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Value of The Wearable Cardioverter Defibrillator (WCD) as a Bridging-Therapy before Implantation of a Cardioverter Defibrillator (ICD)

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Abstract

Wearable cardioverter defibrillators (WCD), initially available in 2002, have recently experienced more routine use in many institutions as a means of preventing sudden cardiac death (SCD) prior to implantable cardioverter defibrillator (ICD) evaluation or implantation. WCD differ from ICD by their noninvasive nature, making them well suited for patient populations who have a chance for significant cardiac recovery (such as after an acute myocardial infarction).

Despite their noninvasive nature, WCD treatment of sustained ventricular tachyarrhythmias is highly successful. An additional feature is the use of response buttons, which reduces the number of conscious shocks. Duration of use varies by condition but is typically several weeks to several months. Numerous studies have shown good compliance with WCD use and excellent efficacy. Although few prospective studies have been published, several are in progress including a randomized control trial of high risk patients after myocardial infarction.

WCD use is rapidly gaining popularity for patients with recent myocardial infarction, recent-onset cardiomyopathies, and acute or subacute myocarditis. Surgical delays in implanting an indicated ICD or after ICD removal are also common. WCD removal occurs when the patient either qualifies for an ICD implantation or is determined to no longer have elevated SCD risk.

Introduction

Sudden cardiac death (SCD) is a common mode of mortality in Western countries, reported to account for 81 deaths per 100,000 person-years in Germany.[1] While SCD may result from bradyarrhythmias, the most common initial life-threatening arrhythmias are believed to be ventricular tachyarrhythmias.[2,3] Defibrillation therapy, if provided timely, is highly effective in reversing ventricular tachyarrhythmias and aborting SCD.[4]

Implantable cardioverter defibrillators (ICD) have demonstrated efficacy in reducing SCD and mortality in general among specific populations identified to have high SCD risk.[5,6,7,8,9,10] However, ICD therapy is not without hazards and due to its invasive nature is generally reserved for patients with permanent SCD risk.

Key Words:
Implantable Cardioverter Defibrillator, Sudden Cardiac Death, Wearable Cardioverter Defibrillator, Ventricular Tachyarrhythmia.

Disclosures:
None.

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Still, there remain patient populations with high SCD risk that are temporary or changeable due to evolving cardiac conditions, and may be better served by non-invasive therapy. For some patients hospitalization for cardiac monitoring (with defibrillation therapy provided by medical personnel) is a rational choice, but in general this solution cannot be justified for long periods of time (i.e., weeks or months). The gap between hospitalization and ICD implantation remains a difficult decision for physicians. During this time a wearable cardioverter defibrillator (WCD) is an appropriate therapeutic option for many patients.

Since first FDA approved in 2001 and CE marked the same year, the WCD has been used on more than 150,000 patients[12] and use continues to grow in Europe and the USA. However, few prospective studies and no randomized trials have been published. In this article the WCD will be reviewed using published data as well as personal experience.

Device Description

The WCD has been described in technical detail several times[13,14,15,16] [figure 1]. In general, it functions similarly to an ICD in that it automatically detects and treats ventricular tachyarrhythmias (VT/VF). However, it has several important differences. First, the WCD delivers a sequence of escalating alarms whenever VT/VF is detected. These alarms are a minimum of 30 seconds in duration. As a result the typical time from arrhythmia onset to shock delivery

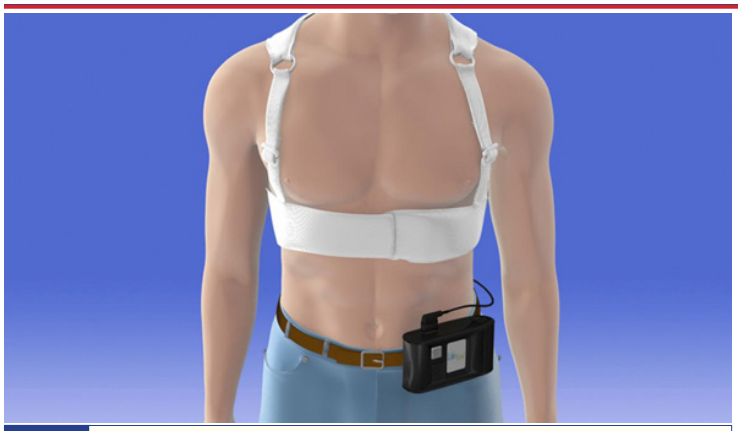

Figure 1: WCD device

is 45 seconds (detection and confirmation time included). As the detection algorithm operates continuously through the alarms, non-sustained arrhythmias (i.e., less than 30 seconds in duration) are not treated by design. Second, a conscious patient may prevent a shock by holding the two response buttons of the WCD. Thus, almost all treated ventricular arrhythmias occur in unconscious patients who generally do not remember the treatment itself. This combination (unconscious, sustained VT/VF) meets the classic definition of sudden cardiac arrest.[17]

