
<td>53/54 (98%)</td>
<td>1 (due to unipolar pacemaker interference with arrhythmia detection)</td>
<td>34 (0.99 per 100 patient months of use)</td>
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Evidence of efficacy for specific indications

**Newly diagnosed NYHA functional class III or IV heart failure and LVEF<30–35%**

The Sudden Cardiac Death Heart Failure Trial (SCD-HeFT) is the largest primary prevention defibrillator trial to date,6 enrolling 2,521 patients with NYHA class II–III heart failure LVEF ≤35% due to ischemic (52%) or non-ischemic (48%) cardiomyopathy. Patients were randomized to conventional medical therapy with placebo, amiodarone, or ICD therapy. Compared with placebo, ICD therapy reduced all-cause mortality from 29% to 22% at 45 months (p=0.007). However, patients who were within 3 months of diagnosis of heart failure were excluded. Largely based on the enrollment criteria of SCD-HeFT, reimbursement for ICD implantation excluded patients early after diagnosis of heart failure, and guidelines suggest exclusion of reversible causes of transient LV dysfunction and optimization of medical therapy prior to device implantation.10 However, in the largest prospective trial of exclusively non-ischemic patients, DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation) randomized 458 patients with EF ≤35% and non-sustained VT to standard medical therapy or single-chamber ICD.17 The primary endpoint of all-cause mortality did not reach statistical significance but showed a trend towards improved mortality at 29 months (14.1% control group versus 7.2%, p=0.08). Prespecified subgroup analysis of the DEFINITE trial showed that recently diagnosed patients did not benefit any less than those with a more remote diagnosis. Furthermore, it has been shown that there were similar occurrences of lethal arrhythmias irrespective of diagnosis duration in dilated non-ischemic cardiomyopathy patients.18 Should ICD implantation be deferred early after the diagnosis of heart failure, while awaiting recovery, the WCD may provide protection while awaiting improvement in LV function. In a recently published US post-marketing study, 0.7% of 546 patients prescribed a WCD for recently diagnosed non-ischemic cardiomyopathy required shocks for VT/VF over a mean follow-up period of 56.5 days.15,16 Although this event rate was relatively low, for selected patients with severe but potentially reversible cardiomyopathy, such as tachycardia- or myocarditis-associated cardiomyopathy, the WCD appeared to be useful as a bridge to LV improvement, ICD implantation, or, if needed, transplantation.

**Early after acute MI with low left ventricular ejection fraction ≤35%**

The 2008 American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS) guidelines for device therapy recommend waiting at least 40 days after acute MI before implantation of an ICD for primary prevention of sudden cardiac death. These recommendations are based on the findings of the Defibrillators in Acute Myocardial Infarction trial (DINAMIT),19 later corroborated by the Immediate Risk

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Stratification Improved Survival (IRIS) trial,\textsuperscript{20} which reported that early ICD implantation 6–40 days after acute MI with LVEF $\leq$ 35\% did not improve early overall mortality. Although there was a reduction in arrhythmic deaths, this improvement was counterbalanced by a higher risk for non-arrhythmic deaths during this early period. A post hoc MADIT II analysis also suggested that ICD implantation was beneficial in patients with remote MI (≥18 months), although very few patients were implanted early. Nevertheless, the optimal timing of defibrillator insertion after MI remains unresolved.\textsuperscript{9–11,12,21}

The Valsartan in Acute Myocardial Infarction Trial (VALIANT)\textsuperscript{9} showed that patients with reduced systolic function were at the highest risk for sudden cardiac death in the first 30 days after MI. A recent subanalysis of SCDHeFT reported that among 712 patients with history of MI, there was no evidence of differential mortality benefit with ICDs as a function of time after implant. The study concluded that the benefit of the ICD is not restricted to remote MI only.\textsuperscript{22} Furthermore, a time-dependent variability to risk of sudden death in post-MI and post-revascularization patients has been reported with a higher risk early after event that then somewhat plateaux over time.\textsuperscript{23} With the potential for higher sudden death risk in patients with low ventricular function early after MI, the WCD has been used for protection of appropriately selected high-risk patients in this group while awaiting recovery and reassessment of LV function after 40 days. In a study of 354 patients wearing a WCD in Germany, arrhythmic events occurred in 5\% of the early post-acute MI patients.\textsuperscript{11} In a post-market study in the United States, 2.9\% of patients with post-MI ischemic cardiomyopathy received appropriate WCD shocks for episodes of VT/VF over a mean follow-up of 47.8 days.\textsuperscript{15,16} The role of the WCD early after MI is being studied in the Vest Prevention of Early Sudden Death Trial/ Prediction of ICD Therapies Study (VEST PREDICTS), an ongoing randomized study that is evaluating whether use of the WCD reduces overall mortality in the first 60 days after acute MI. (Clinicaltrials.gov identifier NCT00628966).

