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The wearable cardioverter-defibrillator vest: Indications and ongoing questions

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ABSTRACT

Multiple clinical trials have demonstrated the efficacy of implantable cardioverter-defibrillators (ICDs) for the prevention of sudden cardiac death (SCD) among specific high-risk populations. However, it remains unclear how to optimally treat those patients who are at elevated risk of cardiac arrest but are not among the presently identified groups proven to benefit from an ICD, are unable to tolerate surgical device implantation, or refuse invasive therapies. The wearable cardioverter-defibrillator (WCD) is an alternative antiarrhythmic device that provides continuous cardiac monitoring and defibrillation capabilities through a noninvasive, electrode-based system. The WCD has been shown to be highly effective at restoration of sinus rhythm in patients with a ventricular tachyarrhythmia, and one randomized trial using the WCD in patients with recent myocardial infarction at elevated risk for arrhythmic death reported a decrease in overall mortality despite no SCD mortality benefit. The current clinical indications for WCD use are varied and continue to evolve as experience with this technology increases.

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Abbreviations and acronyms: AED, Automatic external defibrillator; BIROAD, Bridge to ICD in Patients at Risk of Sudden Arrhythmic Death; BPM, Beats per minute; CABG, Coronary artery bypass graft; CMS, Center for Medicare and Medicaid Services; DINAMIT, Defibrillator in Acute Myocardial Infarction Trial; EF, Ejection fraction; FDA, Food and Drug Administration; GDMT, Guideline directed medical therapy; IAD, Inherited arrhythmia disorder; ICD, Implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; J, Joule; LED, light emitting diode; LV, Left ventricle; LVEF, Left ventricular ejection fraction; MI, Myocardial infarction; NICM, non-ischemic cardiomyopathy; NSVT, non-sustained ventricular tachycardia; PCI, Percutaneous coronary intervention; SCA, Sudden cardiac arrest; SCD, Sudden cardiac death; US, United States; VA, Ventricular arrhythmia; VEST, Vest Prevention of Early Sudden Death Trial; VF, Ventricular fibrillation; VT, Ventricular tachycardia; WCD, Wearable cardioverter-defibrillator; WEARIT, Wearable Defibrillator Investigative Trial.

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Introduction

Since the first description of ventricular fibrillation (VF) termination by means of an externally applied electric shock over half a century ago,[1] substantial progress has been made in the treatment of unstable tachyarrhythmias. The advent of microprocessor technology and improvements in battery storage have enabled the development of compact, implantable devices capable of continuous cardiac rhythm monitoring and automated delivery of electrical energy to the myocardium. The modern implantable cardioverter-defibrillator (ICD) has evolved into an efficacious and widely used therapy for the treatment of patients who are at the highest risk for ventricular arrhythmias (VAs).

Heightened understanding and awareness of the public health burden imposed by sudden cardiac arrest (SCA) has paralleled advances in device-based antiarrhythmic therapies. While a staggering 347,322 adult patients suffered an out of hospital SCA in the United States (US) in 2016, the median survival to hospital discharge after such an event is only 10.4% (per 2017 CARES data).[2] As the majority of these SCA events are due to ventricular tachycardia (VT) or VF, improved mechanisms to deliver prompt defibrillation are critical in addressing this low survival rate.

Multiple randomized trials have demonstrated the clinical efficacy of ICDs for treatment of VAs and for the primary and secondary prevention of sudden cardiac death (SCD).[3–7] Notably, the primary-prevention ICD trials enrolled fairly homogenous patient populations and used low left ventricular (LV) ejection fraction (EF;LVEF) to identify patients at increased risk for VA death. It remains unclear how best to treat patients with elevated risk of SCA who are not among the presently identified groups proven to benefit from an ICD. It also is uncertain how to manage individuals with an accepted indication for device therapy who are unable or unwilling to undergo device implantation.

The use of non-implantable defibrillation devices, including automated external defibrillators (AEDs), may lead to improvements in outcomes of witnessed out-of-hospital cardiac arrests (Fig. 1). Uncontrolled studies have demonstrated improved survival after SCA when AEDs are placed in busy public locations such as casinos and airports.[2,7–11] AEDs are noninvasive, portable, and relatively inexpensive devices that require minimal operator training. However, targeted AED therapy among high-risk patients has not emerged as an effective treatment strategy for SCA. For example, a trial comparing home AED therapy to conventional cardiopulmonary resuscitation among patients with a history of prior anterior wall myocardial infarction (MI) failed to demonstrate an improvement in mortality among the device treated cohort.[12] The notable disadvantage of the AED compared to the implantable defibrillator is the requirement of a bystander to witness the SCA, apply defibrillation pads, and deliver the shock. Delayed defibrillation is associated with reduced survival in multiple observational studies, [10,13,14] and only 36% of patients randomized to the treatment group in the previously mentioned trial suffered a witnessed SCA. Unstable VAs that occur during sleep or when the patient is alone are likely to go untreated when AEDs are the only modality employed for SCD prevention.

