Chapter

The Wearable Cardioverter-Defibrillator

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Abstract

The wearable cardioverter-defibrillator (WCD) is a rechargeable external device that can be worn under the clothing all day long and protects the wearer from potentially life-threatening ventricular tachyarrhythmias. When a dangerous arrhythmia is detected, the WCD can deliver high-energy shocks. The WCD has been shown to be effective in accurately detecting and appropriately treating ventricular tachycardia (VT) and ventricular fibrillation (VF). It is intended for temporary use as a bridge to an implantable cardioverter-defibrillator (ICD), heart transplantation, or left ventricular assist device; patients with heart failure with reduced ejection fraction may benefit from the WCD while their condition improves. It can be used temporarily after explant of an ICD until reimplantation is deemed possible. In select patients with myocardial infarction, a WCD may be useful during the immediate period after infarction. It is indicated for use when a permanently implanted ICD must be explanted because of infection; the patient can use the WCD until the infection resolves, and a new ICD can be implanted. The role of the WCD is emerging as an important therapeutic option to protect patients at elevated risk of sudden cardiac death (SCD).

Keywords: arrhythmia, cardiomyopathy, heart failure, heart transplantation, implantable cardioverter-defibrillator, sudden cardiac death, wearable cardioverter-defibrillator (WCD)

1. Introduction

Sudden cardiac death (SCD) is mainly due to ventricular tachyarrhythmias even though bradycardia may occur. The population at risk for SCD is heterogeneous and includes those whose risk is based on a transient arrhythmia-provoking electrical event, structural heart disease, a channelopathy, heart failure, cardiomyopathy, or other underlying conditions [1]. For patients at elevated risk for potentially life-threatening ventricular tachyarrhythmias but with a transient contraindication for an implantable cardioverter-defibrillator (ICD) therapy, the wearable cardioverter-defibrillator (WCD) is an important therapeutic option (LifeVest 4000®, Zoll, Pittsburgh, Pennsylvania, USA). The external vest delivers high-energy rescue therapy in the event a ventricular tachyarrhythmia is detected along with electrogram storage and remote monitoring [2]. First introduced to market in 2001, the WCD is intended for short-term use, typically for a few months [3].

2. The WCD and its function

Currently, there is only one WCD, the LifeVest 4000®, and no other similar products are on the market. The WCD weighs 800 g and is available in a range of sizes with adjustable straps and an elasticized belt to fit snugly next to the skin under clothing (**Figure 1**). The WCD has three pad-style electrodes for defibrillation and four more electrodes for arrhythmia detection (sensing). It is equipped with a battery-powered defibrillation unit capable of generating several high-energy shocks. When the WCD prepares to deliver a shock, it delivers a small amount of gel to the skin at each electrode, and a biphasic waveform of 75 or 150 J is delivered [4].

The WCD detects arrhythmias using an algorithm of heart rate (including rate stability and onset of arrhythmia) and waveform morphology. In the presence of noise or when a waveform template is not available, the detection function can work using rate alone. Once an arrhythmia is detected, the device signals the patient for about 30 s, allowing the wearer to abort the shock by manually depressing two response buttons. If the rate drops below the detection threshold during this 30-s waiting period, the detection is delayed or the shock prevented, depending on whether the slower rate was brief and temporary or persisted [5]. The WCD offers programmable parameters in that the ventricular fibrillation (VF) zone can be set between 120 and 250 beats per minute (bpm) and the ventricular tachycardia (VT) zone can be programmed from 120 bpm to the lower bound of the VF zone [6]. The clinician may also program the time from arrhythmia detection to therapy delivery from 60 to 180 s for the VT zone and 25 to 40 s for the VF zone [5].

The WCD is rechargeable and comes with two lithium-ion batteries. One battery is used at all times in the device, while the other may be charged in about 3.5 h using a proprietary charging station. Battery life is approximately 2 days, but even if the battery signals the patient that it is getting low, there is usually sufficient charge retained for 10 shocks of 150 J each. During an arrhythmic episode, the WCD will deliver up to five shocks. If the arrhythmia persists, the device detects again and repeats the cycle until the rhythm is converted or the battery is exhausted [5]. Once the WCD delivers therapy, it should be replaced.

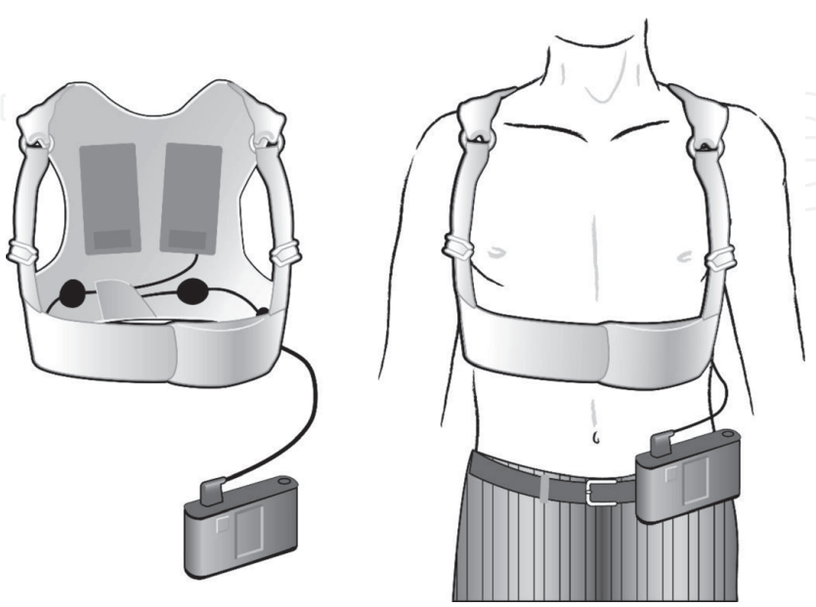

Figure 1.
The WCD (LifeVest 4000® from Zoll) is worn like a vest and is powered by a rechargeable battery, capable of delivering high-energy shocks to convert a potentially life-threatening ventricular tachyarrhythmia. Art by Todd Cooper.

