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REVIEW

The wearable cardioverter-defibrillator: current technology and evolving indications

Sven Reek[1,2]*, Haran Burri[3], Paul R. Roberts[4], Christian Perings[5], Andrew E. Epstein[6], and Helmut U. Klein[7]

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[1]Electrophysiology Service, Hirslanden Klinik Aarau, Aarau, Switzerland; [2]Rhythmologie Aargau, Rain 34, CH-5000 Aarau, Switzerland; [3]Cardiology Service, University Hospital of Geneva, Geneva, Switzerland; [4]Cardiac Rhythm Management, University Hospital Southampton, Southampton, UK; [5]Cardiology, St Marien Hospital Luenen, Luenen, Germany; [6]Cardiovascular Division, Department of Medicine, University of Pennsylvania, Philadelphia, PA, USA; and [7]University of Rochester Medical Center, Heart Research Follow up Program, Rochester, NY, USA

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The wearable cardioverter-defibrillator has been available for over a decade and now is frequently prescribed for patients deemed at high arrhythmic risk in whom the underlying pathology is potentially reversible or who are awaiting an implantable cardioverter-defibrillator. The use of the wearable cardioverter-defibrillator is included in the new 2015 ESC guidelines for the management of ventricular arrhythmias and prevention of sudden cardiac death. The present review provides insight into the current technology and an overview of this approach.

Keywords Wearable cardioverter-defibrillator • Sudden cardiac death • Ventricular arrhythmias • External defibrillation • Life vest

Introduction

The implantable cardioverter-defibrillator (ICD) is central in the prevention of sudden cardiac death (SCD). Current guidelines recommend ICD implantation for secondary and primary prevention in patients with an established high risk of SCD.[1,2] However, in certain patients, the risk of SCD may be increased only temporarily or cannot be determined immediately, because risk stratification takes time. After preclinical testing and the first clinical trial, the wearable cardioverter-defibrillator (WCD) was approved for clinical practice in 2001 to bridge a period of actual or presumed high risk of SCD.[3,4] The number of patients protected by WCD is rapidly growing; hence, it is difficult to give an official number here. According to the manufacturer's database, the 100 000 patient mark had been crossed in 2013 (Sven Reek had communication with Mr. Horst Esser from ZOLL).

The purpose of this manuscript is to describe the technical aspects of the WCD, to discuss the indications, to report the clinical experience, and to provide available results of this approach.

Technology overview

Currently, only one WCD system (LifeVest®, ZOLL, Pittsburgh, PA, USA) is available. The WCD is a system that consists of a harness-style vest that contains non-adhesive dry tantalum oxide capacitive sensing electrodes and self-gelling defibrillator electrodes. This lightweight vest (0.8 kg) is designed to be worn continuously under normal clothing and is available in different sizes. A monitor is worn around the waist (or shoulder harness) and contains the sensing circuits along with batteries and capacitors (*Figure 1*). The device has a system of audible and vibratory alerts to warn a patient of an imminent shock. The patient can abort the shock by pressing buttons on the monitor. Data from the monitor can be transmitted to the patient's physician for offline analysis.

Arrhythmia detection

The harness contains four sensing electrodes (anterior/posterior/right/left) that produce a two-lead filtered ECG. The arrhythmia detection algorithm combines heart rate data with morphology

* Corresponding author. Tel: +41 62 836 7895; fax: +41 62 836 7896. *E-mail address*: sven.reek@hirslanden.ch

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Figure 1 Patient wearing device.

analysis. If morphology analysis is not available due to technical issues (e.g. noise interference), the algorithm reverts to just heart rate detection using rate, stability, and onset criteria. The heart rate is judged by the algorithm from multiple sources (on each channel, using fast Fourier transform). The algorithm compares the analysed heart rates from the two leads. If these rates differ significantly, less weight is applied to heart rate in arrhythmia discrimination. Once heart rate is established, the algorithm triages the rhythm into pre-programmable thresholds for ventricular tachycardia (VT) or ventricular fibrillation (VF). Once one of these thresholds is exceeded, the algorithm moves on to morphology analysis using the two leads in orthogonal axes and compares the real-time tracing to the templates collected in normal rhythm. A sensing circuit allows detection of electrode fall-off, which will result in system reverting to single lead detection.

The detection algorithm uses a 'confidence level' weighted score based upon heart rate, morphology, use of the patient response button, and signal quality.[5] Each of these factors can contribute negatively or positively to the overall result. The design goal was to only shock if the VT was at least 30 s long. Thus, the alarms were designed to last a minimum of 30 s. The algorithm continuously evaluates the ECG during the alarms. Basically, the algorithm reviews a moving window of parameters. If the rate drops below the detection threshold for a brief period (a few seconds), then detection will be delayed (extended to see whether the lower rate persists or whether it was just an aberration), and if it persists, the detection will stop. As a result, the median time from arrhythmia onset to shock delivery is ~45 s (*Figure 2*).

Patient interaction

The system evaluates the patient's consciousness by assessing response to the escalating alerts. Response buttons are located on either side of the monitor (*Figure 3*). The patient needs to press both buttons simultaneously and continue to hold them for therapy to be withheld. If the patient does not press or release them, the escalating warning system continues until finally an audible message for bystanders to stand clear is emitted. This unique patient interaction feature contributes to optimization of the sensitivity and specificity of the algorithm.[6]

Therapy

The device will deliver up to five shocks within a single arrhythmia episode. After five shocks, the device reverts to sensing and will repeat the cycle until either the rate drops below that required for VT/VF detection or the battery has depleted. The time to deliver therapy can be programmed in the different zones (60–180 s for VT and 25–40 s for VF). Appropriate programming of VT and VF zones is crucial to avoid inappropriate shock delivery. Programming VT rate to >180 bpm and the VF zone to >220 bpm substantially reduces the incidence of noise alarms that may lead to frequent response button use.