Courtesy of www.zoll.com

Fig. 1. ZOLL Automated External Defibrillator. Courtesy of www.zoll.com

Wearable cardioverter-defibrillator (WCD)

The WCD is an alternative device that combines the advantages of continuous cardiac monitoring with a noninvasive defibrillation system. The only WCD currently commercially available is the Zoll LifeVest (Zoll Medical, Pittsburgh, PA). The US Food and Drug Administration (FDA) initially approved the LifeVest for clinical use in 2002. The current unit is LifeVest Model 4000, with the device being comprised of a vest assembly worn over the chest and a monitor unit carried in a holster at the waist (Fig. 2). The monitor unit includes the device battery, defibrillation capacitor, response buttons, signal processor, and a display. The monitor unit also acts as a loop recorder with continuous recording of patient's rhythm with transmission of any brady/tachyarrhythmias. The entire system weighs 1.04 kg. The vest is worn under the patient's clothing and holds four nonadhesive electrodes, providing continuous non-standard 2 lead ECG monitoring (anteroposterior and left-right bipolar signals). In

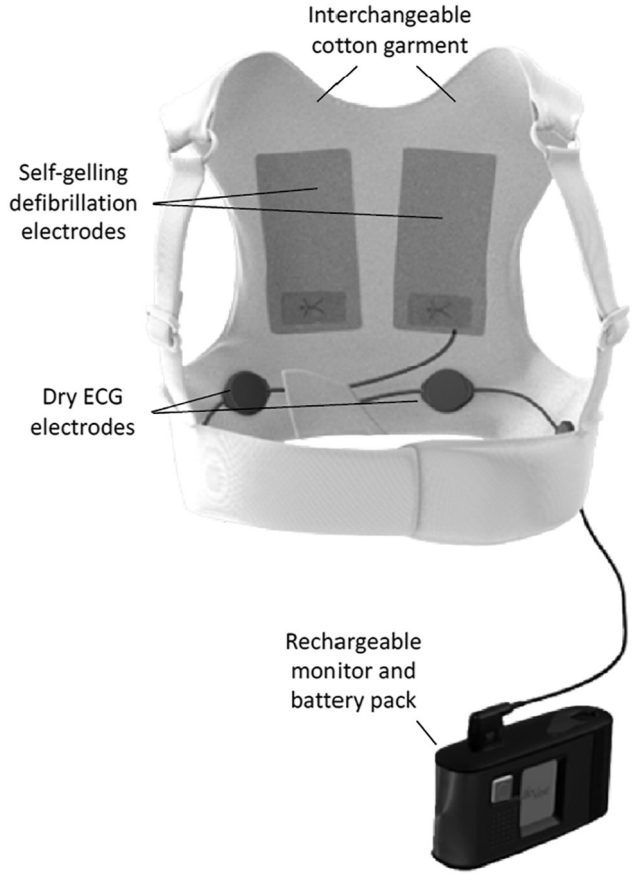

Fig. 2. Wearable Cardioverter-Defibrillator Vest and Monitor Unit.

addition, three defibrillation electrodes are incorporated into the vest (1 anterior and 2 posterior), allowing for defibrillation in the cardiac-apex-to-posterior vector.

The LifeVest employs an advanced arrhythmia detection algorithm that uses heart rate, template matching, dual lead comparison, analog and digital signal filtering, rhythm stability analysis, and arrhythmia duration to guide therapy.[15] The treating physician can tailor the length of delay before shock and rate thresholds for VT/VF in individual patients. When the device senses a treatable arrhythmia, a progressive alarm sequence consisting of a vibration alert, blinking light emitting diode (LED) signals, and audible warnings is initiated. During this period, the patient has the ability to suspend therapy by pressing two buttons located on the alarm module, allowing abortion or delay of the defibrillation shock when consciousness is not impaired. The response time, which is the time prior to delivery of therapy once arrhythmia is detected, is set nominally at 25 s, and is programmable up to 55 s for VF and up to 180 s for VT. This decreases the risk of inappropriate or unnecessary shocks, for example in the case of electrical noise artifacts or stable VT. The VF identification cutoff defaults to 200 beats per minute (BPM), but this is programmable from 120 to 250 bpm. If the warning sequence is not halted by response button activation, the device prepares to deliver therapy. While the WCD is charging, gel is extruded from the defibrillation electrodes (using technology similar to that employed by automobile airbags) to increase conduction and decrease electrical impedance to the skin, which decreases the chance of electrical shock burns. An initial test pulse is delivered to measure thoracic impedance, resulting in automated adjustment of high-voltage shock duration. Therapy is delivered by means of up to five sequential biphasic shocks at programmable energy levels between 75 and 150 joules (J), with a default of 150 J (Fig. 3). The device attempts to deliver each shock on a sensed R wave. If this is not possible after 3 s of monitoring, an unsynchronized shock is administered. Overall, the total time from detection of VT/VF to shock delivery is <1 min. The WCD vest assembly must be replaced after each treatment course.