The treatment shock (150 joules in a truncated exponential biphasic waveform) delivered by a WCD is similar to many external defibrillators. However, the 98% first shock success in commercial use[12] is higher than generally reported during resuscitation trials whether community-based or inpatient.[18] This success is in part due to the speed by which defibrillation occurs, although other factors such as the apex-posterior defibrillation pathway may contribute.[19] In a study of induced VT/VF, WCD defibrillation using 70 joules was successful in 10/10 attempts.[20] Hence, 150 joules likely represents a reasonable margin of safety for WCD users.

The WCD is presently available from only one manufacturer (ZOLL, Pittsburgh, USA). From the time of commercial introduction to the present LifeVest 4000 device, the size and weight of the design has decreased significantly while maintaining the essential features of detection and treatment of VT/VF. Additional enhancements were also added such as automatic downloading of device-stored information, increased stored memory and improvements to benefit patient-device interactions.

The manufacturer has maintained a website since inception for viewing downloaded information including daily use and ECG recordings of alarms received by patients. In the current version of the website it is possible to arrange for automated alerts (email or fax messages) of treatments, compliance and other data. In our practice, we do not use the automation and instead rely instead upon surveillance of the website at a time of our convenience. We find that significant events requiring immediate attention, such as treatments, are reported rapidly by patients and/or witnesses.

Prior Studies

There are a few prospective studies of WCD performance and many retrospective analyses of specific populations. The regulatory approval study for the FDA (WEARIT/BIROAD) reported 6 of 8 VT/VF events were successfully resuscitated and only 6 inappropriate shocks occurred over 900 patient-months of monitoring.[21] The study was designed to compare WCD resuscitation rates to a historical control of 25% success. Longer term mortality was not a study feature, as successful resuscitation in these populations (transplant listed, acute myocardial infarction with ventricular dysfunction, or recent CABG surgery with ventricular dysfunction) would lead to ICD implantation rather than continued WCD use. In essence, the WCD was considered bridge therapy to cardiac transplantation, ICD implantation, or improvement in cardiac function.

The WEARIT II registry has completed US enrollment of 2,000 patients and is awaiting completion of one year follow-up data collection. An interim report after all subjects completed WCD use revealed that there were 120 sustained VT/VF episodes during WCD use in 41 patients (2% of the patient population). Interestingly, only 30 of the episodes were actually treated by the WCD. The other 90 sustained VT/VF episodes were not treated due to response button use by conscious patients.[23]

There are two randomized control trials of WCD use that are currently enrolling subjects. The Vest Prevention of Early Sudden Death Trial (VEST) will examine whether WCD use can reduce SCD among patients with an ejection fraction ≤35% during the initial three months following myocardial infarction. Started in 2008, the study plans to compete enrollment of 1900 subjects in 2016. In the background of DINAMIT[24] and IRIS[25] failing to show utility of ICD implantation early after myocardial infarction in similar patients, the results will be of great interest to the medical community.

The second randomized control trial, WCD use in hemodialysis patients (WED-HED), began enrolling in 2015 and plans to complete enrollment of up to 2,600 subjects by 2019. It will examine the effect of WCD use on SCD among patients 50 years of age or older during the first six months after hemodialysis initiation. In contrast to most trials of primary prevention of SCD, subjects must have an ejection fraction over 35%. Hemodialysis patients are well known to have a high mortality rate, particularly during the first months after initiation, and sudden death accounts for about 25% of mortality regardless of ejection fraction.[26]

There are numerous retrospective analyses using commercial data prospectively collected by the manufacturer. Most are collections of smaller specific patient subgroups such as congenital heart disease[27] or children[28, 29] but three deserve mention as significant evidence of safety and efficacy in real-world application.

The first involves 3,569 patients, which represented all US WCD users between 2002 and 2006.[30] These patients had a median daily use of 21.7 hours and a mean duration of use of 52 days. While wearing the WCD, 59 patients had 80 VT/VF treated. Of 80 VT/VF events, 79 were converted on the first shock. However, 8 patients died after treatment (4 while under medical care, 2 due to signal disruption, 1 pacemaker interaction, and 1 bystander interference). Other deaths during WCD wear were due to asystole (17 deaths), respiratory arrest (2 deaths) and pulseless electrical activity (1 death). This analysis indicates that the large majority of patients are able to use the WCD properly, that most sudden cardiac arrests begin as VT/VF events, and that the WCD is highly effective in converting such arrhythmias. Lastly, the authors compared WCD use to ICD use and found similar survival.