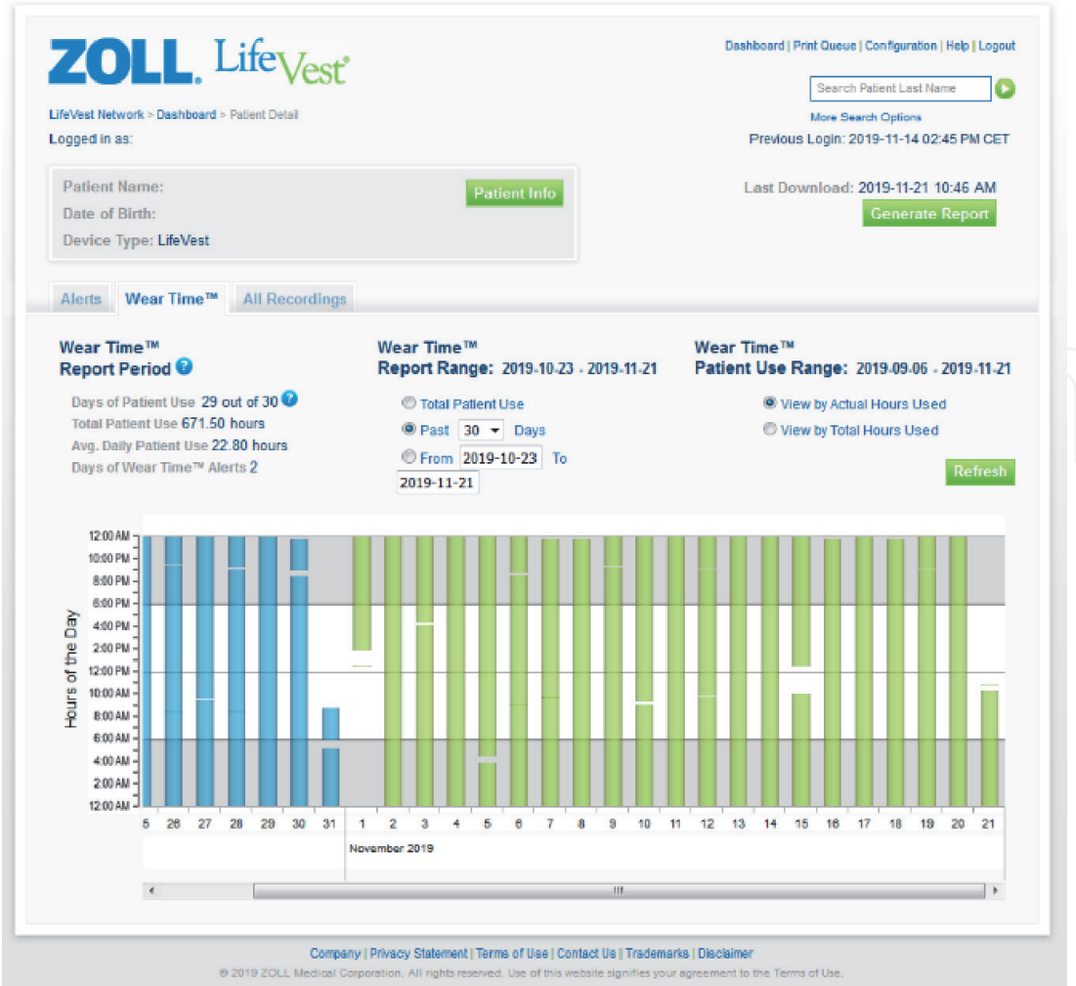

Figure 2.
The wear time: report on the WCD.

Patients are given a transmitter which can transmit data from the WCD directly to the clinic via a secure server. Remote transmissions do not require any patient intervention. Like cardiac implantable electronic devices, the WCD can be programmed to send out alerts when specific triggering events occur. The remote monitoring system records the number of hours per day that the patient wears the WCD, and the patient can activate the device to record an electrogram in the event of symptoms. While the WCD will attempt to make a daily remote transmission, if this is not possible, data transmission should occur at least once a week, and monthly in-clinic visits are recommended for WCD patients [5]. Reports from the WCD are shown in **Figures 2** and **3**.

3. Guidelines for the WCD

The American College of Cardiology, American Heart Association, and European Society of Cardiology (ACC/AHA/ESC) 2006 guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death was the first society-based recommendation for the use of WCD in patients at transient high risk for VF, such as patients waiting for heart transplant; patients at high risk following an acute myocardial infarction or invasive cardiac procedure; and patients whose ICD had to be temporarily explanted, for example, because of an infection [7]. The International Society for Heart and Lung Transplantation

Figure 3.
Report from the WCD about a tachycardia that was detected but did not require therapy delivery.

guidance made the WCD a Class I indication for Status 18 patients awaiting transplant at home [8]. In 2009, the Heart Rhythm Society expert consensus recommended that the WCD be considered as an alternative treatment for patients who needed early ICD revision following device explant in the setting of suspected continuing infection [9]. In 2013, the ACC/AHA guideline stated that the utility of the WCD in high-risk patients in the first 4 to 6 weeks after myocardial infarction was being investigated [10]. The European Heart Rhythm Association, Heart Rhythm Society, and Asia Pacific Heart Rhythm Society (EHRA/HRS/APHRS) Expert Consensus on Ventricular Arrhythmias stated that patients with heart failure

with reduced ejection fraction after a myocardial infarction (with or without revascularization) may benefit from WCD use in weeks to months until recovery [11]. Many patients who might be potential WCD candidates are not routinely included in clinical trials, and the HRS/ACC/AHA Expert Consensus Statement of 2014 suggested that the WCD may be considered as a "bridge to ICD" in certain patients [12]. The following year, in 2015, ESC guidelines suggested that the WCD might be used in patients with transiently impaired LV function, naming certain specific conditions such as myocardial infarction, peripartum cardiomyopathy, and myocarditis, and in patients awaiting heart transplantation or a left ventricular assist device [13].

In 2016, the AHA issued a science advisory about the WCD which was endorsed by the HRS [14]. Among their key concepts: they viewed the WCD as a temporary means for preventing arrhythmic death without the need of bystander response; despite limited evidence from randomized controlled trials, observational data support the notion that the WCD can detect and terminate ventricular tachyarrhythmias; and the use of a WCD is reasonable when there is a clear ICD indication and a current, transient contraindication to ICD implantation. According to this advisory, the role of a WCD is less clear when the risk of arrhythmias is transient, but a WCD still may be appropriate. The most controversial use of the WCD is in patients in the early recovery phase after myocardial infarction or with a newly diagnosed form of nonischemic cardiomyopathy. Many of these patients will not need a permanent ICD but will experience a period of time when they are at increased risk of SCD. Evidence for use of the WCD was C-level (expert opinion) and may be summarized as:

- The use of WCD is reasonable when there is an indication for an ICD, but a transient contraindication or interruption in ICD care (such as infection) temporarily prevents implantation (Class IIa).

- The use of WCD is reasonable as a bridge to more definitive therapy, such as heart transplant (Class IIa).