After a failed first shock, the second therapy is delivered ~60 s after the first detection of VF or 2 min after VT detection. This could be longer depending upon the programmed delay.

Shock therapy is a biphasic truncated exponential waveform and can be programmed from 75 to 150 J. Patients are usually given two rechargeable lithium ion batteries that are charged via a base station. While one is in the monitor, the other is usually on charge. Each battery will run the monitor for at least 2 days. If the battery indicates that it needs recharging, it will usually have sufficient charge to deliver around ten 150 J shocks.

Patient training and follow-up

Appropriate patient training for correct WCD use is provided by the technical personnel of the manufacturer and includes instruction on battery charging and data transfer to the network server. After the initial training, which may last an hour or more, the technical personnel contact the patient within the next few days to avoid potential problems of device use. Patients or their relatives can contact the 24/7 hotline for questions or in case of problems.

Data from any episode can be relayed to a secure server in a similar manner to conventional remote follow-up via the cellular mobile phone network. The monitor attempts to connect once a day if in the proximity of the base station. This allows for an individually tailored set of alerts to be programmed that can monitor arrhythmias, patient use (i.e. hours/day worn), and patient-triggered recordings. Since all VT/VF events are stored in the LifeVest® Network server (https://lifevestnetwork.zoll.com), the physician is automatically notified of an arrhythmia event or shock delivery. This system also provides information on wearing time, ECG quality, and occurrence of false alarms due to noise.

A weekly data transmission is requested, and monthly office visits are recommended. After a shock delivery, the garment needs to be replaced immediately.

Clinical experience with wearable cardioverter-defibrillator

The WCD was first described in 1998.[3] Since then, several case series and registries on the use of WCD have been published (*Table 1*). It has been shown that WCD is safe and effective in terminating VT/VF in high-risk patients with a temporary risk of SCD or when the risk is unknown or cannot be determined yet. So far, no

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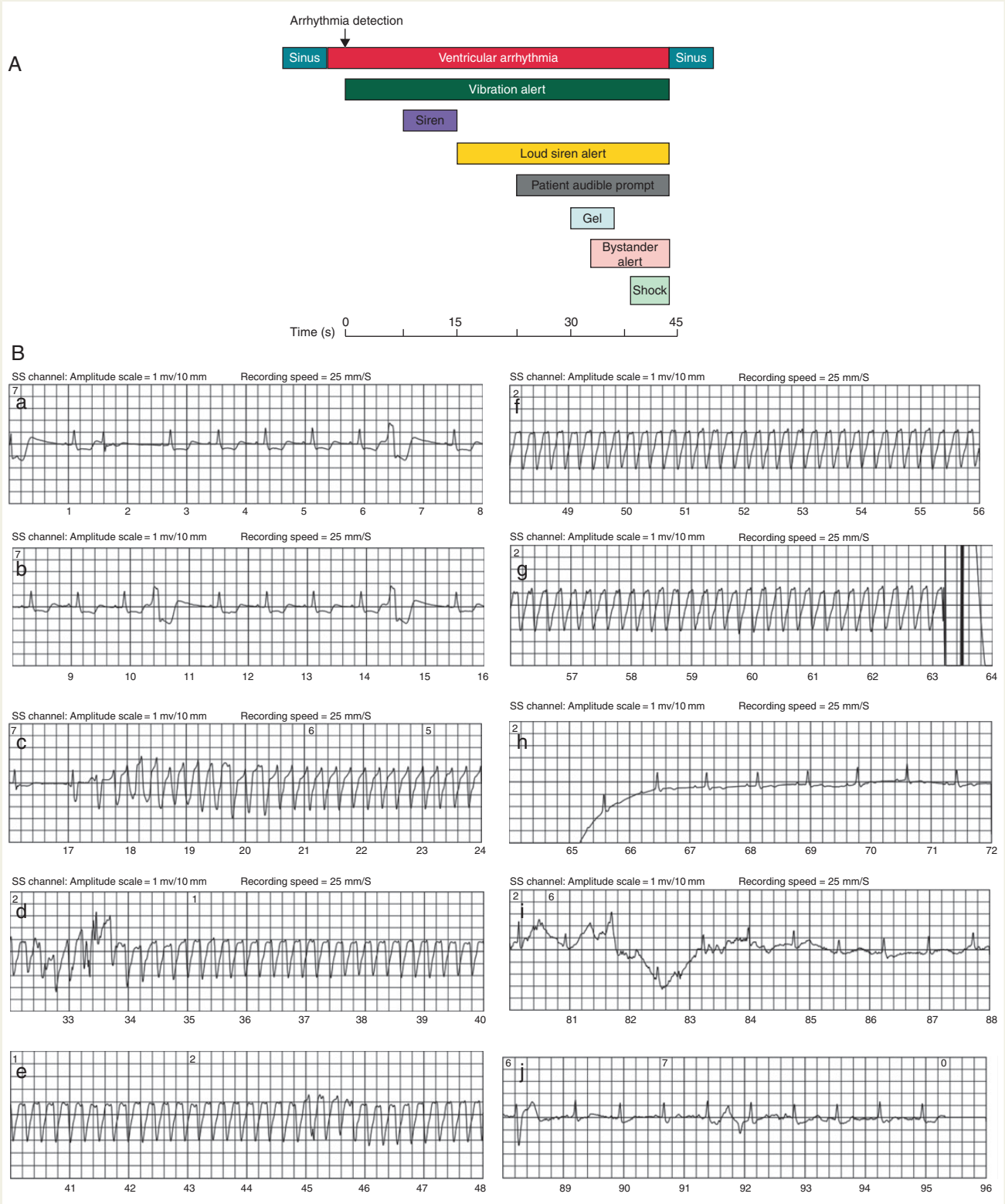

