

Update on Wearable Cardioverter Defibrillator: A Comprehensive Review of Literature

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Abstract

Despite the advancements in the prevention and treatment of cardiovascular diseases, sudden cardiac death (SCD) remains a leading cause of mortality and is accountable for approximately 15% of the total mortality in the USA. The prognosis after sudden cardiac arrest (SCA) varies significantly and depends largely on the underlying etiology and the rapidity and efficiency of resuscitation; however, the outcome remains poor for most of the patients. The main culprits for SCD are coronary heart disease (CHD) and heart failure with reduced ejection fraction (HFrEF). Patients with HFrEF and an ejection fraction (EF) of less than 35% are considered for an implantable cardioverter-defibrillator (ICD) placement if the EF does not improve. A wearable cardioverter defibrillator (WCD) commonly known as a life-vest is sometimes used as a bridging modality until an ICD is implanted. The indication and utility of WCD is still a controversial topic. The purpose of this article is to provide an up-to-date comprehensive review of literature for WCD utilization.

Keywords: Atrial fibrillation; Heart failure; Ventricular tachycardia; Ventricular fibrillation; Tachyarrhythmias

Introduction

Sudden cardiac arrest (SCA) refers to the sudden cessation of cardiac activity with hemodynamic collapse due to sustained ventricular tachycardia (VT) or ventricular fibrillation (VF). Sudden cardiac death (SCD) is the unexpected death occurring within 1 h of symptom onset or occurring in persons found dead within 24 h of being asymptomatic due to cardiac arrhythmias. The current annual incidence of SCD in the USA is approximately 450,000

per year, with an estimate of global annual incidence of 4 - 5 million cases per year [2]. Despite the enormous improvement in cardiovascular care, SCD remains a leading cause of mortality, accounting for approximately 50% of all cardiac mortality, and for about 15% of the total mortality in the USA [3].

The main parameters for risk stratification of SCD are mainly coronary heart disease (CHD) and heart failure with reduced ejection fraction (HFrEF). The risk of SCD increases by 6 - 10 folds in the presence of clinically recognized heart disease, and 2 - 4 folds in the presence of CHD [4]. Patients with CHD and HFrEF are at risk of SCD due to ventricular arrhythmias. Anatomic remodeling, decreased conduction, ion channel alteration, calcium (Ca^{2+}) homeostasis, alterations in neurohormonal signaling, and genetic variables all have a role in ventricular tachyarrhythmias in CHD and HFrEF [5]. The management of SCD include primary and secondary prevention through an implantable cardioverter-defibrillator (ICD). Primary prevention is indicated in patients without history of cardiac arrest or sustained VT who are at increased risk for SCD events. Secondary prevention is indicated in patients with history of cardiac arrest, VT, or syncope secondary to ventricular arrhythmias [4].

Since SCD risk may sometimes be transient, a wearable cardioverter defibrillator (WCD) has been developed and approved for clinical use in 2001 as a proposed solution for short-term risk mitigation in select populations at high risk of SCD.

WCD is a device that patients wear around their trunks in a vest-like fashion, and it delivers a shock when it detects ventricular tachyarrhythmias such as VT or VF. Three defibrillation and four ECG detecting electrodes are included in the WCD system. Aside from defibrillation, the device also functions as a loop recorder, continually recording and transmitting tachyarrhythmias and bradyarrhythmias via modem. It does not, however, offer pacing capability for backup bradycardia pacing or antitachycardia overdrive pacing at this time [6]. WCD can be used as a bridging modality until an ICD is placed [7]. In 2001, the US Food and Drug Administration (FDA) authorized the WCD for clinical use [8]. The purpose of this article is to provide an up-to-date comprehensive review of literature for WCD utilization. We will discuss WCD implementation in HFrEF and post myocardial infarction (MI).