- The use of WCD may be reasonable if there is concern about an elevated SCD risk that is expected to resolve over time or with treatment, for example, ischemic heart disease following revascularization or nonischemic cardiomyopathy being initiated on guideline-directed medical therapy (Class IIb).

- The WCD may be appropriate as a bridge therapy when patients are at elevated risk for SCD in cases where an ICD would reduce the risk of SCD but not improve overall survival, such as within 40 days following acute myocardial infarction (Class IIb).

- WCDs should not be used when the risk for potentially life-threatening non-arrhythmic causes is expected to exceed the risk of ventricular arrhythmias, especially in those situations where longevity is not expected to exceed 6 months (Class III).

4. Clinical trials and other evidence

There are many observational studies about the use of the WCD, but to date only one large randomized clinical trial has been published, the Vest Prevention of Early

Study description	Appropriate therapy	Inappropriate therapy	Wear time	Comments
Acute myocardial infarction				
Barraud et al. 24 consecutive patients with LVEF <30% and recent myocardial revascularization	Two VT occurred (8.3%); one terminated spontaneously, and one was successfully treated	None	Mean 3.0 ± 1.3 months duration Daily wear time 21.5 hours/day	The WCD offered life-saving intervention for one patient
Kondo et al. 24 patients with myocardial infarction	Two patients (8.3%) received appropriate shock; both first shocks were successful	None	Median duration of WCD therapy was 33 days (range 20–67 days) Median daily wear time 23.1 h/day One patient excluded because of irregular use of WCD	In total, 58% went on to get ICD. Ejection fraction improved over baseline ($p < 0.01$) with 50% having an ejection fraction >35% Two patients (8.3%) died of fatal but non-arrhythmic events within 3 months
Controlled studies				
Olgin et al. VEST 2302 patients with myocardial infarction with ejection fraction ≤35% 1524 in WCD arm 778 controls	20 patients (1.3% of WCD group)	Nine patients (0.6% of WCD group)	Mean follow-up was 84.3 ± 15.6 days Wear time for WCD patients was median 18.0 h/d (3.8–22.7) with decreasing wear time over course of study	Arrhythmic death occurred in 1.6% and 2.4% of WCD and controls, respectively (not significant) All-cause mortality rates were 3.1% and 4.9% for WCD and controls, respectively ($p = 0.04$) Of the 48 WCD patients who died, only 12 were wearing the WCD at time of death
Heart failure				
Barsheshet et al. 75 heart failure patients prescribed a WCD in an observational study at 2 centers, SWIFT	Eight arrhythmic events occurred in 6.6% of patients (n = 5), all successful	None	Median wearing duration was 59 days, 80% of patients wore the WCD more than 50% of the day	At the end of study, 28% received an ICD
Duncker et al. PROLONG study 156 patients with ejection fraction ≤35% prescribed WCD for 3 months and then re-evaluated	Eleven patients received a total of 12 appropriate shocks	None	Cumulative 42.7 patient-years of wear time; mean time per patient was 101 ± 89 days Wear time 21.7 ± 4.0 h/day	48/156 discontinued therapy before 3 months (noncompliance, early improvement of ejection fraction, ICD implanted, etc.)

Study description	Appropriate therapy	Inappropriate therapy	Wear time	Comments
				33% of patients improved within 3 months to ejection fraction >35%
Heart transplantation				
Opreanu et al. 121 patients awaiting heart transplantation National registry based on convenience sample 55% NICM, 17% ICM, 27% mixed 32% were NYHA Class III and 34% Class IV	Seven patients (6%)	Two patients (1.7%)	Median wear time 39 days Median daily use 20 h/day	Eleven patients (9%) died in the study
Hemodialysis				
Wan et al. 75 hemodialysis patients with a history of SCA	75 patients (100%) experienced at least 1 SCA event while wearing the WCD 84 total events 136 total shocks delivered	Not reported	Mean duration of wear 62.9 ± 73.1 day (2–308 days) Mean daily wear 18.9 ± 4.6 h/day	Among patients with shockable rhythms, 30-day survival rate was 63.0%
Infected device				
Ellenbogen et al. 8058 patients who had an ICD removed for infection and used WCD as bridge to reimplant	334 patients (4%) experienced 406 VT/VF events, of which 348/406 (86%) were treated by WCD, all successfully 54 patients aborted shocks for arrhythmias that resolved spontaneously 12-month cumulative event rate 10%	159 patients (2%), no associated deaths	Median wear duration 53 days (25–94) Daily wear time not reported	Risk of VT/VF was highest in initial weeks after ICD removal at 0.9%, 0.7%, and 0.7% for first, second, and third weeks, respectively 30-day post-event survival rate was 81% overall 80% of patients in this study got an ICD
Observational studies from a single center				
Bhaskaran et al. Eight WCD patients	None	None	Median duration 77 days Mean daily wear 23.4 ± 0.6 h/day	1/8 patients in the study were noncompliant with WCD

Study description	Appropriate therapy	Inappropriate therapy	Wear time	Comments
Erath et al. 102 WCD patients	Four patients (3.9%)	Two patients (2.0%), both due to SVT	Median duration 54 days Median daily wear 23 h/day	55% received an ICD
Naniwadekar et al. 140 WCD patients 32% ICM, 46% NICM 85.9% African-Americans	Two patients (1.4%) received a total of two appropriate shocks	Two patients (1.4%) received a total of four inappropriate shocks (two SVT, two artifacts)	Median duration 43 days (7–83 days) Mean daily wear time 17.3 ± 7.5 h/day	Seven patients died 32% received an ICD
Roger et al. 105 consecutive patients with newly diagnosed ICM or NICM and ejection fraction ≤35%	Five patients (4.8%)	None	Mean duration of wear 68.8 ± 50.4 days Mean wear time 21.5 ± 3.5 h/day	At the end of WCD wear, 54.8% of ICM and 48.8% of NICM patients indicated for primary prevention ICD
Sasaki et al. Nine patients at risk for SCD	One patient (11.1%)	None	Median duration of use 21 days [7–31] Median wear time 23.7 h/day (23.6–23.9)	One patient died of worsening heart failure 67% received an ICD
Pediatric				
Spar et al. 455 patients (age 3–17 years)	Six patients (1.3%) received a total of 13 shocks	Two patients (0.4%)	Median duration of use 33 days (1–999) Median wear time 20.6 h/day (0.3–23.8)	Seven patients died, none of whom were wearing the WCD at time of death
Psychological aspects				
Weiss et al. 123 WCD patients from a multicenter registry administered several surveys	NA	NA	NA (study followed patients for 6 weeks)	Depressive symptoms decreased from 21% at baseline to 7% after 6 weeks of using the WCD Anxiety decreased from 52% at baseline to 25% at week 6
Registries				
Chung et al. National postmarket registry Retrospective analysis	First shock success was 100% (75/75) for unconscious VA and	Inappropriate shocks occurred in 1.9% of patients in 4788 months of use, or 1.4% per month	Mean duration of wear 52.6 ± 69.9 days (range 1–1590 days)	14.2% of patients discontinued WCD Overall survival rate was 99.2% but