Figure 2 (*A*) Flow chart indicating sequence of patient and bystander alerts after treatment sequence initiated. The patient prompt is: 'Press the response button to delay treatment, electrical shock possible'. The bystander alert is: 'Do not touch patient'. (*B*) WCD shock delivery in a 68-year-old male patient 2.5 months after acute myocardial infarction; initial LVEF 22%; a–c: ECG recording (SS lead) of 16 s prior to onset of rapid VT (295 bpm); d–g: sustained rapid VT until shock delivery after 47 s of VT; h–j: restored sinus rhythm after shock delivery with single PVC.

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Figure 3 Wearable defibrillator system showing device, vest, and remote monitor. Arrow (upper left) indicates patient response button with second button on opposite side of device.

randomized, controlled outcome studies for specific patient populations and indications are available. Nonetheless, several international societies have included the WCD in their consensus statements and guidelines (*Table 2*).

The European experience

The WCD was first used in 1998 at the University Hospital Magdeburg, Germany, in 10 patients with induced VT/VF in the catheterization laboratory.[3] At this time, the WCD delivered monophasic shocks. A new WCD using impedance-compensatory biphasic truncated exponential waveforms was later tested in 12 patients with 22 induced VT/VF episodes with 100% first shock termination.[7] The first prospective clinical efficacy trial of the WCD (WEARIT/BIROAD study) was published in 2004.[4] This was a combined US/Germany study, performed in 289 patients with either severe heart failure, early after myocardial infarction (MI), or after coronary artery bypass surgery (CABG) with reduced left ventricular ejection fraction (LVEF). The trial was terminated after six out of eight successful defibrillations of VT/VF episodes. Inappropriate shocks occurred in 0.7% per month of use.

Despite the promising experience of the WEARIT/BIROAD study, only few university hospitals prescribed WCDs in Germany and a few other European hospitals also prescribed WCDs. In 2010, Klein *et al.* reported the first German experience with WCD in 354 patients from 43 different hospitals.[8] The mean age was 57 years, with 10% of patients being younger than 40 years and 29% older than 70 years. The mean wearing period of WCD was 3.5 months, with a mean wearing time/day of 21.3 h. Arrhythmia events (VT/VF) occurred in 27 patients (7.6%). Shock delivery was necessary in 11 patients with 21 VT/VF episodes. Twenty of 21 VT/VF events were successfully terminated by the first shock with programmed shock energy of 150 J. One patient needed two shocks to terminate VF. Additional VT events were either non-sustained (lasting 15-30 sec) or sustained (lasting >30 sec), but self-terminating arrhythmia or use of the response buttons withholds shock delivery in conscious patients with sustained VT. Inappropriate detection of rapid supra-VT was noted in eight patients, none of them leading to shock delivery because of response button use (inappropriate shocks in <0.1%/month). Asystole occurred in two patients with LVEF < 15% and severe heart failure and both of them died.

Within the last 5 years, WCDs are being increasingly used in Europe. According to the data from the manufacturer (personal communication), ~20 000 WCDs have been prescribed in Europe, the vast majority in Germany, followed by the Netherlands, France, Italy, Switzerland, and Austria. Non-ischaemic cardiomyopathy (NICM) including acute myocarditis with recent onset of severe heart failure is the most frequent reason for WCD prescription, followed by early post-MI, with or without revascularization procedures, patients after CABG or other heart surgery procedures with severely reduced LVEF, syncope of unknown origin with structural heart disease, risk stratification period for suspected inherited arrhythmia syndromes, intermittent ICD explant for infection, delayed ICD implantation because of serious co-morbidities, and finally rare indications such as waiting for heart transplant or use of left ventricular assist device (LVAD) instead of ICD implantation (*Figure 4*). This is slightly different from the prescription practice in the USA where the majority of WCD prescriptions are for the early phase after MI.[9]

A recent analysis showed that 94 of 6043 (1.6%) patients experienced appropriately delivered shocks for rapid VT (>220 bpm) or VF which may have been life-saving (*Figure 2B*).[23] All VT/VF episodes were appropriately detected and treated. Post-treatment survival was 93%. The incidence of inappropriately delivered shocks was 0.4% of all patients provided with the new WCD system. Inappropriate shocks mainly occurred because of noise, rapid regular supra-VT, or atrial fibrillation.

Currently, ~5% of patients for whom the WCD is prescribed are ultimately considered unsuitable for appropriate and safe handling of the system.[24] Despite the increase of WCD prescriptions, death due to improper use of WCD has not been reported in recent years.