WEARIT/BIROAD

The WEARIT/BIROAD study was a multiple-center clinical

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trial evaluating the safety and effectiveness of the WCD and was the pilot study before FDA approval. This study resulted in improvements to the now commercially available WCD. The study included patients aged 18 - 75 at high risk for SCD death who did not qualify for an ICD or could not receive such a device for several months. The WEARIT group consisted of patients with New York Heart Association (NYHA) class III or IV with an estimated EF of less than 30%; the BIROAD group consisted of post-MI coronary artery bypass graft (CABG) patients who received the WCD as a bridge before possible implantation of ICD. These two groups/studies were initially separate and were later combined based on the recommendation from the FDA. WEARIT consisted of 177 patients and BIROAD 112 patients for a total study size of 289 patients. Eight sudden cardiac arrhythmia events are studied two of which were not treated secondary to improper placement of electrodes (this information opened the door for improvements to be made to the commercial version of the WCD). All patients in the study who experienced a sudden cardiac arrhythmia (excluding these two) were successfully converted to a slower rhythm after a single shock [9].

Early post-MI patients with reduced left ventricular ejection fraction (LVEF)

The current professional society guidelines do not recommend ICD implantation for the primary prevention of SCD in the early post-MI phase (within 40 days) as a result of multiple negative trials that did not show any significant improvement in overall mortality [10, 11]. However, due to the increased risk, WCD has been studied in such population. Unfortunately, there are conflicting data on the utility of WCD in the primary prevention of SCD among patients who are less than 40 days post-MI and have LVEF \leq 35%. The Vest Prevention of Early Sudden Death Trial (VEST) trial, which was the first randomized, prospective, multi-center open-label WCD trial, showed that WCD does not reduce SCD from cardiac arrhythmia; however, it reduced all-cause mortality up to 90 days among patients with moderate-severe left ventricular (LV) dysfunction post-MI compared to controls.

VEST Trial

The VEST, published in 2018, was the first randomized, prospective, multi-center open-label trial on the potential benefit of WCD among patients who were enrolled within 7 days of hospital discharge with an EF of 35% or less, to see if it could prevent SCD or death 90 days after MI. A total of 2,302 patients were randomly assigned to one of two groups: WCD+ guideline-directed medical therapy (GDMT) (device group) or GDMT alone (control group). At 90 days, the primary outcome was a combination of SCD and arrhythmic death. Total mortality and non-sudden death were the most important secondary outcomes (i.e., non-arrhythmic). Post-MI patients with or without revascularization, EF of 35%, (mean age of 60.9 ± 12.6 years; mean EF of $28.2 \pm 6.1\%$), age 18 years, and

enlistment within 7 days of hospital release met the inclusion criteria. Totally, 1,524 patients were randomly assigned to the device group and 778 to the control group. Participants in the device group used their WCDs for an average of 18 h per day (interquartile range: 3.3 - 22.7). Over an average of 84 days, the rate of arrhythmic deaths in the WCD plus GDMT group was 1.6%, compared to 2.4% in the GDMT alone group (relative risk, 0.67; 95% confidence interval (CI): 0.37 - 1.21; $P = 0.18$). Total mortality was 3.1% in the device group and 4.9% in the control group (relative risk 0.64; 95% CI: 0.43 - 0.98; uncorrected $P = 0.04$), with non-arrhythmic death being 1.4% and 2.2%, respectively (relative risk 0.63; 95% CI: 0.33 - 1.19; $P = 0.15$). The WCD did not exhibit statistical significance in the efficacy of the WCD among patients with a recent MI and an EF of 35% or less. It did not result in a significantly lower risk of arrhythmic fatalities in the device group as compared to the control group. As a result, the WCD's first randomized controlled experiment had unfavorable findings. The majority of the criticism is on the trial's failure to meet its pre-specified main goal of a decrease in the rate of SCD in the first 90 days following MI. While the outcome was not statistically significant, it did show a good trend, with a 33% reduction in sudden death. Although there was a statistically significant 36% relative risk decrease in total mortality, just concluding that the study was negative and dismissing the potential advantages of WCD is challenging and maybe missing the point [12].