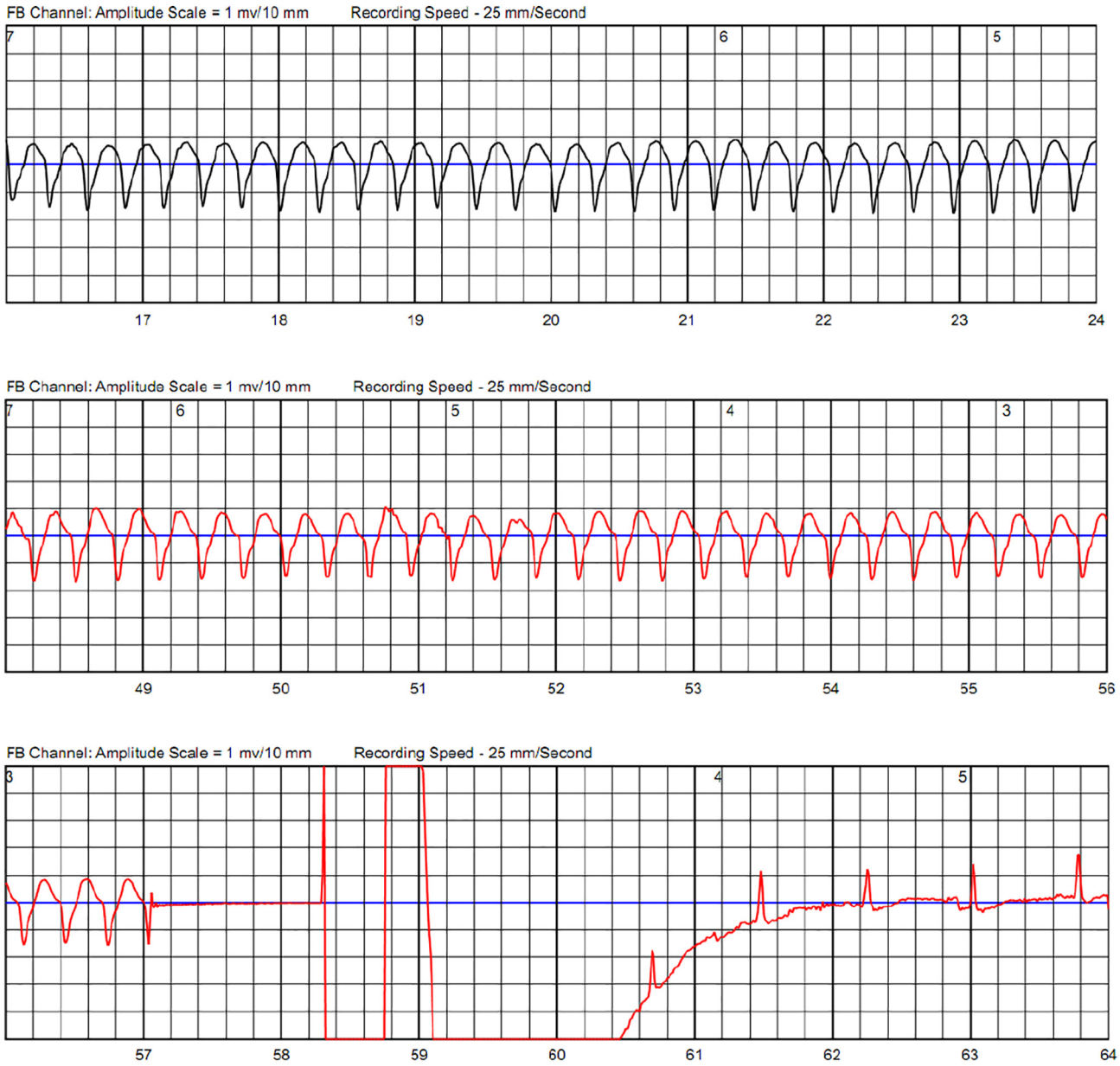

Fig. 3. Successful treatment of ventricular tachycardia by a wearable cardioverter-defibrillator. The rhythm strip was recorded in the anterior to posterior vector and saved by the device as the Front to Back Channel. Between the second and third strips, 24 s of arrhythmia recording has been omitted. After arrhythmia identification, the device issued a progressive alarm sequence alerting the patient to the upcoming shock. Therapy was not suspended and a 150 J biphasic shock was delivered, resulting in restoration of sinus rhythm.

In addition to tachyarrhythmia treatment, the LifeVest also serves as a cardiac monitor. It detects asystole (when the amplitude of ECG input signal falls below 100 microvolts for at least 16 s) as well as other significant ventricular pauses. As mentioned, the LifeVest functions as a loop recorder with the capacity to store and transmit electrocardiograms to facilitate analysis of alarmed events, with continuous data capture of up to 30 days that can be accessed by providers via an online system. The device records the ECG starting 30 s prior to an alarm and 15 s after the alarm, with data being stored and sent to a secure server. The device also delivers spoken bystander alarms, such as "do not touch patient" prior to shock delivery, and instructs bystanders to call an ambulance in the event of asystole.[16]

Effectiveness of WCD therapy

The efficacy of the WCD for the termination of VAs was first reported in 1998. In this initial study, unstable VT/VF was induced in ten survivors of SCA referred for electrophysiologic testing.[17] In all patients, a single monophasic 230 J shock delivered by a WCD successfully terminated the VA. A similarly designed follow-up study using a next-generation WCD employing a biphasic shock again demonstrated the reliable termination of 22 episodes of induced VF among 12 patients.[18] The latter investigation studied both 70 and 100 J biphasic defibrillation energies, providing assurance that the 150 J capacity of the current WCD model is sufficient for the treatment of clinical VAs.