US wearable cardioverter-defibrillator experience

The WCD was approved by the US Food and Drug Administration in 2001 and is covered by most health plans.[25] Indications for use are listed in *Table 3* and include primary and secondary prevention of SCD in patients with ischaemic and non-ischaemic heart disease in a variety of situations especially during the mandatory waiting periods after MI and the diagnosis of cardiomyopathy when medical therapy is being optimized to improve LVEF.[1,25]

In 2010, Chung *et al.* reported the aggregate national experience using the device in 3569 patients with a wide spectrum of indications including LVEF ≤ 35% after recent MI, post-CABG, VT/VF before ICD implantation following ICD explantation, and a presumed genetic predisposition to SCD (*Table 1*).[9] The patients' mean age was 59.3 ± 14.7 years, and the WCD was worn for 52.6 ± 69.9 days. Eighty sustained VT/VF events occurred in 59 patients (1.7%), and first shock was successful in all 76 episodes of unconscious VT/VF

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Table 1 Summary of WCD trials and registries

Study	No. of pts	Inclusion criteria	Design	Main findings
Auricchio *et al.*[3]	10	Pts undergoing EPS for VT/VF	Observational, clinical testing	10/10 episodes of induced VT/VF were successfully terminated with first 230 J monophasic shock in 10 Pts
Reek *et al.*[7]	12	Pts undergoing EPS for VT/VF	Observational, clinical testing	22/22 episodes of induced VT/VF were successfully terminated with first 70 J or 100 J biphasic shock in 12 Pts
Feldman *et al.*[4]	289	WEARIT: heart failure NYHA III/IV BIROAD: high risk after MI/CABG	Prospective cohort study	6/8 episodes of spontaneous VT/VF were successfully terminated during mean FU of up to 4 months
Klein *et al.*[8]	354	High risk after MI/CABG, Pts awaiting HTX, ICD explant + delayed implant, risk stratification	Retrospective, registry data	20/21 VT/VF episodes were successfully terminated by first shock during a mean wear time of 3 months
Chung *et al.*[9]	3569	Various indications according to CMS coverage	Retrospective, registry data	Compliance was high, and SCD mortality was low during WCD use comparable to that of ICD Pts; 79/80 VT/VF episodes were successfully terminated by first shock during a mean wear time of 53 days
Rao *et al.*[10]	162	CSHD, IAS	Prospective observational, registry data	WCD can be safely used in high-risk adults with CSHD and IAS; 3 VT/VF episodes were successfully terminated by the first shock during a mean wear time of 29 days
Saltzberg *et al.*[11]	266	PPCM, NICM	Retrospective, registry data	No arrhythmic events and low mortality rate in Pts with PPCM
Zishiri *et al.*[12]	809	Pts after CABG/PCI with LVEF $\leq$ 35%	Prospective observational, registry data	WCD use was associated with lower short- and long-term mortality than no WCD use in high-risk Pts after CABG or PCI; 12/18 (1.3% event rate) VT/VF episodes were successfully terminated
Epstein *et al.*[13]	8453	Recent MI with LVEF $\leq$ 35%	Retrospective, registry data	133 Pts (1.6%) received 309 shocks for VT/VF during 40-day and 3-month waiting periods after MI; 91% were successfully resuscitated
Duncker *et al.*[14]	7	PPCM	Prospective cohort study	Four episodes of VF were successfully terminated by the first WCD shock in 3/7 Pts during mean wear time of 81 days
Kutyifa *et al.*[15]	2000	High-risk ICM, NICM, CSHD/IAS	Prospective observational, registry data	VT/VF event rates of 3% in ICM and CSHD/IA, respectively, and 1% in NICM during mean wear time of 3 months; 30/30 episodes of spontaneous VT/VF successfully terminated by the first shock
Singh *et al.*[16]	525	Newly diagnosed ICM and NICM	Prospective observational, registry data	Very low arrhythmic risk in Pts with NICM, 2.2% of ICM Pts received appropriate shock for VF

WCD, wearable cardioverter-defibrillator; Pts, patients; EPS, electrophysiological study; VT, ventricular tachycardia; VF, ventricular fibrillation; WEARIT, Wearable Cardioverter Defibrillator Investigational Trial; BIROAD, Bridge to ICD in Patients at Risk of Sudden Arrhythmic Death, NYHA, New York Heart Association functional class, MI, myocardial infarction, CABG, coronary artery bypass surgery; HTX, heart transplantation; ICD, implantable cardioverter-defibrillator; CMS, Centers for Medicare & Medicaid Services; SCD, sudden cardiac death; FU, follow-up; CSHD, congenital structural heart disease; IAS, inherent arrhythmia syndromes; PPCM, peripartum cardiomyopathy; NICM, non-ischaemic cardiomyopathy; ICM, ischaemic cardiomyopathy.

and 79/80 (99%) of all VT/VF episodes. Eight patients died after successful conversion of unconscious VT/VF (89.5% survival of the events). Asystole occurred in 23 patients (17 died), pulseless electrical activity in 2, and respiratory arrest in 1 (all 3 died), representing 24.5% of sudden cardiac arrests (SCAs). This demonstrates that SCD is not necessarily due to VT/VF and that not all patients with SCA can be resuscitated by defibrillation. The authors concluded that wearing compliance was satisfactory with 90% wear time in >50% of patients and that SCD mortality during use was low.

The benefit of WCD use was described in patients with LVEF $\leq$ 35% after CABG or PCI (*Table 1*).[12] Following revascularization procedures, early mortality risk was lower (HR, 0.54; 95% CI, 0.43–0.68; $P < 0.0001$) among 809 patients discharged with WCD compared with 4149 discharged without WCD. Ninety-day mortality post-CABG was 7% without vs. 3% ($P = 0.03$) with WCD. Mortality post-PCI was 10% without vs. 2% ($P < 0.0001$) with WCD use. The use of WCD was also associated with a 39% (HR, 0.61; 95% CI, 0.49–0.78; $P < 0.0001$) adjusted lower risk of long-term mortality at 3.2 years for both CABG (HR, 0.62; 95% CI, 0.38–0.997; $P < 0.048$) and PCI (HR, 0.43; 95% CI, 0.29–0.64; $P < 0.0001$) patients. It is to emphasize that this study was not a randomized prospective study, and therefore, these data have to be interpreted with caution.