Post-MI WCD Study

The goal of the Post-MI WCD research was to learn more about the incidence and survival of post-MI VT/VF in patients with poor EF who were wearing a cardioverter-defibrillator. From September 27, 2005, to July 13, 2011, 8,453 patients from the USA participated in this retrospective research. All of the patients studied had an EF of less than 35% and a history of a recent MI. The WCD was used to treat 1.6% of patients, with a median duration to treatment of 16 days and 14 days in post-revascularization patients. Of patients who were treated 75% were shocked in the first month of use (30 days post-MI), after 3 months, 96% of patients were shocked. The use of the WCD in early post-MI patients thought to be at high risk for abrupt cardiac arrhythmia, a population not protected by ICD implantation, is the focus of this research. Overall, 1.4% of patients can be adequately managed in the first 3 months after a MI, with a patient survival rate of 91%. This suggests that defibrillation may be beneficial to a subset of high-risk individuals immediately after a MI, particularly in the first 30 days following the event [13].

Patients with reduced LVEF early after coronary revascularization

Patients with reduced LVEF \leq 35% have higher risk of 30-day mortality rates and SCD after CABG compared to patients with normal LVEF. There are limited data on the utility of ICD implantation in early post-CABG period, as most of the trials

for primary SCD prevention have excluded patients within 1 - 3 months post-CABG [14-16] or did not show a survival benefit [17]. Thus, ICD implantation is not currently recommended for primary SCD prevention within 3 months post-CABG. However, due to the increased risk, WCD has been studied in such population. Most of these trials have showed significantly lower mortality rates and improved outcomes.

Post-Revascularization Study

The purpose of this study was to estimate the risk of mortality in patients with LVEF less than 35% status post revascularization and to analyze survival in patients protected by a WCD. The study was an observational, retrospective design contrasting post percutaneous coronary intervention and CABG patients with an EF less than 35%. Data were driven by the national database of wearable cardioverter-defibrillators and scores matched to the Cleveland Clinic surgical and interventional registries from August 1, 2002, to December 31, 2009. Mortality differences were studied over 3 years and additional mortality analysis was performed on mortality during the first 90 days in mortality which occurred after day 90. In patients who received percutaneous coronary intervention, 90-day mortality was 2% in patients who received the WCD and 13% in patients who did not receive the WCD. Analysis of these numbers indicates an 85% reduction in 90-day mortality status post PCI. When analyzing 90-day mortality for patients' status post coronary artery bypass grafting, there was 4% mortality in patients who received the WCD and a 7% mortality in patients who did not receive the WCD, this correlates with a 43% reduction in mortality within 90 days in patients wearing the vest. Overall survival was also studied; patients in the WCD group experienced a 10% mortality compared to those without the WCD who experienced 34% overall mortality at a median follow-up time of 2.8 years [18].

WEARIT-II Registry

The WEARIT-II registry, which was completed in 2013, was designed to provide data on the safety and efficacy of the WCD in a real-world context to examine the rate of improved EF and the necessity for ICD installation when WCD usage was discontinued. Between August 2011 and February 2014, 2,000 patients with a prescription WCD (median age = 62 years, median EF = 25%) were eligible for inclusion in a prospective registry. They were divided into three groups: patients with ischemic cardiomyopathy (n = 805, 40%), non-ischemic cardiomyopathy (n = 927, 46%), and congenital/inherited heart disease (n = 268, 13.4%). Clinical data such as the rate of ICD implantation, arrhythmia events, and EF improvement were collected. In 41 individuals, a persistent VT/VF episode occurred. As a result of hemodynamic instability, 90 persistent VT episodes were delayed from treatment, and 30 needed WCD shock therapy. While wearing the WCD, one out of every 14 (7.4%) patients had an arrhythmic episode that required intervention. Only 10 patients got improper WCD treatment