Study description	Appropriate therapy	Inappropriate therapy	Wear time	Comments
3569 WCD patients Compared against Social Security Death Index	99% (79/80) for all VA 89.5% survival of VA events	Multiple reasons for inappropriate shock. Some of these shocks could have been aborted by patients, but patients did respond	Median daily wear time was 21.7 h/day 52% of patients wore WCD >90% of day	no significant difference compared to first ICD implant patients
Daimee et al. 1732 grouped as older (≥65, n = 722) and younger (<65 years, n = 1010)	Older patients had higher event rates per 100 patient-years for sustained VT and VF (32.0 vs. 9.8, (p = 0.027) Older patients, especially those with ICM were more likely to have VT/VF treated with shock (6.9 vs. 2.4, p = 0.034)	Not reported except as being "rare"	Older patients had significantly longer wear times (median 22.8 h/day vs. 22.3 h/day p < 0.001)	Younger patients with NICM had higher event rates per 100 patient-years for atrial arrhythmias (150.0 vs. 74.9, p = 0.055) Older patients were more likely to get an ICD after WCD (41.8% vs. 36.5%, p = 0.034)
Kutyifa et al. 3195 (805 with ICM, 927 with NICM, 268 with congenital heart disease) WEARIT-II Registry	41 patients had 120 episodes of sustained VT, of whom 54% received an appropriate shock	0.5% of patients got an inappropriate shock	Median duration of wear was 90 days Median wear time 22.5 h/day	At the end of WCD use, 42% got an ICD; most frequent reason not to get an ICD was improved ejection fraction
Lamichhane et al. 220 WCD patients in manufacturer's postmarket registry of individuals who wore the WCD > 1 year 33.2% of the patients were African-Americans	4.1% A total of 13 sustained VT episodes with 92.3% success rate (12/13 shocks)	3.6%	Mean duration was 451 ± 290 days Median wear time 20.4 h/day (15.5–22.9)	Two patients died (one refractory VT and one bradycardia transitioning to asystole), and 59% of patients stopped using the WCD before the study ended, either because they got an ICD, their condition improved, they had another intervention (transplant), or other reasons
Retrospective analyses				
Bossory et al. 201 patients from 1 center prescribed a WCD with 1 year follow-up	Five patients (2.5%), nine shocks	One patient (0.5%), SVT	Mean duration was 63 ± 53.7 days Mean wear time 23.0 ± 0.62 h/day	79% of WCDs were prescribed by clinicians who were not EPs

Study description	Appropriate therapy	Inappropriate therapy	Wear time	Comments
Dillon et al. 2105 WCD patients in a retrospective analysis of arrhythmia detection	1.58 appropriate shocks per 100 patient-months 54 total appropriate shocks	0.99 inappropriate shocks per 100 patient-months 34 total inappropriate shocks, most due to interference (47.1%)	Data for 1 year were analyzed Median duration of use was 36 days (3–365) Median wear time 21.3 h/day (0–23.9)	Most frequent reason for wearing the WCD was myocardial infarction, but study included several indications
Ellenbogen et al. population came from 234 consecutive in-hospital episodes of VT/VF in 173 in-hospital patients who had a WCD for primary prevention, history of VA, or other reasons, including device explant; 40% had a history of myocardial infarction	100% had an appropriate shock 68% occurred during weekdays, and 55% of events happened in the daytime	Not reported	Median follow-up 6 days while patients were in the hospital	Most VA occurred in unmonitored units, the ICU, and the ED 24-h survival following therapy delivery was >90%
Quast et al. 79 WCD patients	Two patients (2.6%) for annual rate of 13.6%	One patient (1.3%) for annual rate of 6.7%	Median duration 73 days (50.0–109.8) Median daily wear time 23.3 h/day (22.6–23.7)	In 52.2% ejection fraction improved enough that ICD implant was not necessary
Salehi et al. 127 patients with CM and self-reported excessive alcohol use	Seven patients (5.5%) had nine sustained VT episodes, 100% successful conversion	Not reported	Median duration 51 days Median wear time 18.0 h/day	11 patients (8.6%) died during the 100 days of follow-up, but no deaths were caused by WCD shock failure or undersense
Singh et al. 639 WCD patients ICM and NICM	None for NICM patients Six ICM patients (2.2%), of whom five survived the shock and four survived to hospital discharge	Three NICM patients (1.2%) 0.7% of ICM	Mean duration 61 days (25–102) Mean daily wear 22 h/day	
Uncontrolled studies				
Beiert et al. 114 patients ICM (31.6%) NICM (45.6%) Congenital heart disease (5.3%)	6.1% (no NICM patients were shocked) One patient had an appropriate but ineffective shock and was externally defibrillated	64 patients (56.6%) were signaled inappropriately for a shock, almost all due to artifacts. All shocks were aborted by the	Median duration 52.0 days (range 25–90) Daily wear time 23.1 h/day (19.0–23.8)	One patient in this study died of asystole

Study description	Appropriate therapy	Inappropriate therapy	Wear time	Comments
Infected device removal (11.4%) and others		patients, no inappropriate shocks delivered		
Feldman et al. WEARIT (n = 177) and BIROAD (n = 112) studies WEARIT patients had symptomatic heart failure and ejection fraction < 30% BIROAD patients had acute myocardial infarction and were in waiting period of 30–40 days before an ICD could be implanted	Eight appropriate shocks of which 75% were successful The two unsuccessful shocks were deemed related to improperly placed electrodes	Six inappropriate shocks (0.67% unnecessary shocks/month)	Mean duration of use was 3.1 months (2.6 for BIROAD and 3.4 for WEARIT groups, respectively) Daily wear time not reported	12 patients died (5 of whom were not wearing WCD, and 1 wore it improperly) 68 patients dropped out of study for adverse events or discomfort wearing the WCD
Wassnig et al. 6043 WCD patients	94 patients (1.6%) were shocked Incidence rate 8.5% (95% CI, 6.7–10.7) per 100 patient-years for men and 7.9% (95% CI, 4.8–12.3) for women 94% success rate	26 patients (0.4%), incidence 2.3 (95% CI, 1.5–3.4) per 100 patient-years In 10 cases, the reason was SVT	Median duration varied from 49 to 66 days Median daily wear varied from 22.7 to 23.5 h/day	Patients with explanted ICDs had higher average rates of shock (19.3 per 100 patient-years, 95% CI, 12.2–29.0)
Zylla et al. 106 real-life cases taken from 2010 to 2016	One patient (0.94%) shocked for VF, successful	Two patients (1.9%) 12.3% had an average of >1 inappropriate shock alarms per day (shocks aborted)	Median duration of wear 58.5 days Mean wear time 22.7 h/day Younger patients (≤ 50 years) less compliant	17% discontinued therapy for various reasons: discomfort, frequent alarms, reimbursement problems, technical issues