Device guidelines and insurance coverage in the USA require waiting periods of either 40 days or 3 months before implanting

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Table 2 Representation of WCD in guidelines and position papers

2006	ACC/AHA/ESC 2006 Guidelines for management of patients with ventricular arrhythmias and prevention of sudden cardiac death.[17]	Quotation of FDA approval of the WCD for cardiac patients with a transient high risk for VF such as those awaiting cardiac transplantation, those at very high risk after a recent MI or an invasive cardiac procedure, or those requiring temporary removal of an infected ICD for antibiotic therapy.
2006	International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates.[18]	Class I indication for WCD prescription for status 1B patients who are discharged home given that the wait for transplantation remains significant.
2009	Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management.[19]	Recommendation to consider the WCD as an alternative to early ICD re-implantation after device explant when there is concern of ongoing infection.
2013	ACCF/AHA guideline for the management of ST-elevation myocardial infarction.[20]	Usefulness of a WCD in high-risk patients during the first 4 to 6 weeks after ST elevation myocardial infarction is under investigation.
2014	EHRA/HRS/APHRS Expert consensus on ventricular arrhythmias.[21]	Patients with impaired LV function early after MI with or without revascularization are at increased risk for SCD and may benefit from WCD until reassessment of LV function.
2014	HRS/ACC/AHA Expert consensus statement on the use of ICD therapy in patients who are not included or not well represented in clinical trials.[22]	The WCD may be an option as a 'bridge to ICD' for selected patients at high risk of sudden cardiac death due to ventricular arrhythmias, although the data are scant.
2015	ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.[2]	In patients with transient impaired LVEF, the WCD may be used until LV function has recovered sufficiently, following insults such as myocardial infarction, post-partum cardiomyopathy, myocarditis or interventions such as revascularization associated with transient LV dysfunction. Similarly, patients with a history or at risk of life-threatening VAs or who are scheduled for cardiac transplantation may be temporarily protected with the WCD.

ACC, American College of Cardiology; AHA, American Heart Association; ESC, European Society of Cardiology; FDA, Food and Drug Administration; WCD, wearable cardioverter-defibrillator; VF, ventricular fibrillation; MI, myocardial infarction; ICD, implantable cardioverter-defibrillator; ACCF, American College of Cardiology Foundation; EHRA, European Heart Rhythm Association; HRS, Heart Rhythm Society; APHRS, Asia Pacific Heart Rhythm Society; ESC, European Society of Cardiology; LVEF, left ventricular ejection fraction.

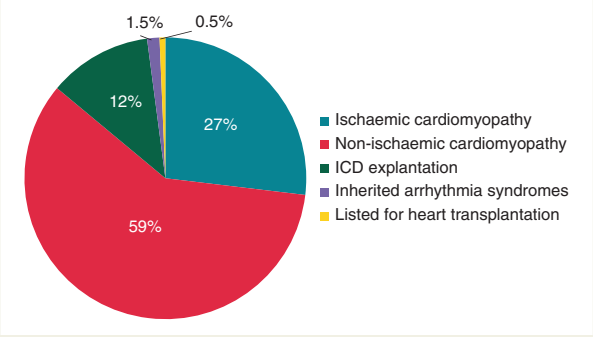

Figure 4 Distribution of indications for WCD prescription in Europe between April 2010 and October 2013 in 6043 patients (modified from Ref. 23).

an ICD post-MI depending on whether or not acute revascularization was undertaken.[1] Epstein *et al.*[13] used the manufacturer's database to describe the use of WCD during these mandated waiting times for patients perceived to be at high risk for SCD (*Table 1*). Of 8453 patients, 133 (1.6%) received 309 appropriate shocks of whom 91% were successfully resuscitated. Of the latter, 3 died within 2 days and 41 died ≥3 days after shock delivery. For patients who received shock therapy, LVEF was ≤30% in 106, and the median time from the index MI to WCD therapy was 16 days. Overall, during the 40-day and 3-month waiting periods post-MI, WCD successfully treated SCA in 1.4%, and the risk was highest in the first month of WCD use. The authors concluded that WCD may benefit individual patients selected for high risk of SCD early post-MI.

Patient experience and satisfaction

The concept of the WCD requires that the device is worn most of the time. Therefore, patient compliance is essential and has been a matter of concern. The use of WCD can be easily monitored online. Registry data show that patient compliance is high. Chung *et al.*[9] reported that 52% of patients used the WCD > 90 and 71% of patients >80% per day. In the German case series, daily use was >90% in 72% of patients.[8] Longer periods of use correlate with higher daily wear times.[5,15]

So far, there has been no prospective evaluation of patient satisfaction or psychological impact of WCD use. Klein *et al.*[8] performed an interview in 60 patients. The vast majority reported that the device was easy to handle after appropriate training and gave them a feeling of safety and trust. Reasons for patient complaints were mostly the weight of the monitor unit and disturbance by noise alarms causing sleeping disturbances in 25%. These were the main reasons to stop wearing WCD prematurely in 5–14% of assigned patients.[8,9,26]

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Table 3 Summary of accepted and potential WCD indications

Clinical situation	Period of WCD wearing	End of WCD usage
Accepted indications[a]		
Acute myocardial infarction with LVEF ≤ 35%	40–90 days	LVEF improvement or indicated ICD implantation
Before/after revascularization procedures (CABG/PCI) with LVEF ≤ 35%	3–4 months	LVEF improvement or indicated ICD implantation
Recent onset cardiomyopathy NICM or presumed myocarditis with acute heart failure and/or LVEF ≤ 35%	3–6 months	LVEF improvement or indicated ICD implantation
Intermittent bridging after ICD removal (e.g. infection)	1–2 months	Completion of antibiotic therapy and ICD re-implantation
Delayed but indicated ICD implantation	2–3 months or longer	Resolution of cause of delay
Bridge to heart transplantation	Variable	Until heart transplantation
Potential indications		
Period of risk stratification in cases with syncope/cardiac arrest of unknown origin; cases with suspected inherited arrhythmia syndromes	Usually 1–3 months	Until risk has been defined
Protection in patients with LV assist device	Undetermined	Until heart transplantation, at the end of a risk stratification prior or until ICD implantation
Potentially dangerous ECG changes with drugs (e.g. QT prolongation)	Variable, depends on continuous drug administration or elimination kinetics	Withdrawal of the drug and normalization of ECG changes

WCD, wearable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; ICD, implantable cardioverter-defibrillator; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; LV, left ventricular.
[a]For these indications, the WCD was approved by the US Food and Drug Administration in 2001.[25]

When should we use the wearable cardioverter-defibrillator?

