Clinical update

Risk stratification for implantable cardioverter defibrillator therapy: the role of the wearable cardioverter-defibrillator

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The benefit of implantable cardioverter-defibrillator (ICD) therapy depends upon appropriate evaluation of a persisting risk of sudden death and estimation of the patient’s overall survival. Assessment of a stable and unchangeable arrhythmogenic substrate is often difficult. Structural abnormality and ventricular dysfunction, the two major risk parameters, may recover, and heart failure symptoms can improve so that ICD therapy may not be indicated. Risk stratification can take time while the patient continues to be at high risk of arrhythmic death, and patients may need temporary bridging by a defibrillator in cases of interrupted ICD therapy. The wearable cardioverter-defibrillator (WCD) combines a long-term electrocardiogram (ECG)-monitoring system with an external automatic defibrillator. The LifeVest® (ZOLL, Pittsburgh, PA, USA) is composed of a garment, containing two defibrillation patch electrodes on the back, and an elastic belt with a front-defibrillation patch electrode and four non-adhesive ECG electrodes, connected to a monitoring and defibrillation unit. The WCD is a safe and effective tool to terminate ventricular tachycardia/ventricular fibrillation events, unless a conscious patient withholds shock delivery. It may be used in patients in the early phase after acute myocardial infarction with poor left ventricular function, after acute coronary revascularization procedures (percutaneous coronary intervention or coronary artery bypass grafting) and reduced left ventricular ejection fraction (≤35%), in patients with acute heart failure in non-ischaemic cardiomyopathy of uncertain aetiology and prognosis. The WCD may be helpful in subjects with syncope of assumed tachyarrhythmia origin or in patients with inherited arrhythmia syndromes. The WCD may replace ICD implantation in patients waiting for heart transplantation or who need a ventricular-assist device. This review describes the technical details and characteristics of the WCD, discusses its various potential applications, and reports the currently available experience with the wearable defibrillator.

Keywords
Wearable cardioverter-defibrillator • Sudden cardiac death • Risk stratification • ICD therapy

Introduction

The benefit of implantable cardioverter-defibrillator (ICD) therapy for secondary and primary prevention of sudden arrhythmic death (SCD) has been proved by large landmark trials leading to class I indication in all current guidelines.1–4 Two trials showed no overall benefit for ICD use early after myocardial infarction.5,6 Defibrillator implantation within the first 40 days after acute myocardial infarction (AMI), or <3 months after coronary artery bypass grafting (CABG) is not indicated.7

Current practice of ICD therapy is not without critical remarks, and a more patient-oriented indication with more specific risk stratification beyond reduced left ventricular ejection fraction (LVEF) is demanded, but seems to be very difficult.8 Implantable cardioverter-defibrillator implantation in the presence of ‘correctable causes’, leading to ventricular tachycardia (VT)/ventricular fibrillation (VF) episodes, is not advisable. Nevertheless, ‘correctable causes’ are not easy to detect; and the assessment of these causes is time consuming despite improved diagnostic methods. Reversal of correctable causes is often unpredictable. Not all VT episodes are life threatening or need ICD intervention, and there is evidence that unnecessary ATP or shock delivery is associated with increased morbidity and mortality.9

A retrospective evaluation of the US National Cardiovascular Data Registry revealed that almost 23% of all implanted ICD devices between 2006 and 2009 were non-evidence-based implantations.10 About 40% of non-evidence-based ICD implantations were performed too early after AMI or after CABG surgery, and many patients...
received ICDs with newly diagnosed or at end-stage heart failure. These findings call for better compliance to evidence-based practice in order to avoid unnecessary device implantation.

To bridge the period of risk assessment, a device is needed that provides continuous electrocardiogram (ECG) monitoring outside a hospital setting, yields wireless retrievable event recording, and in case of VT or VF event, is able to deliver immediate defibrillation without need for bystander intervention.