AMI, acute myocardial infarction; CI, confidence interval; CM, cardiomyopathy; EP, electrophysiologist; ICD, implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; NICM, nonischemic cardiomyopathy; NYHA, New York Heart Association; SCA, sudden cardiac arrest; SCD, sudden cardiac death; SVT, supraventricular tachycardia; VA, ventricular arrhythmia; VF, ventricular fibrillation; VT, ventricular tachycardia; WCD, wearable cardioverter-defibrillator.

Table 1.
An overview of the main uses of the WCD, therapy deliveries, and key findings [15, 17–44].

Sudden Death (VEST) study (n = 2302) [15]. All patients had had a recent myocardial infarction and a left ventricular ejection fraction ≤35%; some but not all patients had undergone revascularization. Patients were randomized into two arms: guideline-directed medical treatment (control) or a WCD. In the first 90 days after myocardial infarction, the WCD did not result in a lower rate of arrhythmic death, but total mortality was lower in the WCD group (3.1% vs. 4.9%, p = 0.04, uncorrected) [15]. Despite the fact that the VEST study did not result in a lower rate of arrhythmic death for WCD patients, there are important aspects of this study that deserve deeper scrutiny. Unwitnessed arrhythmic death is difficult to ascertain, and five of the nine VEST subjects deemed to have died due to an arrhythmia were wearing the WCD at the time, and the WCD showed no evidence of a tachyarrhythmia. Since arrhythmic death is rare, even a small number of misinterpretations in a study like this may skew results. Moreover, the study was designed assuming patients would wear the WCD at least 70% of the time, and compliance dropped as the study progressed. Since fewer patients wearing the WCD died, it has been argued that there was not a single active treatment group in the study (WCD group) but rather two: patients randomized to the WCD group broken down into those who wore the WCD and those who did not [16]. Of the patients in the WCD arm of the study who died, 75% were not wearing the WCD at the time [15].

Early after the WCD was first cleared to market, an observational study called the Wearable Defibrillator Investigative Trial (WEARIT) enrolled 177 ambulatory patients who had New York Heart Association (NYHA) functional Class III or IV heart failure and an ejection fraction <30%. It was subsequently combined with a similar observational study, the Bridge to ICD in patients at risk of sudden arrhythmic death (BIROAD), which enrolled patients who had an AMI and needed bridge therapy for up to 3 months (n = 112). In 901 patient-months, the mean duration of wear was 3.1 months. Among the WEARIT patients, there were two appropriate and successful therapy deliveries in the same patient several days apart, and there were four appropriate, successful therapies delivered in two of the BIROAD patients. Two unsuccessful therapy deliveries occurred, both of which involved the improper wear of the WCD. Altogether, 12 patients died over the course of the study, none of whom were wearing the WCD at the time. Over the 901 patient-months, there were 6 inappropriate therapy deliveries in 6 patients (0.7% per month) [17].

The WEARIT-II Registry enrolled 2000 patients, of whom 805 were diagnosed with ischemic cardiomyopathy, 927 with nonischemic cardiomyopathy, and 268 with congenital heart disease [18]. During the study, 41 patients experienced a total of 120 episodes of VT, of whom 54% received an appropriate shock. Inappropriate shocks occurred in 0.5% of patients. Many of the patients in WEARIT-II had improved their ejection fraction over the course of time they wore the WCD, and at the end of WCD treatment, only 42% got an ICD.

The Study of Wearable Cardioverter Defibrillator in Advanced Heart-Failure Patients (SWIFT) was a nonrandomized prospective study at two centers evaluating the use of the WCD in 75 patients hospitalized with advanced heart failure symptoms and LV dysfunction. Patients wore the WCD for 3 months after hospital discharge. Two-thirds of the patients (66%) had nonischemic cardiomyopathy. Eight arrhythmic events occurred in five patients, all successfully terminated by the WCD. No inappropriate therapies were delivered, and no patients died in the course of the study. When the study concluded, 28% were implanted with an ICD [19].

A summary of these trials appears in **Table 1**.

5. Patient populations

5.1 Transient contraindication for an ICD

One of the main reasons for WCD use is ICD system infection, which poses a clinical challenge in that the best course of action is to extract the device and lead(s), submit the patient to a course of antibiotic therapy, and then replace the ICD system with a new device [7, 9, 45]. The rate of infections associated with cardiac implantable electronic systems continues to increase, even at high-volume centers [46]. Antimicrobial therapy may last 10–14 days or longer, depending on the nature of the infection and the patient's response. During this time, the patient is without an ICD. Leaving the ICD in place while treating an infection is associated with a high mortality rate (31–66%) [47, 48], but removing the device also increases the patient's mortality rate, albeit from 8–27% [49–51]. Thus, the clinician faces three challenges: if the device is replaced too early, the patient risks re-infection; if the patient is deprived of the device too long, there is a risk for potentially life-threatening arrhythmias; and placing the patient under close monitoring in the hospital or a long-term care facility is cost prohibitive and deleterious to the patient's quality of life. In such cases, the use of a WCD can be a valuable interim solution for arrhythmic rescue.

In a study of 97 ICD patients whose devices had to be explanted for infection, patients were prescribed a WCD for the mean antimicrobial treatment course of 21 days. As they recovered from infection, two patients experienced a total of four VT episodes, all of which could be successfully treated [52]. In a retrospective analysis of 8058 patients who received a WCD from 2002 to 2014 when an infected ICD was removed, 4% experienced ventricular tachyarrhythmias, and the rate of arrhythmic episodes was greatest in the first 3 weeks after device explantation (0.9, 0.7, and 0.7%, respectively), and the risk for ventricular tachyarrhythmias after device removal was 4% during the first 2 months and 10% at 1 year [25].