About one-quarter of ICDs may not be indicated and are inappropriately implanted; conversely, the same proportion of patients in whom an ICD is indicated do not receive this therapy.[27] The WCD can be used to determine appropriateness for ICD implantation, specifically a persistent risk for life-threatening arrhythmias (low LVEF after guideline-directed waiting periods for optimized medical therapy) or, in case of a reversible cause, to prevent unnecessary ICD implantation. The 2015 ESC guidelines give a IIb, level of evidence C indication for WCD in case of 'adult patients with poor LV systolic function who are at risk of sudden arrhythmic death for a limited period but are not candidates for an ICD (e.g. bridge to transplant, bridge to transvenous implant, peripartum cardiomyopathy, active myocarditis, and arrhythmias in the early post-MI phase)'.[2] Potential indications for WCD are listed in *Table 3*.

Wearable cardioverter-defibrillator use early after myocardial infarction

Even after immediate revascularization in cases of acute MI with significantly compromised LVEF, ~10–15% of patients will continue to suffer from severely reduced LVEF. The VALIANT trial showed that the incidence of SCD was 2.3% within the first month after MI and decreased significantly within the following months.[28] However, two studies, DINAMIT and IRIS, demonstrated that overall mortality was not reduced with ICD implantation early after MI despite significantly reduced SCD events.[29,30] For this reason, guidelines generally do not recommend implanting an ICD within 40 days of an acute MI.[1,2]

Several studies describe the use of WCD to bridge the 40- or 90-day period after MI with or without revascularization.[4,8,9,12,13,15,16] Whether this strategy will improve overall outcome is being evaluated in the ongoing VEST trial.[31] Patients with an acute MI and LVEF ≤ 35% are randomized prospectively to either WCD or conventional medical therapy within the first 90 days after MI.

The REFINE trial showed an 18% increase in LVEF within the first 2 months after acute MI.[32] The WEARIT-II Registry showed that ~40% of patients with acute MI improved their LVEF beyond the justifying value for ICD implantation within 3 months.[15]

The 2013 ACCF/AHA guideline for the management of ST-elevation MI recommends WCD for up to 3 months in patients with reduced LVEF in the early phase of acute MI.[20] The 2015 ESC guidelines more critically recommend WCD within 40 days of an acute MI in selected patients (those with incomplete revascularization, pre-existing left ventricular dysfunction, or occurrence of ventricular arrhythmias after 48 h).[2]

Wearable cardioverter-defibrillator use after revascularization procedures

Implantation of ICD after elective revascularization procedures (CABG or PCI) in patients with reduced LVEF (≤ 35%) is not recommended for 3 months as left ventricular function may improve.[1] Data from Zishiri *et al.*[12] have demonstrated that patients during this time period after revascularization procedures experience

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significantly less SCD and all-cause mortality when protected by WCD compared with a similar patient cohort without WCD. Therefore, high-risk patients after revascularization procedures can be protected by the WCD until ICD implantation is either guideline based or may not be indicated.

Wearable cardioverter-defibrillator use in patients with non-ischaemic cardiomyopathy and myocarditis

Dilated cardiomyopathy in the absence of coronary artery disease (NICM) represents a heterogeneous group of diseases including inflammatory, toxic, metabolic, genetic, or auto-immunological processes that most often are discovered in the context of acute heart failure. Arrhythmic events or aborted SCDs are not rarely first signs of NICM. Implantable cardioverter-defibrillator implantation for primary prevention of SCD is currently recommended after >3 months of optimal medical therapy after the first diagnosis of heart failure and depressed LV function (LVEF ≤ 35%) with NICM.[1,2]

Recent onset cardiomyopathy (ROCM) is not rarely associated with a recovery of LVEF or reverse remodelling. However, arrhythmic risk and recovery of LVEF may be unpredictable after initial diagnosis. Several studies describe the use of WCD during the initial 3–4 months after newly diagnosed NICM.[4,8,9,15,16] The results show that the rate of appropriate shocks in patients with NICM is generally lower than that in ICM. In a very recent study, the event rate was 0 in 56.7 patient-years of use.[16] The authors concluded that the use of WCD in this population needs to be evaluated in prospective studies.

Several subgroups of patients with ROCM may have a higher risk of SCD and were under-represented in these case series. In a cohort of 181 patients with myocarditis, 13 died suddenly. The risk was highest in the first 18 months.[33] Autopsy data suggest myocarditis in SCD of young athletes at rates of 9–44%.[2,34,35] Severe heart failure, immunohistological signs of inflammation, and lack of β-blocker therapy were risk factors for cardiac death and transplantation.[33] Bridging the first months of a newly diagnosed myocarditis with the WCD may therefore be an important step to final decision-making for either longstanding or unnecessary ICD therapy.