Following a few years of clinical investigation,11,12 the wearable cardioverter-defibrillator (WCD) was approved and introduced into clinical practice ~9 years ago after the first prospective multicentre study: 'Wearable Defibrillator Investigative trial and bridge to ICD in patients at risk of arrhythmic death' (WEARIT/ BIROAD study).13

Until today, ~100 000 patients worldwide used the WCD, mostly in the USA and Germany (personal information from ZOLL Medical Corporation, Pittsburgh, PA, USA).

The objective of this review is to describe the technical characteristics of the WCD, its role for risk assessment in patients considered at risk of arrhythmic death, and to report the clinical experience and currently available results of the WCD.

The wearable cardioverter-defibrillator

Currently, there are two WCD models available, the older LifeVest 3100® and the new LifeVest 4000® [ZOLL Lifecor Corporation (ZOLL), Pittsburgh, PA, USA]. Both use a chest garment to hold in place two large posterior and one apical self-gelling defibrillation electrodes, as well as four (43 × 10 mm) non-adhesive capacitive dry tantalum oxide electrodes for long-term ECG monitoring (Figure 1). The ECG electrodes are mounted on an elastic belt (~680 g tension), that is part of the chest garment. The elastic belt fits around the chest at the approximate level of the xiphoid process. The ECG-sensing electrodes provide two non-standard leads, front-back and left-right site bipolar ECG signals, for continuous electrocardiographic analysis.

The three defibrillation electrodes contain 10 self-gelling gel capsules each. Blue-coloured defibrillation gel is emitted from small ‘exploding’ gel capsules between the defibrillation electrodes and the skin immediately prior to shock delivery in order to lower the electrode–skin interface impedance, and to prevent skin irritation after shock delivery. Incorporated into the garment electrodes is a vibration plate to generate tactile notification as the first of a sequence of alarms once VT or VF is detected. The defibrillation electrodes are inserted into pockets of the garment, and all electrodes can be removed when the garment needs to be cleaned or replaced after shock delivery.

The garment electrodes are connected to the defibrillator and monitor unit (~490 g for the smaller 4000 unit). The monitor unit contains a battery, a biphasic defibrillation module (capacitors and high-voltage converter), a digital signal processor for ECG analysis, an LCD display, and the patient response buttons, offering the

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**Figure 1** The LifeVest® model 4000. (A) Garment and elastic belt with the connected monitor and defibrillator unit. Visible are the two back defibrillation electrodes and three (of four) non-adhesive ECG recording electrodes mounted on the elastic belt. (B) The LifeVest® model 4000 put on with the monitor unit in a hip holster. (C) Ten self-gelling gel capsules inserted in each of the defibrillation patch electrodes. Visible also one electrocardiogram recording electrode. (D) The LifeVest® 4000 monitor and defibrillator unit with response button and the LCD display for recording of the baseline electrocardiogram.
possibility to withhold defibrillator discharge as long as consciousness prevails. Also integrated into the monitor unit is a speaker for audible alarm and voice messages. The defibrillator/monitor unit is carried in a hip holster or with a shoulder strap (Figure 2).

The LifeVest® system (ZOLL Pittsburgh, PA, USA) includes a battery charger, two batteries (each lasting a minimum of 24 h), and two garments.

Once the programmed detection parameters are fulfilled, a sequence of alarms is initiated, starting with vibration in the belt electronics, followed by low- and high-volume two-tone alarms and finishing with a voice warning to bystanders that a shock may be delivered (Figure 3). The patient can press the response buttons within 20 s to withhold the capacitor discharge as long as consciousness prevails. If the response button is released or not used because of immediate unconsciousness, an impedance-adapted biphasic truncated exponential shock is delivered. The LifeVest® is able to deliver up to five shocks in case the arrhythmia continues after the first shock. Fulfilling the programmed VT/VF detection criteria lasts 5 to 10 s, tachycardia confirmation another 10 s, and the arrhythmia alarm runs for 25 s. Together with the necessary capacitor charging time as well as the attempt to synchronize the shock to the R-wave signal, the time elapsing between the onset of the tachycardia and shock delivery lasts \( \approx 45-55 \) s as long as the shock is not inhibited by holding the response buttons (Figures 3 and 4).