5.2 Bridge to cardiac transplantation/left ventricular assist device

Heart transplantation or the use of a left ventricular assist device is the only potentially long-term therapeutic option for some patients, but during the waiting period, patients are at high risk for dangerous arrhythmias and may have other comorbid conditions as well. In a study of 121 patients prescribed with the WCD while waiting to receive a donor heart (mean 127 days), 7 patients (5.8%) were shocked appropriately, and all survived [23]. Two inappropriate therapy deliveries occurred deemed to be caused by rapid ventricular response to atrial fibrillation. In this study, two patients died of asystole during the waiting period; asystole is not treated by the WCD because it lacks a pacing capability [23].

5.3 Low ejection fraction in reimbursement-mandated waiting period

In the USA and other parts of the world, patients with an ejection fraction ≤35% may be required by reimbursement authorities and guidelines to wait out a specific period of time before an ICD may be implanted; these time periods range from 30 to 90 days. This includes patients with cardiomyopathy.

5.4 NYHA Class IV heart failure

This group of patients meets the requirements for Class IV heart failure but is not otherwise indicated or qualified to receive an ICD. Some of these patients may

be waiting for cardiac transplantation, while others may be contraindicated for ICD implant for other reasons (frailty, comorbidities, patient refusal, and so on). The Study of Wearable Cardioverter Defibrillator in Advanced Heart-Failure Patients (SWIFT) was a prospective study of 75 advanced heart failure patients at 2 centers. All patients had low ejection fraction (21.5 ± 10.4% at baseline), were prescribed a WCD, and were followed up for 3 months. In the SWIFT study, 66% of patients had nonischemic cardiomyopathy. Over the course of the study, eight arrhythmic events occurred in five patients, including three episodes of nonsustained VT and one episode of polymorphic VT; all episodes were appropriately treated. No patient in the study received inappropriate therapy delivery. At the end of the study, 28% of patients went on to permanent device implantation, and the cumulative mortality rate at 3 years in this population was 21% for patients with nonischemic cardiomyopathy compared to 21% for those with ischemic cardiomyopathy [19].

5.5 Ischemic and nonischemic cardiomyopathy

Patients with ischemic cardiomyopathy may be indicated for a primary prevention ICD if they have an ejection fraction ≤35% and NYHA functional Class II or III or if they have an ejection fraction ≤30% with NYHA Class I [53]. Nonischemic cardiomyopathy covers a range of conditions that may include inflammatory, toxic, metabolic, genetic, or autoimmunological processes, and arrhythmic activity, including SCD, may be one of the first symptoms of nonischemic cardiomyopathy [5, 13]. Such patients typically fall into the reimbursement-mandated waiting period before a primary prevention ICD can be implanted, and many patients with recent-onset cardiomyopathy recover left ventricular ejection fraction and even experience reverse remodeling to the point that ICD implantation is unwarranted [5]. In cardiomyopathy patients, it is not clear if and how long patients should wait before ICD implantation is either deemed reasonable or unnecessary [5]. Ischemic cardiomyopathy patients may have higher rates of events than nonischemic cardiomyopathy patients [42]. Pharmacological therapy for cardiomyopathy may also improve the ejection fraction, and the WCD may be helpful as medical therapy is optimized [53].

In a retrospective single-center study of patients from June 2004 to May 2015, focus was placed on patients with newly diagnosed cardiomyopathy (254 nonischemic and 271 ischemic) [41]. Patients wore the WCD for a median of 61 days (interquartile range 25–102 days) and for a median of 22 h/day (17–23 h). The study produced 56.7 patient-years of data for nonischemic cardiomyopathy patients, during which no patients got appropriate shocks, but 1.2% (n = 3) were shocked inappropriately. There were 46.7 patient-years of data for ischemic cardiomyopathy, where 2.2% (n = 6) were shocked appropriately and two inappropriately (0.7%) [41].

5.6 Acute myocardial infarction

The role of defibrillation has been controversial in acute myocardial infarction (AMI) patients since the defibrillator in acute myocardial infarction trial (DINAMIT) reported that early ICD implantation failed to confer a mortality benefit in this arrhythmia-rich population [54]. Current guidelines recommend that following myocardial infarction, patients with compromised left ventricular function do not receive an ICD for a 3-month to 40-day waiting period, whether or not they have been revascularized [53]. In the weeks immediately following a myocardial infarction, patients are vulnerable to a number of potentially lethal conditions, many unrelated to ventricular tachyarrhythmias, so that the mortality rate for myocardial infarction patients with or without an ICD is roughly the same (7.2% for

both, assuming linear mortality rates in the first 3 months, based on DINAMIT study data) [54]. This imposes a "waiting period" on myocardial infarction patients before a device may be implanted and during which time they may be especially vulnerable to SCD. For many patients and clinicians, this creates a tension between abiding by evidence-based guidelines and meeting reimbursement requirements yet still providing reasonable means to rescue post-AMI patients from SCD [6]. The WCD has been proposed as an interim device for this population during this waiting period before a permanent ICD may be implanted. Further complicating this picture is the fact that some myocardial infarction patients will recover left ventricular function in the weeks following their heart attack to the point that they do not require an ICD at all. Thus, it may be argued that for these patients, the use of the WCD may be to provide possible rescue during recovery from the myocardial infarction and to avoid unnecessary ICD implantation [6].

It has been observed that myocardial infarction patients prescribed a WCD and shocked appropriately and successfully to convert a ventricular tachyarrhythmia nevertheless have high mortality rates. While this remains to be elucidated, it suggests that either ventricular tachyarrhythmias in the immediate aftermath of a heart attack are indicative of poor outcomes or the arrhythmia and/or the rescue shock has a destabilizing effect on the patient [55]. The Valsartan in acute myocardial infarction trial (VALIANT) evaluated 14,609 myocardial infarction patients with low ejection fraction for SCD. VALIANT reported myocardial infarction patients with an ejection fraction ≤30% had a mortality of 2.3% per month in the first 30 days after the myocardial infarction (and that 83% of all patients who died of sudden unexpected death died within the first 30 days of hospital discharge). Every decrease of 5% in the ejection fraction was associated with a 21% increase in SCD risk in the first 30 days after myocardial infarction [56].

The Vest Prevention of Early Sudden Death (VEST) trial found that in myocardial infarction patients with low ejection fractions (≤35%), the WCD did not significantly reduce arrhythmia-associated deaths compared to the control group who did not have a WCD [15]. The rates of arrhythmic death were 1.6% in the WCD and 2.4% in the control group (relative risk 0.67, 95% confidence interval, 0.37–1.21, $p = 0.18$) [15]. It must be noted in this connection that arrhythmic death can be challenging to adjudicate when the patient dies without a witness. However, even comparing all-cause mortality data did not provide a significant benefit for WCD patients over those who did not have a WCD [15].