**Early post-surgical revascularization patients with LVEF $\leq$ 35\%**

Patients with significant LV dysfunction have higher 30-day mortality rates after CABG. However, similar to the situation early after acute MI, this population may be at risk for non-arrhythmic causes of death, and the benefit of early implantation of ICDs for primary prevention of SCD early after revascularization has not been well established. An early study of epicardial ICD implantation at the time of CABG (CABG Patch) did not report survival benefits,\textsuperscript{24} and several other primary prevention studies have excluded patients within 1–3 months after coronary revascularization.\textsuperscript{6–8}

As shown in the WEARIT/BIROAD studies, the WCD may provide useful bridge protection for the first 1–3 months after CABG, allowing healing and potential recovery of LV function.\textsuperscript{14} In the study of 354 patients who wore the WCD in Germany, 25\% of the WCD use was for patients in the early phase after CABG associated with pre- or early postoperative LV dysfunction, prolonged or difficult hemodynamic recovery, or early postoperative life-threatening ventricular arrhythmias.\textsuperscript{11} The WCD was prescribed for 3 months with an arrhythmia event rate of 7\%. In a study of 3569 patients in the United States using the WCD, 8.9\% of WCD use was for post-CABG indications; appropriate VT/VF shocks occurred in 0.8\% of these patients over a mean follow-up of 46.5 days.\textsuperscript{15,16} In patients with low LV function prior to or after CABG, LVEF should be reassessed at follow-up. If sustained VT/VF has occurred, or if the LVEF remains $\leq$ 35\% after the first 3 months after CABG, transition to an ICD is usually indicated.\textsuperscript{10}

**Bridge to indicated or interrupted ICD therapy**

In some patients with indications for ICD therapy as detailed in the 2008 ACC/AHA/HRS device therapy guidelines,\textsuperscript{10} the implant procedure may need to be delayed or deferred due to comorbid conditions, infection, recovery from surgery, or vascular access issues. Patients with ICDs may develop device infection or endocarditis that requires system extraction. Unless the patient is pacemaker dependent, reimplantation in some patients may be deferred until the infection is completely cleared after an appropriate course of antibiotics. In addition, ICD or lead malfunctions may result in a vulnerable period that leaves the patient unprotected until the device or leads can be replaced. The WCD may provide a bridge of protection for VT/VF during these periods until ICD therapy can be implanted or resumed. In the German study,\textsuperscript{17} WCDs were used in 10\% of patients after ICD explantation, with arrhythmic events reported in 8\%. In the US post-market study the device was used in ICD explanted patients (23.4\% of the 3,569 patients), with arrhythmic events occurring in 5.2\% of patients.\textsuperscript{16}

**Bridge to heart transplant**

Patients with severe heart failure awaiting heart transplantation represent a group at particular high risk for SCD.\textsuperscript{25} Implantation of ICDs is often recommended for patients discharged while awaiting transplantation. However, in patients without ICDs, the WCD may be a reasonable non-invasive alternative approach, especially if the waiting time is expected to be short, as in patients with blood groups A and B.\textsuperscript{26} In a study of 91 UNOS Status 1B cardiac transplant candidates discharged home, 25 had an ICD and 13 a WCD.\textsuperscript{26} Two patients died suddenly at home: one on inotropes not wearing his WCD, and another who declined use of a WCD. In the 13 patients wearing the WCD (mean 566 ± 955 h), three asymptomatic events occurred with one shock delivered for rapid atrial fibrillation. In the WEARIT study of WCD...
use in 177 patients with NYHA functional class III or IV heart failure, one patient received two appropriate successful defibrillations. In the German study of 354 WCD patients, 6% wore the WCD while awaiting heart transplantation and experienced a high arrhythmic event incidence of 11%. The International Society for Heart and Lung Transplantation Guidelines state as a class I recommendation that an ICD or WCD should be provided for Status 1B patients who are discharged home given that the wait for transplantation remains significant. The role of WCD therapy is less clear in patients with left ventricular assist devices (LVADs). With LVADs, circulatory support may be sufficient even in the event of VT/VF. However, a recent study reported the presence of an implanted ICD was associated with improved survival in patients undergoing LVAD support. Whether the WCD could impart similar survival benefits in patients awaiting transplantation with VAD support has yet to be studied.