Stable VT allows R-wave synchronized shock delivery. If the R-wave cannot be identified, an unsynchronized shock is delivered. Programmable parameters of the LifeVest® are listed in Table 1.

The LifeVest® has a memory buffer integrated into the monitor unit that allows to store and to retrieve the ECG signal 30 s prior to the start of the arrhythmia alarms along with 15 s after the alarm stops. The LifeVest® 4000 unit can hold days of ECG data. All stored ECG event data are retrievable by the caring physician from the ZOLL server once the data are transmitted.

The WCD is not contraindicated in patients with implanted pacemakers; however, the pacing stimulus artefact has to be smaller than the potential VF–ECG signal. Therefore, in case of patients with implanted pacemakers, bipolar pacing is mandatory in order to avoid tracking of the pacing spike as ‘regular rhythm’ during VF.}

Figure 2 The LifeVest® 4000 model worn by a patient. (A) Front view, (B) back view. Visible is the cable from the garment to the monitor and defibrillation unit.
Appropriate use of the WCD needs patient’s cooperation and careful training to guarantee correct device use and assembling. The LifeVest® will deliver an asystole alarm, and starts ECG recording with severe bradycardia (<20 b.p.m.). However, the current device does not have any pacing capability.

**Risk assessment early after acute myocardial infarction**

An important risk parameter to predict the outcome after AMI is reduced LVEF.

Today, we estimate that ~15–20% of all AMI patients will show an LVEF ≤35% at the time of revascularization for AMI. However, recovery of reduced LVEF after AMI with or without immediate percutaneous coronary intervention (PCI) is often unpredictable.

Data on the outcome of patients with acute AMI, in particular the incidence of sudden death, are derived from theValsartan in Acute Myocardial Infarction Trial (VAILANT trial). Seven per cent of all patients had SCD or experienced cardiac arrest within 6 months after AMI. Patients with an LVEF ≤30% had the highest incidence of SCD with 2.3% within the first month. Data from another study showed comparable results with the highest rate of SCD within the first month after AMI, and 1.2%/year resulting in a 5-year cumulative incidence of SCD of 6.9%. The decreasing risk of SCD after the first month of AMI may be due to a gradual recovery of depressed left ventricular function. An earlier study demonstrated that 3 months after AMI 22% of all patients with abnormal LV function at the time of AMI recovered to normal LV function, even with a study cohort of only 27% with PCI. In the Risk Estimation Following Infarction-Non-invasive Evaluation study (REFINE), a 19% increase of LVEF occurred within the first 2 months after AMI.

A retrospective analysis of patients with LVEF ≤35% at hospital discharge demonstrated that after 5 months LVEF had improved from a mean of 29–36% in 41% of the patient cohort. The VAILANT trial showed that higher baseline heart rate, lower creatinine clearance, lower baseline LVEF, and atrial fibrillation were strong predictors of SCD within the first 30 days after AMI.

Two important trials failed to demonstrate an overall benefit of early ICD implantation despite significant reduction of SCD in the ICD study arms. Therefore, current guidelines defer ICD implantation prior to 40 days after AMI.

The reason for this ‘sudden cardiac death paradox’ is not easy to explain. Early after AMI, the arrhythmogenic substrate with its electrical and structural remodelling process differs from the chronic and more stable phase of remote myocardial infarction. Autopsy data from a small substudy of the VAILANT trial showed that recurrent myocardial infarction, ventricular rupture, acute pump failure, and even stroke or pulmonary embolism accounted for SCD, most often within the first month after AMI. Presumed true arrhythmic death (~51% of the autopsy group) occurred more often between the first and the third month after AMI.

Whatever reason may be responsible for the non-beneficial effect of early ICD implantation, there is a need to protect those patients from dying suddenly who will improve left ventricular function. Even 40 days after AMI may be too short to assess LVEF recovery.

**Figure 3** The LifeVest® detection, treatment, and alarm system. (A) Two channel electrocardiogram recording (front-back; site-site recording); (B) detection time, shock delivery, and electrocardiogram recording after shock delivery; (C) the time sequence of alarms with vibration, two siren tones, and a warning voice.
and to reduce early heart failure. Prior to defer or decide for ICD implantation, a 3-month use of the WCD may better assist to predict prognosis and potential ICD benefit because the WCD continuously monitors and transmits ECG data while protecting the patient.