Data supporting the effectiveness of WCDs outside of the electrophysiology laboratory was derived predominantly from multiple case series, including two large cohorts from the US and Germany,[19,20] and a single prospective clinical trial.[21] Nationwide registry data from 3569 patients treated with the Zoll LifeVest in the US between 2002 and 2006 were recorded in a clinical database maintained by the device manufacturer. These patients wore the WCD for at least 1 day (mean duration, 53 $\pm$ 70 days), and mean daily use was 19.9 $\pm$ 4.7 h. Of note, 14% of users discontinued the WCD due to discomfort or adverse reactions. Indications for the WCD included ICD explantation (23%), VA before planned ICD implantation (16%), recent MI (16%), post coronary artery bypass graft (CABG) surgery (9%), and recent diagnosis of cardiomyopathy with a LVEF≤35% (28%). In this cohort, 80 sustained VT/VF events in 59 patients (1.7%) were observed, with a very high efficacy: first-shock efficacy was 99% (79/80), post-VT/VF survival was 90% (72/80), and overall survival of registry patients of 99.2%. Most of these VAs occurred in patients whose ICD had been explanted, and 5.2% of these patients experienced VT/VF during the period of WCD use.[19] Inappropriate shocks were experienced by 67 of the 3569 patients (1.9%) during a total of 4788 months of device use.

The Wearable Defibrillator Investigative Trial (WEARIT) and the Bridge to ICD in Patients at Risk of Sudden Arrhythmic Death (BIROAD) Trial were two prospective, multicenter, non-randomized clinical investigations designed to assess the safety and efficacy of WCD use in high-risk patient populations.[21] Patients were excluded from either study if they were candidates for immediate ICD implantation, but could be enrolled if a significant delay in device implantation was anticipated. Of note, these studies began recruitment prior to publication of the landmark primary prevention ICD trials, MADIT II and SCD-HeFT.[4,5] The WEARIT study enrolled outpatients who had NYHA Class III-IV symptoms with LVEF of <30% and did not meet criteria for an ICD at that time. The BIROAD study was undertaken to evaluate the use of a WCD as a bridge to ICD decision in patients at elevated risk for VAs. This trial enrolled a much more heterogeneous population, including individuals with a recent MI or CABG within 4 months complicated by high risk features, as well as patients unable or unwilling to receive an ICD in a timely manner. At the request of the FDA, the studies were eventually combined and reported as the WEARIT/BIROAD trial.

A total of 289 patients had been enrolled when the study was stopped after reaching pre-specified safety and efficacy thresholds.[33] Eight episodes of VT/VF were observed in the combined study population; six of these events were successfully terminated by the WCD. The two unsuccessfully treated episodes occurred in patients with improperly mounted defibrillation electrodes (the defibrillating pads were reversed and therefore not in contact with the skin). Subsequent changes in device design eliminated the potential for this error. Notably, the WEARIT/BIROAD study used an earlier version of the WCD that delivered monophasic defibrillation waveforms; present models now employ biphasic shocks, and an alarm sounds for improperly connected electrodes. This was the first study to demonstrate clinical efficacy and operability of the WCD.

The WCD experience among 2 cohorts of German patients also has been recently described.[20,22] Between 2000 and 2008, 354 patients were treated with a WCD for an average duration of 106 days, with mean daily use of 21.3 h.[20] In 20 of the 21 VT/VF events detected, the first discharge was successful with the remaining VF event requiring two device-initiated defibrillation attempts to successfully treat the rhythm. The recent German cohort studied 6043 patients who were prescribed a WCD between April 2010 and October 2013. The patient population was grouped into various cardiovascular indications for WCD, with the majority being newly diagnosed dilated cardiomyopathy (37%), ischemic cardiomyopathy (ICM) (27%), recent ICD explantation (12%), non-ischemic cardiomyopathy (NICM) (12%), and myocarditis (10%). This German cohort appeared to tolerate wearing the WCD better than the US cohort. The median WCD usage was an impressive 23.1 h per day over a median of 59 total days of wear. Only 3% of the patient population had 3 or fewer total days of WCD wear. 120 of these patients were treated with a total of 163 shocks, ranging from 1 to 5 shocks per episode. 94 patients were shocked for VAs, with 94% (88/94) of patients being successfully converted into a slower heart rhythm and 93% (87/94) surviving at least 24 h post-shock.

It should be emphasized that nearly all of the present evidence supporting WCD use is derived from uncontrolled studies (with only one recent randomized trial), and the majority of reported experience is in the form of registry data. While it is clear that early defibrillation is beneficial and that the WCD can reliably provide timely therapy in much the same way as an ICD can, the tendency to consider WCD and ICD treatment as exactly equivalent should be avoided in the absence of studies directly comparing these two fundamentally different devices.