5.7 Renal failure

Compared to one SCD death per 1000 patient-years in the general population, hemodialysis patients face a 50-fold greater risk of arrhythmic death at 43 deaths per 1000 patient-years [57, 58]. Patients on hemodialysis present clinical challenges in that they are often comorbid and frequently geriatric, may be frail, and are prone to infections. End-stage renal disease and hemodialysis expose these patients to a very considerable risk of arrhythmic death, but many hemodialysis patients are not appropriate candidates for ICD therapy. Compared to historical data, the WCD has been associated with improved survival in renal failure patients [24].

5.8 Other conditions

5.8.1 Takotsubo cardiomyopathy

Takotsubo cardiomyopathy, sometimes called "broken-heart syndrome," is a form of cardiomyopathy where the myocardium weakens and remodels. This

condition is potentially reversible, but while patients experience the cardiomyopathy, they are at risk for potentially life-threatening ventricular tachyarrhythmias, and some develop concomitant QT interval prolongation, further increasing their risk for arrhythmia [5]. In a study based on all data from the USA involving WCD wear from 2007 through 2012, a total of 102 takotsubo patients were identified by the ICD-9 code 429.83. This population was overwhelmingly female (89%) with an initial ejection fraction of 27 ± 6% who wore the WCD for a mean duration of 44 ± 31 days with a mean follow-up of 440 ± 374 days. During the WCD wear time, 2% of patients (n = 2) received an appropriate shock, 1% (n = 1) received two inappropriate shocks, and 2% (n = 2) suffered bradyarrhythmias that required pacing. Two patients in the study died (one asystole and one from an arrhythmia while not wearing the WCD) [59].

5.8.2 Peripartum cardiomyopathy

Peripartum cardiomyopathy results in left ventricular dysfunction that can predispose the patient to SCD. About half of these patients will recover significantly or entirely over the course of about 6 months even without intervention; however, some will not, and all are at high risk for arrhythmias during the course of the condition [5]. In a study of 12 consecutive women with peripartum cardiomyopathy observed at a single center (of whom seven wore the WCD), four episodes of VF occurred in three of the patients wearing the WCD, all of which were successfully terminated. One patient experienced numerous alarms for inappropriate shocks but was able to abort them so that no inappropriate shocks occurred. No deaths occurred. During therapy for heart failure, over the course of the 12-month follow-up, ejection fractions improved significantly from 24.0 ± 11.8% at baseline to 46.6 ± 7.6%. Patients with a lower ejection fraction at baseline improved more than those with a higher ejection fraction at baseline [60].

5.8.3 Long QT syndrome

Long QT syndrome (LQTS) is a heritable and potentially fatal cardiac channelopathy that exposes patients to the risk of SCD. LQTS patients are typically treated with beta blockade, left cardiac sympathetic denervation, and, in some cases, a permanent ICD. It is unclear what, if any, role the WCD might play for treating LQTS. A retrospective review of 1027 LQTS patients who were prescribed a WCD as a bridge to possible ICD implantation or other treatments found no inappropriate shocks that were administered by the WCD and only 1 patient received an appropriate shock to terminate VF [61]. Since LQTS is a lifelong condition, the WCD is not an optimal permanent solution in this population, but it may be helpful as newly diagnosed patients consider their therapeutic options or for LQTS patients on medical therapy who are entering high-risk periods of life, such as having to take a medication that might prolong their QT interval further or in postpartum women [61].

6. Special populations

The WCD is available in different sizes and has an elasticized waistband and adjustable straps, making it suitable for use in a variety of patients, including children. The role of the WCD in certain special populations is being addressed, but there is limited evidence about these groups.

6.1 Pediatric patients

Guidance is available to schools and teachers for children prescribed the WCD. In particular, it is important that educators realize that unlike the automatic external defibrillator systems available in many schools, the WCD will detect arrhythmias and treat them without any bystander intervention [62, 63]. Children seem to adjust well to the WCD. In a study of 231 pediatric WCD patients between the ages of 8 and 17 years monitored a median of 39 days with daily wear time around 21 h/day, a step-counter accelerometer device reported that activity levels for these children increased significantly over baseline in the first 3 weeks after getting the WCD ($p < 0.001$) [64]. This suggests that the WCD does not inhibit or curtail the children's activities and may help them achieve recommended levels of daily exercise.

6.2 Cancer patients

Some patients with cancer may be at elevated risk for dangerous arrhythmias because of chemotherapy-induced cardiomyopathy or long QT syndrome caused by drugs but may be contraindicated for device implant because of their malignancy or other reasons [65].

6.3 Geriatric patients

The prevalence of cardiovascular disease is high in the geriatric population, but there may be reluctance to consider an older patient for WCD therapy, in particular because it may be uncomfortable or feel restricting to them. In a large study of 1732 patients with ischemic and nonischemic cardiomyopathy, patients were grouped by age into younger (<65 years) and older groups (≥65 years). The older group ($n = 722$) wore the WCD more hours per day (median 22.8 vs. 22.3, $p < 0.001$) and had higher rates of events (31.95 vs. 9.82, $p = 0.027$). Younger patients with nonischemic cardiomyopathy had a higher rate of atrial arrhythmias (150.1 vs. 74.9, $p = 0.055$), and more following WCD therapy, a greater number of older than younger patients got a permanent ICD (41.8% vs. 36.5%, $p = 0.034$). Patients in both age groups tolerated WCD therapy well [34].

7. Appropriate and inappropriate therapy

The WCD has been shown to deliver appropriate high-energy therapy to convert dangerous ventricular tachyarrhythmias. In a postmarket registry of 3569 WCD patients (mean duration wear was 52.6 ± 69.9 days), first shock success occurred in 99% of cases (79/80) for all episodes of conscious VT/VF and in 100% of cases ($n = 76$) of unconscious VT/VF [33]. Because the WCD is an external device, it is far more exposed to sources of electromagnetic interference (noise) than implanted devices, which may result in oversensing, inappropriate arrhythmia detection, and inappropriate therapy delivery. Patients are signaled about 30 s prior to therapy delivery and may abort the shock by pressing two buttons [39, 40]. For this reason, the rate of inappropriate therapy delivery with the WCD is relatively low, occurring in approximately 0.4–3.0% of patients [6, 18, 33, 43]. See **Table 1**.

The WCD delivers rescue shock therapy only and has no pacing capability. Asystole, a recognized risk factor for dangerous ventricular tachyarrhythmias, may occur in patients with compromised cardiovascular function, such as low ejection fraction. While an ICD can detect and offer pacing support during an asystole

episode, the WCD cannot pace such patients, and there is a risk that an untreated asystole may be fatal [66].