We have reported our experience with 354 patients who used the WCD until October 2007. Of those, 138 patients (39%) were hospitalized for AMI with LVEF ≤ 35% who received the WCD within 3–5 days after AMI. About 65% underwent immediate PCI; the mean initial LVEF was 24.7%.

The mean wearing time after AMI was 91 ± 13 days. LVEF was re-assessed after 3 months and was found significantly improved to a mean LVEF of 33.6%. In 48 patients (35%), LVEF did not improve beyond 35% or even decreased. In all patients with non-improved LVEF, ICDs were implanted. Patients with an improved LVEF > 35% (57%) continued with medical treatment. Seven patients (5%) experienced appropriate WCD shocks for rapid VT or VF; all tachyarrhythmic episodes were terminated successfully with the first WCD shock (Figures 4 and 5).

The US experience with the WCD comprises 341 patients (12.5% of the total reported WCD cohort) after AMI with a mean wearing time of 48 days after AMI. LVEF was <35% in all patients. Appropriate WCD shocks for VT/VF occurred in 3% (10 patients and 12 VT/VF episodes). This report also contains 104 patients (3.8%) with recent myocardial infarction who had LVEF ≥ 35%. None of these patients received WCD shocks or died.

**Risk management after revascularization procedures**

Patients with severely reduced left ventricular function (LVEF ≤ 35%) who undergo CABG show an increased mortality, particularly within the first month (~7%). Current guidelines do not recommend ICD implantation prior to 3 months after CABG because the percentage of patients that will improve LVEF after revascularization is unpredictable. The WCD may be used for 3 months after CABG in patients with low LVEF (≤ 35%), particularly in those with difficulty to achieve haemodynamic stabilization after CABG surgery.

Our own WCD experience with patients after CABG and low LVEF after surgery comprises 88 patients. Within 3 months after CABG, six patients (7%) experienced VT/VF episodes with immediate termination by the first WCD shock (Figure 6). In 32 patients...
Risk stratification for ICD therapy with WCD

35% and did not receive ICDs; the remaining patients were lost to follow-up. The US experience reported on 243 patients (8.9% of the total WCD cohort) with a mean WCD wearing time of 1.5 months after CABG procedure. VT/VF events occurred in three patients, two were terminated by the first WCD shock; one patient died during a VF episode.

Interesting are recently published results of WCD use after revascularization procedures in patients with LVEF 35%; 809 WCD patients after PCI and CABG from the US National WCD (LifeVest®, ZOLL, Pittsburgh, PA, USA) data base were compared with 4149 PCI and CABG patients from the Cleveland Clinic database without WCD use. Three-month mortality after CABG in the WCD group was 3%, and 7% in the non-WCD cohort; mortality after PCI was 2% in WCD patients and 10% in the non-WCD users. Wearable cardioverter-defibrillator use early after CABG showed a 57% lower mortality, early after PCI an 80% lower mortality after 3 months compared with non-WCD use. Using the WCD showed an adjusted 38% lower risk of death in CABG patients over a mean follow-up of 3.2 years ($P = 0.04$); early WCD use in PCI patients had a 57% lower risk of death ($P < 0.0001$).

### Risk stratification in patients with non-ischaemic cardiomyopathy and acute heart failure

Non-ischaemic dilative cardiomyopathy (DCM) represents a complex entity comprising inflammatory processes, various forms of myocarditis, idiopathic structural changes, genetic abnormalities, toxic, and hormonal, as well as auto-immunological and metabolic disturbances.

Implantable cardioverter-defibrillator therapy for primary prevention of SCD in patients with chronic DCM has been accepted after the Sudden Cardiac Death Heart failure trial (SCD-Heft) and defibrillators in non-ischaemic cardiomyopathy treatment evaluation (DEFINITE); ICDs are recommended in patients 3 months after the diagnosis of heart failure NYHA class II–III and LVEF ≤ 35%.