Clinical use of WCD therapy

As the WCD is a readily removable, noninvasive device that is significantly less expensive than contemporary ICDs, the clinical threshold for prescribing a WCD is likely to be lower than that for an ICD. In addition, the ease of discontinuation of use heightens the importance of maximizing patient compliance to ensure effective treatment. Given these issues, WCD therapy is best suited for clinical scenarios in which the risk of VA is temporary, or when the wearable device can be used to bridge the patient to a more definitive treatment (e.g., ICD implant or heart transplant). The WCD can also be considered for patients with a temporarily elevated risk of VA in the absence of a proven ICD indication. Current ICD implantation guidelines stress the importance of avoiding ICD therapy in patients with reversible VA disorders or risk factors.[23] Accordingly, the WCD has been proposed for short-term use in patients with multiple conditions associated with VT/VF; including myocarditis,[24] newly diagnosed or prior NICM,[25–28] use of proarrhythmic drugs, recent CABG surgery complicated by a low LVEF,[29,30] peri-partum cardiomyopathy,[31] cardiac sarcoidosis[32] or severe coronary disease prior to revascularization. The WCD is well suited to most of these clinical scenarios, as the VT/VF risk factors associated with such conditions may diminish over time with medical therapy leading to improvement of LVEF, thus no longer requiring ICD therapy.[33–36]

The WCD should also be considered for patients who have a conventional ICD indication but are not candidates for immediate surgical

implantation. This situation is most commonly encountered in the setting of ICD generator or lead infection with bacteremia at times requiring 4–6 weeks of antibiotics following extraction. Wan et al. reported this exact indication in 8058 consecutive patients from 2002 to 2014 who had an ICD explanted for device infection and were prescribed the WCD.[37] This retrospective study noted that 334 (4%) patients experienced VT/VF events, with 81% of patients receiving device reimplantation, demonstrating that the WCD is an effectively protective bridge during the antibiotic therapy period. Even longer term WCD utilization of ≥1 year after ICD explant has been reported and continues to be an effective alternative.[38] A cost-effective analysis of this strategy was economically favorable if the WCD was used for at least 2 weeks; the device was a superior financial option compared to continued hospital stay or discharge to a skilled nursing facility, with the added benefit of continued protection against SCD.[39]

Patients who are actively listed for cardiac transplantation represent another high-risk population in which ICD implantation may be delayed or not currently warranted. The yearly mortality among such patients approaches 25%, with SCD (presumably due to VAs) accounting for the majority of these fatalities. ICDs have been associated with improved survival among cardiac patients awaiting transplant.[40] However, an ICD would likely not be required after transplantation. Therefore, the WCD is an attractive option for bridging patients with severe LV systolic dysfunction to transplant (e.g., when ICD implantation is declined or time to transplant is short), with data to support its utility.[41]

Temporary prophylaxis against arrhythmic death may also be warranted in patients who are suspected of having an inherited arrhythmia disorder (IAD), including the Brugada syndrome, long QT syndrome, and arrhythmogenic right ventricular cardiomyopathy. Rao et al. reported on 119 patients with diagnosed or suspected IAD and 43 patients with congenital structural heart disease who were issued a WCD from 2005 to 2010 while ongoing cardiac testing was being conducted or after ICD explant.[42] A total of 6 patients (all with IAD) received WCD shock therapy with successful termination of VT/VF events with no VA deaths occurring during WCD use. As demonstrated, the WCD can be prescribed during a patient's initial genetic and electrophysiologic workup, allowing the diagnosis to be confirmed before committing the patient to lifelong ICD treatment. It is also reasonable to prescribe a WCD after an ICD indication is established in situations in which the patient requests more time to consider implantable therapy (e.g., a young active patient with probable long QT syndrome).

WCD therapy after MI

While patients with systolic LV dysfunction are at significantly elevated risk of SCD in the period immediately following MI,[43] the ICD does not have an established benefit in this setting. The Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) examined ICD implantation in patients 6 to 40 days after a MI complicated by a reduced LVEF (≤35%) and impaired cardiac autonomic function.[44] Follow-up at a mean of 30 months failed to identify an improvement in mortality with this treatment strategy. Although ICD therapy reduced the incidence of sudden VA death, this benefit was offset by an increase in non-SCD. The explanation for this overall lack of benefit remains elusive. It is possible that defibrillation of an unstable arrhythmia shifted mortality from VA death to progressive heart failure death. Alternatively, some aspect of ICD implantation and subsequent therapy, including the operative procedure, defibrillation, threshold testing, or ventricular pacing may have contributed to the observed increase in non-SCD. Several years later, a second randomized controlled trial (IRIS) also evaluated early placement of ICD with patients recruited following a recent MI (MI within 31 days), with LVEF ≤40% and heart rate ≥ 90 bpm and/or non-sustained VT (NSVT).[45] Patients were followed for an average of 37 months, with no significant difference in overall survival detected whether ICD was implanted or not. The ICD group, as in the DINAMIT Trial, did have a lower incidence of SCD, but this was counterbalanced by an increase in non-SCD. It should be noted that DINAMIT and IRIS were long term studies with inclusion criteria including abnormal heart rate variability/elevated heart rate/NSVT, which may have selected patients for increased risk of non-SCD rather than SCD. There is also the possibility that ICD placement itself so early after MI had negative effects on overall mortality. Treatment with a WCD has been proposed as a mechanism to deliver the benefits of ICD therapy in the immediate post-MI period without exposing the patient to the potentially destabilizing side effects of device implantation.[46] Using the Zoll national database, Epstein et al. evaluated patients with recent MI (within 3 months) and EF ≤ 35% who were prescribed a WCD.[47] They found that of the 8453 patients prescribed WCDs, 133 patients (1.4%) received appropriate shocks, with 91% resuscitated from their VAs. The risk of VA was highest during the first month after MI (median 15 days), with 75% of treated patients receiving WCD therapy during this time and 96% during the first 3 months of use. This cohort's data further supported use of WCDs to prevent SCD in patients with a recent MI and reduced EF, but corroboration with a randomized controlled trial was still needed.