Patients with Takotsubo cardiomyopathy demonstrate a clinical heterogeneity. Some patients may develop ventricular arrhythmias especially within the first weeks of diagnosis. The incidence varies from <1% to >8%.[36–38] Especially patients who develop QT prolongation with Takotsubo cardiomyopathy are at increased arrhythmic risk and can be protected by WCD until LVEF recovery.[37,39,40] Deeprasertkul *et al.*[41] describe WCD use in 102 patients with Takotsubo cardiomyopathy. Two patients received appropriate shocks during a mean follow-up of 44 days and survived.

Some patients with peripartum cardiomyopathy may present with severely reduced LVEF and increased risk of SCD.[42,43] About half of these patients will show significant or even full recovery of LVEF. Effective protection with WCD for 3–6 months has recently been demonstrated in patients with peripartum cardiomyopathy and LVEF ≤ 35%. Duncker *et al.*[14] observed four VF events with successful WCD shocks in 3 out of 7 patients during a median wear time of 81 days.

Bridge to heart transplantation

Using WCD to bridge the period of risk while awaiting transplantation has been reported.[18,44] Opreanu *et al.* report WCD use in 121 patients awaiting heart transplantation. Patients used the device for an average of 127 days until ICD implantation or transplantation. Seven patients received appropriate shocks; all of them survived. There were two patients with inappropriate shocks for atrial fibrillation with rapid response. Two patients with asystole episodes died. The use of WCD in this population showed high compliance, efficacy, and a low complication rate.[44]

Patients with LVADs are at high risk of ventricular tachyarrhythmias. Implantable cardioverter-defibrillator therapy is common, but goes along with a relatively high complication rate.[45] Protecting those patients with the WCD instead of using an ICD may be a reasonable alternative; however, until now no study data are available.

Temporary protection after implantable cardioverter-defibrillator explant

When infection of the ICD mandates system removal, antibiotic therapy is often necessary for weeks before re-implantation. During this period, the WCD is an appropriate approach to prevent long-lasting and expensive hospital staying until a new device can be implanted.[19,46]

Other potential applications of the wearable cardioverter-defibrillator

Patients with advanced renal dysfunction who need haemodialysis bear a higher risk of SCD, particularly within the first few months of haemodialysis. Since ICD implantation bears a relatively high risk of complications, using the WCD for a few months until the clinical situation is stabilized represents a promising alternative to ICD therapy.[47–49]

Many drugs are known to prolong the QT-interval and increase the risk of life-threatening arrhythmias. Wearing WCD for the time of necessary drug intake may help to lower the risk of SCD in selected cases. The use of WCD to bridge curative radiotherapy for cancer has been described.[50] This strategy may be useful in case the ICD is damaged by radiotherapy or needs to be explanted because it causes shielding, or in case ICD indication needs to be re-evaluated based on remission of the cancer.

Costs and cost-effectiveness of the wearable cardioverter-defibrillator

The WCD is not available for sale by the manufacturer, but is rented in monthly increments to the patient. The price of the device is $3300 per month in the USA. In Europe, it is ~3000€/month including servicing. The WCD has gained full reimbursement approval in Germany, France, Switzerland, Austria, Luxembourg, USA, and Japan, whereas in countries like the UK, Netherlands, and Italy, costs of WCD have to be paid by the hospitals.

Cost-effectiveness of WCD strongly depends on the indication for use and correct patient selection. Registry data indicate that the number needed to treat to save one life with WCD varied between 70 and 110 over a median of 53–57 days.[26] A cost-effectiveness analysis using a Markov model, early after MI, has

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recently been published.[51] Patients with an LVEF of <35%, after MI or who had undergone coronary revascularization, were studied for a 3-month period with or without WCD. The model assumed that 56% of the patients would be eligible for an ICD implantation at the end of the waiting period. The monthly cost of WCD for the model was $2754, with an SCA rate of 2.25% during the first month and 1% during the 2 subsequent months. The WCD strategy improved life expectancy by 0.261 years with an incremental cost-effectiveness ratio (ICER) of $60 600 per quality-adjusted life year (QALY). The model was sensitive to the SCA rate, with a reduction of the ICER to $42 100 per QALY if the rate was 4% during the first month, and increased to >$100 000 per QALY when the rate in the first month was <1.163%. Arrhythmic event rates in all published series using WCD after MI were above this threshold.[4,8,9,13,15,16] The model was also sensitive to the cost of WCD. If the monthly cost was reduced to $2000, the ICER improved to $49 100 per QALY. Conversely, if the cost was increased to $3500 per month, the ICER became less attractive at $71 900 per QALY.

Another cost-effectiveness analysis of WCD in the setting of ICD explant for up to 8 weeks due to infection has been recently published.[52] The ICER of WCD strategy was $26 436 per QALY as compared to discharge home without WCD. In-hospital monitoring and discharge to a specialized nursing facility resulted in higher costs and worse clinical outcome. The analysis was sensitive to WCD efficacy, SCA event rate, and delay to ICD re-implantation. The WCD strategy remained cost-effective with the base-case assumptions, as long as the delay to re-implantation was at least 2 weeks.

These data suggest that bridging a temporarily increased risk of SCD using WCD may be cost-effective in selected patient groups. Cost-effectiveness is mainly determined by the event rate during the wearing period and the frequency of ICD implantations thereafter. When WCD was used to bridge a time period for risk stratification in patients with ICM or NICM, only ~40% of patients received an ICD implantation thereafter.[9,15,16] Therefore, unnecessary ICD implants that had been avoided should be included into cost-effectiveness analyses. As with all cost-effectiveness analyses using Markov models, results are speculative. This is particularly true for the WCD since there are no randomized trials, which makes it difficult to evaluate the true clinical effectiveness of the therapy.