**Syncope of uncertain etiology but high risk for VT/VF**

Patients who have syncope, but without cardiac arrest, documented arrhythmias, or need for resuscitation, may still have high-risk features or potentially reversible causes that warrant use of a WCD during prolonged risk stratification phases. In such patients in whom ICD implantation may not be immediately indicated or feasible, simple ambulatory event monitoring will not provide therapies in the event of a life-threatening arrhythmia. A WCD can serve the dual purpose of event monitoring while also having the capability of treating ventricular tachyarrhythmias with defibrillation. In the Klein, et al, study of 354 patients, 18% wore the WCD during a prolonged risk stratification phase after initial evaluation for syncope of undetermined etiology, including 10% of patients with myocarditis or newly detected cardiomyopathy with either syncope of unknown origin or survival of an episode of cardiac arrest (5%). In this group, the arrhythmia event rate was 13%. Thus, the WCD may be able to bridge this period of prolonged risk stratification until arrhythmic risk can be ascertained or improved.

**Bridging while undergoing risk stratification in patients with inherited arrhythmogenic disorders**

Patients with inherited arrhythmogenic disorders such as congenital long QT syndrome, short QT syndrome, arrhythmogenic right ventricular dysplasia, catecholaminergic polymorphic VT, right ventricular outflow tract VT, LV outflow tract VT, and Brugada syndrome often have a varied and sometimes difficult to predict clinical course. While ICD implantation is appropriate and effective for the higher-risk patients, prolonged risk stratification and attempts at therapeutic strategies may involve electrophysiologic testing, event loop recording, genetic testing, trials of beta-blockers, antiarrhythmic agents or other specific medications such as verapamil, or radiofrequency catheter ablation before a final determination about the definite need for placement of ICD implantation can be made. The WCD can function as an effective bridge and protection for patients while they undergo further risk stratification and decision about the need for an ICD.

**Other potential uses**

Although not yet studied, other potential uses of the WCD proposed for future study include high-risk patients undergoing hemodialysis, a group of patients at high risk for infection and other complications of ICD therapy, as well as patients needing monitoring for proarrhythmia during initiation of antiarrhythmic drug loading.

**Use of the wearable cardioverter-defibrillator in children**

Experience with the WCD is limited in children, but a small series has been reported by Everitt and Saarel. In this study four children aged 9–17 years had cardiomyopathy related to anthracycline-induced cardiomyopathy, with two using the WCD as a bridge to transplant. Compliance was problematic for a 14-year-old boy who had a VF arrest with the vest unfastened. He was resuscitated by emergency personnel and eventually discharged home with additional instruction, but died of multisystem organ failure. Of note, two children, aged 15 and 17, required adjustment of the WCD with downsizing or refitting of the vest to achieve better electrode contact and reduction in noise. Thus, in children special attention is required to assure compliance and fitting for optimal use.

**Bradycardia events**

It is important to note that the current WCD cannot deliver pacing therapies to treat bradycardia events. In the German study, two asystole events were recorded, and both patients died. In the US post-marketing registry study, 23 of 3,569 patients (0.6%) experienced asystolic events. Asystole was associated with a high mortality rate with death occurring in 17 (74%).

**Inappropriate shocks**

In both ICDs and WCDs, shocks may be inappropriately delivered due to noise, device malfunction, or detection of supraventricular tachycardias above the rate criteria. In the WEARIT/BIROAD studies, six unnecessary shock episodes (in the absence of a ventricular tachyarrhythmia) occurred in six patients wearing the WCD (0.67%/month over 901 months of patient use). In the German report of 354 patients wearing the WCD, only three inappropriate shocks occurred, all due to noise and none.
due to sinus tachycardia or other SVT. In the United States study of 3,569 patients during 4,788 months of WCD use, inappropriate shocks occurred in 1.9% (1.4% per month). Reported inappropriate shock rates appear to be similar to those of the ICD, and potentially could be lessened by the ability of the patient to abort shocks while awake by pressing response buttons. Also, when noise occurs, the WCD emits a noise alarm. Recording of noise can often be stopped by body movement or tightening of the electrode belt, and shocks can be avoided by pushing the response buttons.