In a recent study, patients with acute heart failure of <6 months with depressed LVEF (≤ 30%) demonstrated LV recovery to almost normal function in 43% of all patients within the subsequent 6 months, making ICD implantation unnecessary. Another study with acute heart failure showed LVEF recovery to 55% within 40 months, whereas a matched control group of chronic heart failure patients did not improve LVEF.

The organized program to initiate lifesaving treatment in hospitalized patients with heart failure registry (OPTIMIZE-HF) showed that heart failure patients with preserved LV function (LVEF >40%) had similar in-hospital and 3-month follow-up mortality than patients with severe LV dysfunction.

Advanced heart failure NYHA class III–IV is not rare in clinically suspected myocarditis. In a large cohort of 181 patients with myocarditis, 50% were in NYHA class III–IV and 45% had LVEF <45%. Within 5 years, 22.1% had cardiac death or underwent heart transplantation (7.7%). Of the 26 patients with cardiac death, 13 patients (50%) had SCD. Highest mortality occurred within the first 18 months after hospitalization.
Acute heart failure, even with NYHA class IV, particularly with suspected myocarditis, can recover to even normal LV function. Therefore, these patients may benefit from temporary protection against SCD. Use of the WCD in acute heart failure has been described recently in a small prospective registry. Further studies with larger patient cohorts are necessary to demonstrate benefit of the WCD in acute heart failure patients.

We have used the WCD in 35 patients with acute heart failure and suspected myocarditis. During a mean wearing time of 3 months, two female patients (5.7%) experienced VT/VF episodes, which were successfully terminated by the WCD (Figure 7). In 25% of the 35 patients, including the two patients with VT/VF events, an ICD was implanted. The reported US WCD experience comprises 546 patients with recent non-ischaemic cardiomyopathy. During a mean WCD wearing time of 56 days, four patients received shocks for VT or VF events. The different incidence of VT/VF events may be explained by an unequal patient population of the two retrospective observational analyses.

Two other forms of acute cardiomyopathy can develop severe LV dysfunction, at least temporarily, and may need protection against SCD. The Takotsubo cardiomyopathy is a rare stress-induced cardiomyopathy, characterized by reversible LV dysfunction and impressive ventricular wall motion ballooning. In a large Inpatient Database of Takotsubo patients, an in-hospital mortality of 4.2% during a mean hospital staying of 6.1 days was reported. Ventricular fibrillation or cardiac arrest occurred in 2.8% of all patients and in 27% in patients with additional co-morbidities such as renal failure or sepsis. Two studies reported an in-hospital SCD event of 5% and an overall incidence of VT/VF episodes in 9%. Time to normalization of LVEF in Takotsubo cardiomyopathy may last weeks or even months. The WCD may be applied already as an in-hospital device, and later for out of hospital protection until left ventricular recovery is measurable.

Post-partum cardiomyopathy, a rare myocardial disease occurring either in the last month of pregnancy or within the first 6 months after delivery has an unpredictable prognosis and does not develop as abrupt as the Takotsubo cardiomyopathy. Post-partum cardiomyopathy can occur in 1:1500–1:3000 births; its pathophysiology, clinical course, and prognosis are still a matter of research. Left ventricular function may be severely reduced, and full recovery of LVEF within 6 months is reported in ~50%. Cases of LVEF ≤25% have a poor prognosis with a mortality rate of up to 19% and need for heart transplantation in 6–11%; the mode of death was heart failure in 45%; SCD occurred in 38%. Improvement of LVEF to >45% within 2 months predicts full functional LV recovery. Protection with the WCD may be helpful for a few months until recovery of ventricular function is confirmed.
Risk of sudden arrhythmic death in patients waiting for heart transplantation or need of ventricular-assist devices

Sudden death or VT/VF episodes are not rare in patients waiting for heart transplantation or who need ventricular-assist devices. Implantable cardioverter-defibrillator implantation is often recommended for heart transplantation- or LV-assist device candidates. However, ICD implantation in these patients is not without risk; complications after ICD implantation are not uncommon, and additional costs with unpredictable length of ICD use have to be considered.