Limitations and shortcomings

The benefit of the WCD is dependent on patient selection, appropriate device use, patient compliance, and appropriate programming to avoid inappropriate shocks.[5] Owing to the lack of randomized trials, indications for WCD use are based on expert opinion and clinical judgement. Currently, the vast majority of WCDs have been prescribed by arrhythmia specialists who are experts in the field of ICD therapy and prevention of SCD. If the WCD were to be prescribed by physicians less experienced in the management of arrhythmias, the benefit may be lower and increased complications may occur.

Patient compliance is mandatory for appropriate WCD performance. Careful training and instruction prior to WCD wearing are

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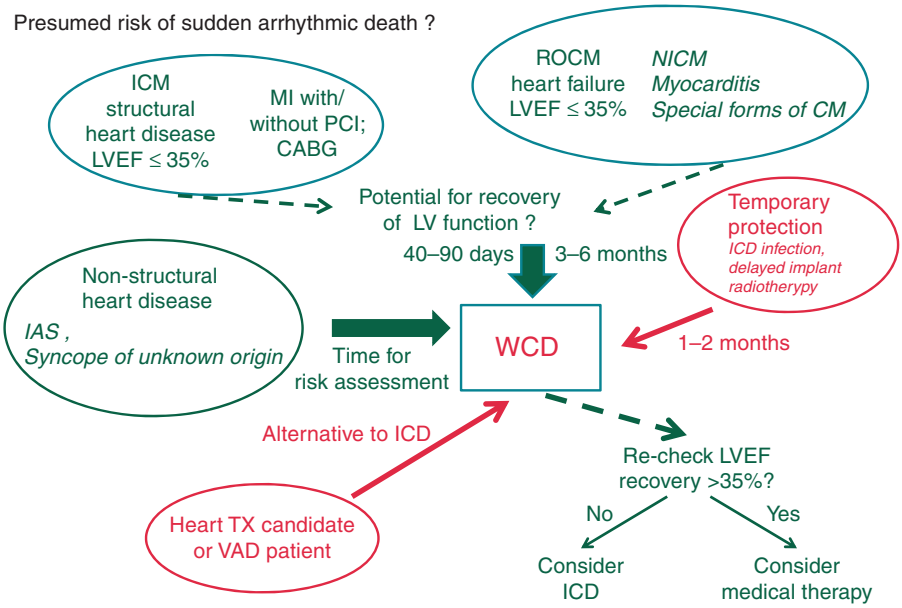

Figure 5 WCD decision-making algorithm to optimize ICD therapy. Current indications include patients who meet criteria for ICD implantation when implant is delayed or as an alternative to ICD implantation for certain time periods (red). WCD should also be considered in patients with severely reduced LVEF who are thought to be at high risk of SCD when the risk is only temporary or cannot be determined yet (turquoise). WCD, wearable cardioverter-defibrillator; ICD, implantable cardioverter-defibrillator; ICM, ischaemic cardiomyopathy; NICM, non-ischaemic cardiomyopathy; HTX, heart transplantation; VAD, ventricular assist device; IAS, inherent arrhythmia syndromes; MI, acute myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass surgery; ROCM, recent onset of cardiomyopathy; CM, cardiomyopathy; LVEF, left ventricular ejection fraction.

necessary. A well-fitting electrode belt is important to ensure reliable arrhythmia detection. The main reason for inappropriate detection is noise from the sensing electrodes. Inappropriate shocks can be avoided by pressing and holding the response buttons. About 5% of all patients who are considered candidates for the WCD will be unsuitable or unwilling to wear the WCD. In most reports, between 5 and 14% of patients stopped WCD use prior to the planned wearing time, mostly because of the monitor weight and wearing discomfort.[8,9,26]

The detection algorithm records bradycardia and asystole events, but does not provide back-up anti-bradycardia or anti-tachycardia pacing. Registry data reported asystole in 0.4–0.6% of patients while wearing WCD.[8,9,13] The majority of these patients died. Sudden cardiac death during WCD wearing may also occur after appropriate and successful shock delivery (95–98% of all WCD shocks successfully terminate VT/VF events with the first shock) due to electromechanical dissociation, particularly in patients with severely reduced ventricular function.

Conclusions

The WCD is a useful tool to bridge a temporarily increased risk for SCD that safely terminates ventricular tachyarrhythmias with high clinical success. Approximately 1–2% patients per month receive an appropriate shock, with <1% of inappropriate shocks due to advanced detection criteria and the alert system that allows patients to withheld therapy. National and international societies now recommend WCD use in different patient populations and clinical scenarios.[2,18–20,22,53,54] The main indication for WCD is as a bridge to ICD implantation or until the arrhythmic risk subsides. A major limitation is the lack of prospective, randomized trials for the discussed underlying diseases or debatable ICD indications. Therefore, the guidelines are quite general and mainly based on expert opinion (*Table 2*). A suggested algorithm to use the WCD to bridge a time period of undetermined risk of SCD is depicted in *Figure 5*.

Current guidelines for ICD therapy are mostly based on trials that started to enrol patients >10–15 years ago. Since then, insight into the pathophysiology of arrhythmias, methods of risk stratification, and therapeutic approaches have improved. Implantable cardioverter-defibrillator therapy is not free from complications, and we learned that with new therapies LV function may recover, and with this, the risk of SCD will decrease. It is time to re-evaluate the true arrhythmic risk for primary prevention of SCD in some of the underlying cardiac morbidities with new randomized controlled trials. The WCD will be the right tool to help performing these trials. The clinical value of the WCD must be measured not only by the number of terminated arrhythmic events, but also by successfully performed risk assessment and by the number of prevented unnecessary ICD implantations.

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