The Vest Prevention of Early Sudden Death Trial (VEST) was a much awaited large multicenter randomized trial designed to determine whether WCD therapy reduces VA death in the first 90 days after being hospitalized for a myocardial infarction with LVEF ≤35% (assessed at least 8 h after MI/revascularization or at >48 h following CABG surgery).[48] The treatment arm was given a WCD within 7 days of hospital discharge, along with guideline directed medical therapy (GDMT) vs. the typical therapy arm, who were given only GDMT. Follow up consisted of a phone call at 1 month, and then in person follow up at 3 months. The average LVEF was 28% with 83.6% of participants having received percutaneous coronary intervention (PCI) during index hospitalization. There were 1524 participants in the WCD group and 778 in the control group. Mean follow up was 84.3 ± 15.6 days. Patients in the device group wore the WCD for a median of 18 h, with a mean of 14 ± 9.3 h. No difference in VA death, the primary outcome, was found (1.6% in device group and 2.4% in control group, $p = 0.18$), but there was a decrease in total mortality (3.1% in device group and 4.9% in control group with relative risk of 0.64; CI, 0.43–0.98; uncorrected $P = 0.04$). Among the device group patients who died, only 12 of 48 were wearing WCD at time of death, and of the 25 deaths adjudicated as having a VA cause, only 9 were wearing the WCD at the time of death. Of these 9 participants wearing the WCD, 4 had ventricular tachy-VA with successful conversion to sinus rhythm but with recurrent VT or agonal rhythms.

When assessing adverse events related to the device, there was 10.8% chance of at least one arrhythmia alarm per 24 h of wear time, with the median duration of alarm being 7 s. 29 participants in the device group received at least one shock, with 20 participants receiving at least one appropriate shock (69%) and 9 receiving at least one inappropriate shock. Interestingly, a lower proportion of patients in the device group than in the control group reported shortness of breath (38.8% vs 45.3%, $p = 0.004$).

There are several possible explanations for why the trial was negative for VA mortality but marginally positive for overall mortality. The trial may have been underpowered for the primary outcome. In addition, there were various forces causing trend toward the null hypothesis, ranging from issues with adjudication, to suboptimal compliance, to frank crossover between groups. Arrhythmic death can be difficult to determine, and in the VEST trial, 5% of deaths were deemed to be of indeterminate cause and were removed from the primary analysis. Device wear time was also lower than expected when compared to prior registry data. 81% patients in the treatment arm were using the WCD at the beginning of the follow-up period, but only 41% were still wearing it at 90 days. Possible causes of lower than expected wear time could be frequent device alarms (72% with tachyarrhythmia alarms), skin irritation (15.3% with rash), inappropriate shocks, and emotional distress. In addition, some patients randomized to not receive the WCD were

prescribed the WCD outside of the VEST protocol, and some WCD group patients never wore the WCD at all.

An as-treated analysis found significantly fewer deaths in those actually wearing the device (rate of arrhythmic death: 0.37 per 100 person-months) than those not the wearing device (rate of arrhythmic death: 0.86 per 100 person-months, uncorrected $P = 0.03$) suggesting that better WCD wear time may have changed the primary outcome from negative to positive (16/25 VA deaths in WCD group were not wearing the device). Taking into account this as-treated analysis, it appears the patient most likely to benefit from the WCD is a highly motivated patient willing to wear the device throughout the day.

A recently performed meta-analysis by Masri et al. reviewed all studies published after January 1, 2001 that mention "WCD" or "LifeVest".[49] In their analysis of 27 observational studies and 1 randomized controlled trial, they found an incidence of appropriate WCD therapy 5 per 100 persons over 3 months. Among patients with ICM, appropriate WCD therapy was much higher in observational studies (11 per 100 persons over 3 months) compared to the randomized controlled trial (VEST Trial; 1 per 100 persons over 3 months). These observational study results can be reconciled with the VEST Trial results based on compliance and wear time data. In VEST, the median daily WCD wear time was 18.0 h (IQR 3.8–22.7), and mean daily wear time was 14.0 ± 9.3 h. Comparatively, in the largest observational study of WCD in post-MI, patients wore the WCD for a median of 21.8 h per day (mean wear time was not reported).[47] Similarly, in the second largest observational study in patients with ICM, median daily wear was 21.7 h and mean daily wear time was 19.9 ± 4.7 h.[19] Among the 48 VEST trial participants randomized to WCD who died during the follow-up period, 36 (75%) were not wearing the device at the time of death. Tragically, one patient passed away suddenly after removing the WCD to shower. Overall, the mean daily wear time decreased from 16.3 ± 9.8 to 8.3 ± 10.6 h by the end of the trial (Fig. 4). The discrepancy in wear times between observational studies and the randomized VEST trial may stem from differences in the patient populations and their perspectives on WCD therapy, disclosure of clinical equipoise as presented in the randomized trial, and even physician biases that were communicated to the patient.