**Patient acceptance and compliance**

Efficacy of the WCD in the prevention of SCD is highly dependent on patient compliance with appropriate wearing of the device. In the WEARIT/BIROAD study, 22.5% of the 289 subjects withdrew before reaching a study endpoint with size and weight of the monitor being the most frequent reason. The WCD was discontinued for comfort or lifestyle issues in 30% of WEARIT patients and 11% of BIROAD patients. Skin rash and/or itching occurred in 17 patients. In the German study by Klein et al., of 354 patients, the mean wear time was 106 days (range 12 days to >7 years) with mean daily wearing time of 21.3 h/patient. Excellent compliance (defined as 22–24 h/day) was achieved in 72%, good compliance (20–22 h/day) in 13%, moderate compliance (12–20 h) in 10%, and poor compliance (<12 h) in 5%. In this study, 60 of 86 patients wearing the WCD in 2007 underwent an acceptance survey. Half complained of the weight of the device, and half reported sleeping problems, particularly when noise alarms occurred more often. However, safety and trust in the device was reported to be the most important factor for almost all patients, and 25% of the patients preferred the WCD to the ICD. In the US post-market study of 3,569 patients, median and mean daily use was 21.7 h and 19.9 h, respectively. Daily use was >90% in 52% of patients and >80% in 71% of patients. Longer duration of monitoring correlated with higher compliance rates, with patients using the WCD >60 days averaging 20.8 h/day, and patients using it <15 days averaging 17.2 h. The WCD use was stopped prematurely in 14.2% because of comfort issues or adverse reactions, primarily complaining of size and weight of the monitor. The rate of WCD discontinuation appeared similar to a study reporting that 15% of patients stop using aspirin, angiotensin-converting enzyme inhibitors and beta-blockers within 30 days of MI. Improved compliance and acceptance may be seen in newer current devices, which are 40% smaller in size and weight. Because compliance is critical to device effectiveness, proper comfortable fitting and intensive education are indicated to ensure and reinforce the importance of continuous use.

**Contraindications/cautions**

There is one report in the literature of a fatal device–device interaction between the WCD and a unipolar pacing system. An 18-year-old patient listed for cardiac transplantation because of his failing Fontan developed VT that was initially detected by the WCD. However, large unipolar pacing artifacts and specific WCD arrhythmia detection algorithms caused the WCD to revert to non-recognition of the arrhythmia, which led to the patient’s death. Because unipolar pacing devices interfere with arrhythmia recognition, patients with unipolar atrial and ventricular pacing devices should not use the WCD. The wearable defibrillator should also be used cautiously in patients who have difficulty hearing alarms or pushing buttons. These abilities are important to prevent inappropriate shocks and shocks while conscious.

**Limitations of the WCD**

The WCD is limited by its external nature, requiring patient interaction and compliance for effective protection against SCD. Proper fitting is required to achieve adequate skin contact to avoid noise and frequent alarms. The device cannot be worn while showering or bathing; it is recommended that caregivers or other people be in close proximity during interruption of WCD use. Compliance can also be inhibited by the weight of the device and discomfort from the vest. The occurrence of SCD in patients from bystander intervention, ECG signal disruption, or unipolar pacing artifacts inhibiting tachycardia detection also highlights the need for proper patient instruction and patient selection. In addition, the WCD currently has no capability for treating asystolic events, which are associated with a high mortality rate. The WCD is not designed to monitor for or treat atrial arrhythmias, although diagnosis may be made by manual inspection of recorded ECGs. Finally, the WCD cannot provide antitachycardic pacing, which can reduce patient shocks. With these limitations, should an ICD be indicated, implantation of an ICD would be preferable and perhaps significantly more efficacious than the WCD, because patient compliance is irrelevant to ICD therapy, asystolic events could be treated, and antitachycardia pacing may be useful to avoid shocks. Nevertheless, should ICD implantation need to be deferred, a WCD may provide useful temporary protection.

**Summary**

The WCD is an externally worn device capable of automatic ventricular tachyarrhythmia detection and termination. Although studies have reported efficacy similar to that of implanted ICDs in terms of survival and first shock efficacy, the WCD is limited by its inherent need for patient interaction and compliance. Nevertheless, the WCD can provide useful protection against SCD for a variety of indications, including early after MI or coronary revascularization with low LV function, as a bridge for newly diagnosed non-ischemic cardiomyopathy, syncope, or need for prolonged risk stratification with need for SCD prevention, or as a
bridge to transplantation or to indicated or interrupted ICD therapy. However, proper fitting and patient instruction regarding use and compliance with the WCD are vital to ensuring efficacy of the WCD in preventing SCD. Continuous and future developments mirroring ICD features are desirable and may include provision of external emergency pacing for asystolic events and automatic wireless transmission of data.

References


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