Another study by the same group compared propensity-matched revascularized (post-CABG surgery or PCI) patients who either used a WCD or were part of a registry maintained by the institution.[31] All patients had significant ventricular dysfunction (ejection fraction

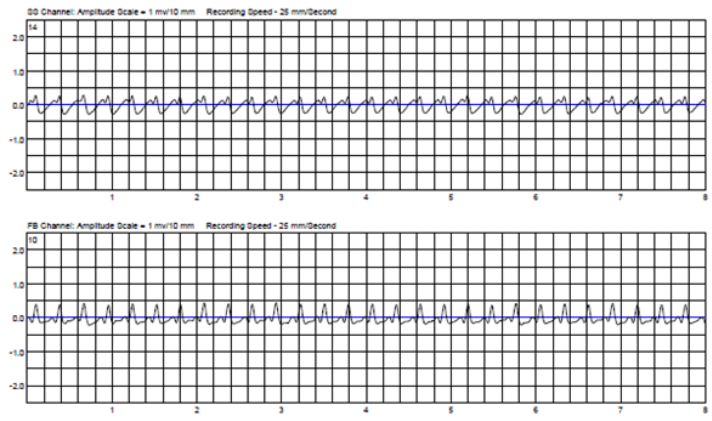

Figure 2: ECG of patient's VT event

≤35%). The mortality at 90 days was found to be lower for WCD users (7% mortality compared to 3% in WCD users for CABG patients, 10% to 2% for PCI patients) and this effect persisted after propensity matching. The improved survival was not entirely attributable to the detection and treatment of V/VF events as only 1.3% of patients had an appropriate therapy. The authors speculated the larger than expected difference may have been due to the fact that WCD users received more consistent follow-up for ICD evaluation and/or that the ECG monitoring may have revealed additional treatable conditions. Notably, monthly mortality was significantly higher in the first three months of follow-up for both groups.

The final study used the outcomes of 8,453 patients who wore a WCD after acute myocardial infarction.[32] A total of 133 patients (1.6%) were appropriately treated and 91% were successfully resuscitated. The time from index myocardial infarction to treatment was a median of 16 days, with 75% of treatments occurring in the first month and 96% within the first three months. This parallels the well-known early mortality of these patients. Patients who were resuscitated had a one year survival rate of 71%. This study demonstrates that patients selected for SCD risk are most likely to have a sudden cardiac arrest event early, before ICD consideration, and that resuscitated patients have a promising survival trend after WCD use has ended.

First-Hand WCD Experience

At our institution, we have used the WCD on a regular basis since mid-2010. Our experience with over 225 patients mirrors the commercial findings of the US, that is, we find the WCD is well tolerated by patients. A subset was presented during the 2013 fall meeting of the Germany Cardiology Society. In that subgroup, patients used the WCD a median of 22 hours per day and the average duration of use was 72 days. There were no treatments, but one patient experienced a conscious VT and successfully used the response buttons for 55 minutes, preventing a conscious shock [figure 2]. This patient subsequently received an ICD. This patient exemplifies two points. First, the WCD may deliver fewer appropriate shocks than an ICD as conscious patients can prevent being shocked on VT. Reducing the numbers of shocks in ICD patients delivered has recently been found to improve mortality.[33,34,35,36,37,38] Second, without the monitoring of the WCD this event may have been missed and the patient would have not received an ICD. Monitoring for sustained VT is an underappreciated, yet very valuable, aspect of WCD therapy.

As only 43% of our patients needed permanent protection with an ICD, one of the major advantages of WCD use lies in the fact that it was easily removed after medical optimization or simple time permits cardiac function to recover. An extra 2 to 3 months is a significant amount of time for evaluation before deciding on permanent therapy that is not completely benign. While ICD therapy clearly improves survival in defined populations for some patients, other patients will experience unnecessary painful shocks, device infections, and other morbidities.[39]

Discussion/Patient Selection

The WCD is best utilized as a method of bridging patients over high risk periods for SCD until ICD implantation or evaluation can occur. At our institution, we most frequently use the WCD for patients who have significant ventricular dysfunction, thus raising SCD risk, but also have a reasonable chance of recovering cardiac function. In addition, we use the WCD when patients have an uncertain risk of SCD, such as patients who may have a genetic predisposition to SCD but have not yet undergone a full evaluation, and for discharging patients safely when an ICD is indicated but cannot be implanted due to a surgical contraindication.