Despite the challenges in wear time and the resultant bias toward the null hypothesis, there remained a reduction in all-cause mortality in the VEST Trial (uncorrected $P = 0.04$), and a significant reduction in non-VA death and all-cause mortality in as-treated analyses (rate ratio 0.09 and 0.26, $P = 0.009$ and < 0.001, respectively). This suggests WCD use confers benefit, and the degree of that benefit depends upon compliance and wear time.

Complications of WCD use

WCD therapy is well tolerated overall and is not associated with significant morbidity or mortality.[19–22] Despite the existence of the WCD's therapy-withholding response buttons, inappropriate therapy remains the most common associated complication. Among the 289 patients enrolled in the WEARIT/BIROAD study, six inappropriate shocks occurred in six patients. With 901 total months of patient follow up, this represented an inappropriate shock rate of 0.67% per month of WCD use.[21] In the German WCD cohort, only three inappropriate shocks were delivered among the 354 patients studied.[20] In the larger German cohort of 6043 patients, only 0.4% received inappropriate shocks, and the inappropriate shock rate was 0.6% in the VEST trial.[22,48] An analysis of roughly 9000 patients treated with a WCD for over 18,000 aggregate months revealed 265 inappropriate shocks, suggesting an even lower inappropriate therapy rate of 0.009 episodes per month.[50] The previously mentioned meta-analysis by Masri et al. noted an inappropriate shock incidence of 10 per 100 persons over 3 months (1 per 100 persons over 3 months in ICM) with appropriate shock incidence of 23 per 100 persons over 3 months in all groups (13 per 100 persons over 3 months in ICM).[49] In all reports, the most common etiology of an inappropriate shock was signal artifact or supraventricular tachycardia.

One of the most compelling features of the WCD is the ability of the patient to abort therapy if consciousness is maintained, allowing for significant reductions in inappropriate treatment. The rate of incorrect identification of VT/VF by the device may be as high as one episode per 13.4 days.[20] Inability of the patient to prevent therapy in this setting has been attributed to multiple factors, including engagement in an activity that prohibits device deactivation, sleep, or failure to repetitively deactivate the device in the setting of recurrent inappropriate sensing. A reported 57,451 audible arrhythmias alarms caused by the WCD were reported during the VEST trial with average rate of alarms being 0.033 per hour or 10.8% chance of at least 1 arrhythmia alarm during a 24 h wear period. Although the alarm is an important feature, it can affect compliance for the device, either negatively or positively.

As previously noted, the as-treated analysis from the VEST trial suggests higher wear time is important to achieve improved outcomes. Device usage was discontinued prior to reaching a study endpoint in 68 of the 289 patients (25%) enrolled in the WEARIT/BIOROAD trial.[21] The most commonly cited reason for self-discontinuation of WCD treatment was due to discomfort or lifestyle issues. In VEST, there was no significant difference between WCD and control patients in reported insomnia, back pain, or fatigue. However, a rash in any location (15.3% vs 7.1% $p \leq 0.001$, 13% vs 3.8% on torso) and itch in any location (17.2% vs

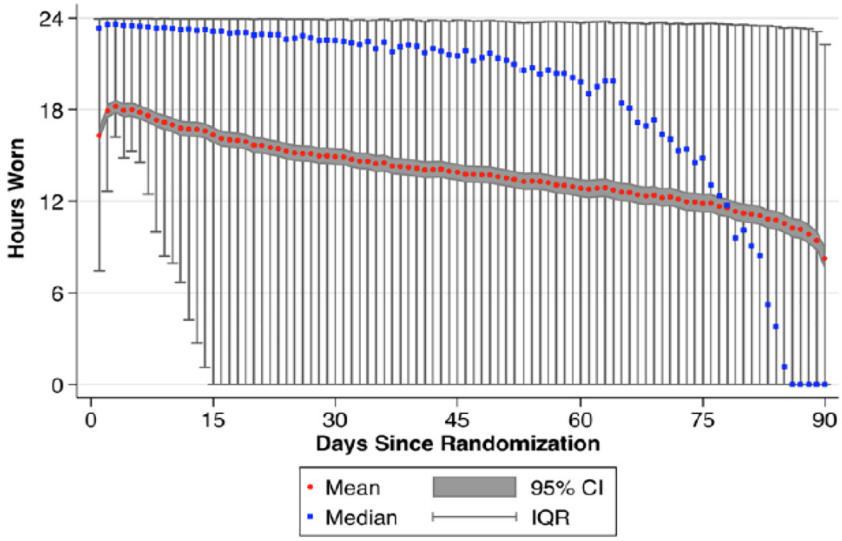

Fig. 4. Hours wearable defibrillator worn in VEST trial, including non-users[48]

6.4%) was more common in the WCD group.[48] A recent small, single-center, retrospective study assessing quality of life via a questionnaire of 109 WCD patients showed that 48% reported restriction in daily routine and sleep disturbances, with only 64% reporting "feeling safe" with the WCD.[51] Further, large systematic studies are needed to assess the psychological impact of WCD, in order to improve compliance.