during follow-up. The WCD was worn by the patients for a total of 90 days, with a median daily usage of 22.5 h. When the WCD was removed, 41% of patients had improved LVEF to the point that an ICD was no longer needed, whereas 42% of patients had LVEF that did not improve by more than 35% and required permanent ICD implantation. The WEAR-II registry's 1-year follow-up data indicated 96% overall survival and 90% survival in patients who suffered VT/VF after using the WCD. It was hypothesized that WCD might be used safely to protect patients at risk of SCD until a choice is made about whether or not to utilize an ICD. In addition to preventing SCD, the WCD gives useful information on the patient's cardiac function that is of significant clinical value in the immediate aftermath of a cardiac event [19].

WCD Meta-Analysis

WCD meta-analysis was done in 2018 to assess the incidences of sustained VT events and evaluate the benefit and cogency of WCDs among at-risk cardiac patients. It included the 11 retrospective, multi-center observational studies containing a total of 19,882 non-overlapping patients that contained statistics from January 1998 to July 2017. The meta-analysis looked for studies that: 1) evaluated adult patients wearing WCDs; 2) provided information on one or more outcomes of interest (e.g., all-cause and VT/VF-related death, VT/VF event, proper and improper shock therapy, and appropriate VT/VF termination); and 3) were full-text studies published in English. The rates of all-cause and SCD-related mortality among WCD patients were 1.4% (95% CI: 0.7 - 2.4) and 0.2% (95% CI: 0.1 - 0.3), respectively, according to this meta-analysis. In 2.6% of patients (95% CI: 1.8 - 3.5), VT/VF occurred. In 95.5% of patients, VT/VF was effectively terminated after an appropriate shock. A total of 1.7% of patients received an appropriate shock and 0.9% received an inappropriate shock. This meta-analysis concluded that WCDs are highly effective at successfully terminating life-threatening VT/VF events among cardiac risk patients [20].

WEARIT France

The WEARIT France project, which began on February 2, 2017, and ended on March 3, 2019, was a post-market multi-center observational study that aimed to gather data on WCD usage in terms of compliance and adherence. It comprised a retrospective examination of 1,157 patients who had finished their WCD treatment between May 2014 and December 2016, as well as prospective patients who received WCD prescriptions in clinical practice from January 2017 to March 2018 in 88 French sites. Shocks provided for adjudicated sustained VT/VF as well as shocks delivered for all episodes that were not adjudicated sustained VT/VF were the primary outcomes. The ratio of patients surviving at the completion of the WCD's usage to the entire population who were given WCD was used to determine the secondary outcome. There were no exclusion criteria for this study. Inclusion criteria included patients with ischemic cardiomyopathy (82.1%), following implanted car-

dioverter-defibrillator explant (10.3%), and before heart transplantation (7.6%). On average, patients used WCD for 62 days, and wear time on average was 23.4 h. In multi-level analysis, lower compliance was related to younger age (odds ratio (OR) 0.97, 95% CI: 0.95 - 0.99, $P < 0.01$). The first 30 days were responsible for 62% of all VT/VF incidents, whereas the latter 30 days were responsible for 38%. Except for one patient who required two shocks to end the arrhythmia, almost all patients who got a treatment shock had their VT/VF episode successfully terminated after one treatment, and the post-shock survival rate was 100%, including patients who required hospital stays. Inappropriate shocks were found to be rare in the study (0.7%). In the general population, 32.5% of patients improved their EF and no longer required an ICD, whereas 50.6% of the population required an indefinite ICD after WCD usage was discontinued. In the ischemic group, which accounted for 82% of all enrolled patients, 46.6% had improved EF and no longer required an ICD. This real-world evidence backs with previous research on the effectiveness and safety of short-term WCD usage in high-risk individuals. It further confirmed that when WCD is appropriately implemented, with enough patient education and dedicated follow-up utilizing a particular remote monitoring system, patient compliance is high, and the device is well-tolerated [21].