8. Patient factors

There are specific patient factors that warrant consideration when prescribing this novel therapeutic option. Many patients will have no concept of what a WCD is or how it works.

8.1 Patient education

Manufacturer's representatives may be available to help train patients in the proper function of the WCD, and, if they are not available, the clinical team should make sure the patient knows how to wear the vest, how to adjust it for proper fit, how to replace the battery, how to charge the battery, and how to transfer data from the WCD to the network. For this reason, the WCD requires the patient be able to understand and manage these tasks and be willing to do them. An initial training session should make sure the patient can put on the vest and insert batteries that may last an hour or more. It may be helpful for a second follow-up contact with the trainer over the course of the next few days to help with any questions or problems the patient may still have. The manufacturer has a 24-h technical support hotline for urgent questions [5].

8.2 Compliance

Compliance is an issue in all areas of medicine but particularly in the case of the WCD which patients may find restrictive or uncomfortable. A postmarket registry study (n = 3569) found that patients who used the WCD for a longer duration of time (days of wear) were significantly more likely to wear in more hours per day ($p < 0.001$) [33]. Over time, the WCD has been redesigned to make it lighter in weight and more comfortable for extended wear. Remote monitoring can alert the clinic as to actual wear time for an individual patient [67]. Compliance may be encouraged by educating the patient as to the nature of ventricular tachyarrhythmias and how the device protects them.

8.3 Psychological factors

It has been speculated that patients prescribed a WCD may experience emotional distress and view the device as a constant worrisome reminder of their own mortality. Patients may also feel isolated if they do not know anyone else who has ever worn such a device. Patients have sometimes reported that they find the device symbolic of their own vulnerability [33]. Of course, such adverse emotions may occur in all patients facing the sudden news that they have a serious cardiovascular condition regardless of whether they are prescribed a WCD or some other therapy. Psychological distress is an important clinical consideration because it is potentially modifiable. There may be ways to reduce depressive or anxious symptoms in clinically meaningful ways. Depression worsens outcomes and actually serves as a predictor for both mortality and shock therapy [68, 69]. Depression has been associated with a nearly doubled risk for all-cause mortality in ICD patients [69]. Furthermore, depression and anxiety may adversely affect patient compliance, adherence to pharmacological therapy, and lifestyle.

In another study of 123 patients considered WCD candidates, at baseline 21% showed signs of clinically depressive symptoms, and 52% had anxiety. Six weeks after WCD therapy commenced, rates of depression and anxiety dropped to 7 and 25%, respectively [32]. It is not clear if patients recovered their emotional equilibrium as a result of WCD therapy or as a matter of course as they got used to their new identities as cardiac patients.

8.4 Device-device compatibility

When a patient has more than one electronic cardiac device, the potential of device-device interaction exists. The literature reports one case of a fatal device-device interaction between a permanent pacemaker and a WCD [70]. In this case, the patient received unipolar dual-chamber pacing, but when he developed VF, no therapy was delivered as the device inappropriately detected the large unipolar pacing spikes as cardiac signals [70].

A study sponsored by Zoll examined pacing in 60 patients testing the AAI, VVI, and DDD modes in both unipolar and bipolar device configurations to determine if the WCD would detect the pacing spikes; patients were signaled before shock delivery and could use the patient response buttons to avert the therapy delivery. Only unipolar DDD pacing was detected by the WCD's algorithm and only in 10% of patients (6/60). This study suggests that pacing may occur concomitantly with WCD use if unipolar configurations are avoided [2]. If unipolar pacing must be used in a particular patient, then the WCD is contraindicated. Another study of the concomitant use of the WCD and a pacemaker showed that double-counting and waveform alterations might also occur in certain bipolar pacing modes and in single-chamber as well as dual-chamber pacing [44]. Caution is urged in using the WCD in patients with pacing support from an implanted pacemaker system.

9. Costs

The WCD is "rented" to patients for a monthly fee, and reimbursement provisions vary by country. Since costs can be substantial, there is a need to better stratify patients into those who truly need a WCD for arrhythmic rescue and those who might be unlikely to benefit from it [41]. Cost-effectiveness models show that the number needed to treat to save 1 life with a WCD falls in the range of 70–110 patients over a median of 53–57 days [26]. There are situations in which the WCD poses a decided cost advantage. For example, cardiomyopathy patients who might otherwise be considered a candidate for permanent primary prevention ICD implantation may benefit from using the WCD during a recovery period; data shows that ~60% of such patients will recover to the point that an ICD implantation is not necessary [18, 33, 41]. Thus, the costs for the temporary use of the WCD may be offset by the decision not to implant an ICD. In patients whose ICD must be removed for infection, it is sometimes necessary to keep the patient in the hospital or discharge him or her to a skilled nursing facility for weeks during antimicrobial therapy and recovery. The patient is at risk for SCD throughout this time. A cost-effectiveness analysis found that the WCD was cost-effective in this situation in that it allowed the patient to be discharged home; the analysis is based on the assumption that there was a 2-week 5.6% risk of SCD in the population and the patient had to wait at least 2 weeks before ICD replacement [71].

10. Future directions

The WCD technology effectively treats VT/VF, but bradycardia pacing support would likely prevent SCD to an even greater extent. Adding pacing capability to the WCD would be an important and life-saving step forward.

A major obstacle in WCD therapy remains patient adherence. Unfortunately, not all patients are motivated to comply with the prescription to use the WCD, and unnecessary deaths occur because of poor compliance. Therefore, motivating the patient to adhere to therapy is of utmost importance. A combined approach with technology reminders (e.g., text messages via smartphones) and close follow-up by device professionals is crucial.

Much has been accomplished in the past 30 years to better treat the risk of SCD, and the WCD is definitely an important milestone in our advancing knowledge. Nevertheless, much more needs to be done to reduce the rates of arrhythmic death even more.

A Class II recall of the WCD occurred in January 2018, covering 33,000 devices. This problem, in which certain vests displayed a warning message to the effect that they could not charge sufficiently to deliver therapy, has been addressed.

11. Conclusions

The WCD is an important advancement in the armamentarium for cardiovascular disease and demonstrates safe, effective therapy, but patient compliance remains a concern. The WCD is an interim therapeutic alternative to the ICD. In some cases, the WCD may help patients recover significant systolic function to the point that an ICD is no longer necessary. Patients who need the WCD should receive individual one-on-one instruction in how to use the device, and clinicians should be prepared that there may be a degree of psychological distress. Nevertheless, these devices are important advancement in cardiac care for people at risk of dangerous arrhythmias.

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Conflict of interest

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