Patients who have a chance of cardiac recovery are perhaps the most exciting use for WCD. These patients have experienced a recent cardiac event (acute myocardial infarction, revascularization, or diagnosis of non-ischemic cardiomyopathy), have dilated cardiomyopathy requiring medical optimization, or have acute or subacute myocarditis. In all of these patients groups, immediate ICD implantation is not recommended until disease stabilization is established.[40,41]

In our case series, myocarditis was a frequent diagnosis, accounting for 45% of the patients. Prior to the WCD, myocarditis patients presented a difficult decision as the majority will recover yet significant SCD risk exists regardless of ejection fraction. Thus ICD implantation during the acute/subacute period is currently reserved for those who have a secondary prevention indication. As the disease progresses only about 21% of patients will develop dilated cardiomyopathy[42] and require permanent SCD protection through ICD implantation. Patients with late gallium enhancement during cardiac magnetic resonance imaging appear to have higher risk of mortality and SCD during the recovery phase[43] but screening for SCD is not well defined at this time. We frequently rely on WCD use for such patients until either risk resolves or the requirements for an ICD are met.

For decades, the initial months after an MI has been recognized as an especially high risk period for SCD.[44] As a clinical strategy, the sizeable proportion of patients recovering ventricular function after MI makes the choice of a WCD particularly attractive in the post-infarction period. Still, trials of ICD use early after MI (DINAMIT and IRIS) have not proven beneficial.[24, 25] This lack of benefit has been ascribed to insufficient power, competing risks of mortality, the risk of surgical implantation close to the time of the cardiac event, and/or negative effects of ICD shocks leading to increased heart failure.[24,45,46,47] Although the outcome of VEST remains in the future, the 2014 HRS/ACC/AHA Expert Consensus[40] acknowledged that patients with significant ventricular dysfunction may benefit from WCD use prior to ICD evaluation.

The question of why WCD use may be successful when ICD implantation has failed in two trials is a valid one to ask. First, the differences in treatments between ICD (VT/VF) and WCD

(unconscious, sustained VT/VF) may result in fewer appropriate WCD therapies.[23] In our patient population, a conscious patient with a sustained VT used the response buttons until the VT spontaneously terminated, nicely demonstrating how the reduction in therapies may occur. This is an important aspect as ICD shocks were associated with increased non-sudden cardiac mortality in DINAMIT and IRIS, even as SCD was reduced. Second, it has been suggested that defibrillation lead implantation may cause local irritation of the myocardium, triggering VT/VF early after the procedure.[48] This issue does not exist with the non-invasive WCD and again may result in fewer defibrillation therapies. Lastly, transthoracic defibrillation may have a different clinical impact than intracardiac defibrillation on recently infarcted hearts. Shocks from ICD leads appear to result in the release of cardiac enzymes significantly more than higher energy shocks from subcutaneous defibrillators,[49] presumably due to the high focal energy gradients within the heart.[50] This incremental trauma may play an important role in the recently infarcted heart. Thus, there is good reason to anticipate better outcomes from WCD use than the results of ICD studies for this important group of patients.

Like their ischemic counterparts, many patients with non-ischemic cardiomyopathy recover significant ventricular function after diagnosis. Peripartum cardiomyopathy and chemically-induced cardiomyopathy (e.g., alcoholic cardiomyopathy) are associated with up to 90% recovery after causative factors are removed. Even patients with idiopathic dilated cardiomyopathy commonly improve with medical optimization.[51] Early protection from SCD remains important as SCD occurs during the optimization period without SCD protection[51] and, if an ICD is implanted, those with recently diagnosed non-ischemic cardiomyopathy are just as likely to experience ICD shocks.[52] It has also been noted that patients who improve ventricular function after ICD implantation receive shocks at similar rates to those who do not improve.[53,54] Based on the number of articles demonstrating that non-ischemic cardiomyopathy patients frequently improve after ICD implantation, it may make sense to use a WCD for longer periods of time - perhaps up to a year - in patients who tolerate it.[40]

Conclusion

The WCD is a welcome additional to the therapeutic options for SCD prevention. Its non-invasive nature and effectiveness in terminating VT/VF make it an excellent choice for patients that do not yet meet the indications for permanent SCD protection afforded by ICD implantation. Although prospective studies are few, many retrospective analyses indicate that 1) patient acceptance and compliance with use is excellent, 2) effectiveness in terminating VT/VF is high, and 3) shocks are minimized by allow conscious patients to use response buttons. Patients with myocarditis, acute myocardial infarction with ventricular dysfunction, and cardiomyopathy with ventricular dysfunction may benefit by WCD use until the potential for recovery has been determined.

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