US National WCD Experience

The US National WCD Experience was a retrospective study that evaluated the efficacy, wear duration, and long-term survival of patients who got a WCD to those who had an ICD. It included 3,569 patients who wore the WCD at some point between August 2002 and December 2006, with an average age of 59.3 ± 14.7 years. Patients who wore a WCD were compared to Cleveland Clinic patients who got an ICD. VT/VF episodes occurred in 1.7% of the patients. The initial shock successfully stopped 100% of unconscious VT/VF episodes and 99% of all VT/VF occurrences. In 52% of patients, daily WCD usage was adequate $> 90\%$ of the time, and in 71% of patients, daily WCD use was appropriate $> 80\%$ of the time. Median daily use was 21.7 h. A longer monitoring period was associated with increased wear time rates and a lower risk of unexpected death during use. Overall acute survival was 99.2% when WCDs were used. For 3 years and 3 months, the death rates in the ICD and WCD groups were not statistically different. Long-term survival statistics, on the other hand, showed that WCD therapy is equivalent to ICD therapy, indicating that the WCD can be used as a bridge to permanent ICD installation [22].

German WCD Study

The German WCD study was a non-randomized observational study designed to acquire metrics on the use and efficacy of WCDs regarding the prevention of SCD caused specifically by VF or VT. The study included 6,043 patients from Germany (median age 57 years old, 78.5% male) and took place from April 2010 to October 2013; the study included patients with heart transplants, genetic heart disease, ICD explants, ischemic

cardiomyopathy, and most commonly non-ischemic cardiomyopathy. Of the 6,043 patients enrolled in the study 1.6% (94 patients) were treated by the WCD in response to a ventricular tachyarrhythmia/fibrillation, and 88 (94%) were successfully converted into a slower rhythm. Of the patients who received a shock to terminate VT/VF 89% required one treatment shock to terminate the arrhythmia. The use of the WCD was suggested by the German Cardiology Association as well as the European Society of Cardiology; the WCD was advised for patients with a poor LV function who are not candidates for ICD treatment and are at risk of SCD. WCD usage soon after ICD explantation, especially when ICD re-implantation is not possible, as a bridge to transplantation for waitlisted patients, and use during acute phase myocarditis till recovery or ICD implantation received a class IIa-C recommendation. Patients with dilated cardiomyopathy or non-ischemic cardiomyopathy who are expected to improve their LVEF, as well as patients with dilated cardiomyopathy or non-ischemic cardiomyopathy who are expected to improve their LVEF, were given a class IIb-C recommendation [23].

Conclusions

WCD utilization remains an equivocal topic. Many studies such as WCD meta-analysis, WEARIT, German WCD and post-MI WCD concur on the efficacy of WCD in terminating ventricular tachyarrhythmia. In conclusion, there has been a consistent data supporting the use of WCD in heart failure patients with low EF but not in post-MI patients. The VEST trial did not exhibit statistical significance in the efficacy of the WCD among patients with a recent MI. However, The Post-revascularization, WEARIT-II registry, and WEARIT France studies showed significantly lower mortality rates and improved outcomes in patients with low EF. The most plausible indication for WCD use is as a bridging modality until an ICD is implanted as evident by the US National WCD experience trial. We are optimistic that the ongoing studies will provide a valuable addition to the current data available.

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Conflict of Interest

The authors declare that they do not have a conflict of interest.

Author Contributions

Mrhaf Alsamman: studies 11, 12, and conclusion. Adesh Prashad: studies 6 - 10. Tehreem Khalid: studies 1 - 5. Ramy Abdelmaseih: introduction, and revision. Rakesh Prashad participated in drafting the article and revising it. All authors participated in review. They were involved in writing and revising the article prior to submission.

Data Availability

The authors declare that data supporting the findings of this study are available within the article.

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