Guideline recommendations for WCD use

In the April 2016 issue of *Circulation*, the AHA published a science advisory on use of the WCD, which was endorsed by the Heart Rhythm Society.[52] It concluded that:

1. Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care, such as infection (Class IIa).
2. Use of WCDs is reasonable as a bridge to more definitive therapy, such as cardiac transplantation (Class IIa).
3. Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of LV dysfunction; for example, in ischemic heart disease with recent revascularization, newly diagnosed NICM in patients starting GDMT, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable (Class IIb).
4. WCDs may be appropriate as bridging therapy in situations associated with increased risk of SCD in which ICDs have been shown to reduce SCD but not overall survival, such as within 40 days of MI (Class IIb).
5. WCDs should not be used when non-VA risk is expected to significantly exceed VA risk, particularly in patients who are not expected to survive >6 months (Class III).

All 5 recommendations carry a "C" level of evidence.

The *Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death*, jointly published in 2017 by the American College of Cardiology, American Heart Association, and the Heart Rhythm Society, recommend WCD for primary prevention in ischemic heart disease patients with LVEF ≤40% with MI <40 days prior and/or revascularization <90 days prior (Class IIB indication), with recommended reassessment of LVEF after this waiting period at which time ICD implantation may be reconsidered using the updated results. The second recommendation is for use of the WCD in newly diagnosed NICM (LVEF ≤35% at <90 days after first diagnosis) heart failure patients or NICM with LVEF ≤35% not yet on optimal GDMT (Class IIB) who are candidates for ICD following reassessment of LVEF at ≥3 months.

The International Society for Heart and Lung Transplantation gives a Class IC recommendation to the use of WCD in outpatients listed as Status 1B for cardiac transplantation upon discharge from hospital.[53] It should be noted that the above guidelines were all published prior to presentation of the VEST results, the only randomized controlled trial of the WCD thus far. It is unclear if this trial will have any significant impact on the current guidelines, which designate a Class IIB ("may be considered") recommendation for the patient population involved in the VEST trial.

The Centers for Medicare and Medicaid Services (CMS) approved WCD coverage in July 2005. WCD therapy is currently reimbursable by CMS when prescribed for patients with a prior ICD requiring explantation or in situations in which an ICD would be indicated (e.g., a documented episode of sustained VT or VF in the absence of a reversible cause and >48 h after MI, in familial or inherited conditions such as long QT syndrome or hypertrophic cardiomyopathy which are associated with unstable VAs, and as primary prevention in patients with LVEF ≤35%) but cannot be implanted due to other clinical factors.

Contraindications to WCD therapy

There are few true contraindications to WCD use. A high voltage pacing artifact produced by an implanted pacemaker may lead to either oversensing and inappropriate tachy-VA treatment or pacing artifact misclassification resulting in shock inhibition.[54] As such, patients who are paced using a unipolar atrial or ventricular lead are not candidates for the current WCD. The WCD alerts the patient to an upcoming shock through audible, visual, and tactile alarms. Caution should be exercised when prescribing this device to individuals with significant hearing or other sensory difficulties. Furthermore, patients who are unable to abort therapy through response button activation secondary to either motor or cognitive impairment should not be prescribed a WCD. The FDA originally only approved the WCD for adult patients at least 18 years of age, and this restriction remained until 2015 when, following the release of data regarding its efficacy in the pediatric population, the WCD was approved for children who weigh at least 41 pounds with chest size of at least 21 in.[55,56]. Finally, WCD treatment is not advised in patients who are pregnant or are exposed to a significant amount of electromagnetic interference.

It should be noted that, in contrast to ICDs, wearable defibrillators do not presently have pacing capabilities. This may be most relevant in the immediate post-defibrillation period, during which asystole of variable duration may be encountered, or in monomorphic VT for which antitachycardia pacing may terminate the VA, allowing shock avoidance. A retrospective analysis of 142 shocks delivered by the WCD to treat VT/VF identified four episodes of post-shock asystole >10 s in duration.[57] Three of the four patients survived. If a significant bradycardia is sensed by the WCD, the device will issue an audible alarm to bystanders to contact emergency medical services. Patients with a concomitant need for bradycardia therapy should not be treated solely with a WCD.

Conclusion

The WCD is a device that provides continuous cardiac monitoring and defibrillation capabilities through a noninvasive, electrode-based system. WCD therapy has been shown to be highly effective at restoration of sinus rhythm in patients with VAs, and multiple clinical cohort trials document its utility in the treatment of patients who are either unable to undergo ICD implantation or are without an accepted indication for such invasive therapy. Because of variable patient adherence and lack of long term follow-up except in registry data, the WCD should not be considered a replacement for ICD therapy. A randomized trial using the WCD in a post-MI patient population at elevated risk of VA death did not report a VA mortality benefit, but did show a reduction in overall mortality. Clinical indications for WCD use are varied and continue to evolve as further experience with this relatively new technology emerges.

Statement of conflict of interest

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