Therefore, it seems reasonable using the WCD to bridge the period of high arrhythmic risk prior to heart transplantation. Our own WCD experience comprises 22 patients on the waiting list for heart transplantation. Two patients had WCD shocks for VT/VF during a mean wearing time of 3.4 months. Implantable cardioverter-defibrillator implantation was performed later in seven patients; in three of them transplantation was withheld because of LV function improvement, four patients preferred ICD implantation instead of continuing with the WCD for an unpredictable waiting time. The International Society of Heart and Lung Transplantation Guidelines 2006 recommend (class I, level of evidence C) to use the WCD as a temporary bridging tool for patients at home waiting for heart transplantation.

Risk assessment in patients with syncope of presumed tachyarrhythmic origin

The cause of syncope often remains unknown and diagnostic procedures take time to decide for the right therapeutic consequence. Tachyarrhythmias causing syncope may be suspected, but often are not recorded. Although the likelihood of a tachyarrhythmic background causing syncope is higher in patients with structural heart disease, life-threatening tachyarrhythmic events also occur in younger individuals with no structural abnormalities but with inherited arrhythmia syndromes, such as the long-QT (LQT)-syndrome, Brugada syndrome, short-QT-syndrome, catecholaminergic polymorphic ventricular tachycardia (CPVT) or idiopathic VT but also...
hypertrophic cardiomyopathy (HCM). Some forms of congenital heart disease may also carry an unpredictable risk of SCD.

Diagnostic procedures in patients with syncope of presumed tachyarrhythmic origin comprise electrophysiological, haemodynamic, neurological and imaging testing, and may also need genetic sequencing and provocative testing. Until confirmation of either no permanent risk or a persisting arrhythmic abnormality, patients may be monitored and protected with the WCD.

Our experience with the WCD in cases of syncope of suspected tachyarrhythmic origin comprises 34 patients.23 The mean WCD wearing time was 2.3 months; inherited arrhythmia syndromes were the assumed underlying cause of syncope in 11 patients. Ventricular tachycardia/ventricular fibrillation or Torsades de pointes (TdP) occurred in seven (20%) of the total group, leading to four delivered and three withheld shocks (Figure 8). Two patients (LQTS type 1 and Brugada syndrome) with inherited arrhythmia syndromes experienced WCD shocks.

Experience with WCD use between 2005 and 2010 in patients with either congenital structural heart disease or inherited arrhythmia syndromes was published recently.44 Three VT/VF episodes during a mean WCD wearing time of 29 days were terminated by WCD shocks in three patients, all had inherited arrhythmia syndromes.

Protection during interruption of implantable cardioverter-defibrillator therapy or before scheduled implantable cardioverter-defibrillator implantation

Infection of an ICD system and ICD lead malfunction are serious problems of defibrillator therapy. The incidence of device infection varies between 0.5 and 1.5% with first device implantation and increases two times after ICD replacements.45 Infection may affect only the generator pocket, but in general involves the complete lead system and may cause serious systemic infection, sepsis, and infective endocarditis.46 In some patients, ICD implantation may have to be postponed due to co-morbidities or other unsolved medical problems. These scenarios may require continuous monitoring and defibrillator back up with the WCD until a new ICD system can be implanted.

Our WCD cohort comprises 35 patients with temporary ICD removal, in the majority of cases for device infection. WCD wearing lasted 3–6 weeks.23 Four of 35 patients (11%) experienced...
VT/VF events, terminated by the first WCD shock. One patient with an explanted ICD waiting for heart transplantation died of asystole without a VT/VF event (Figure 9).

The US WCD experience reports on 638 patients that needed WCD protection because of temporary ICD explants. In 33 patients (5%), the WCD delivered shocks for VT/VF episodes.24

An expert consensus paper of the Heart Rhythm Society (HRS) recommends use of the WCD after temporary ICD removal because of infection.47

Potential new applications for the wearable cardioverter-defibrillator in patients with increased risk of sudden arrhythmic death

The association between renal dysfunction and cardiovascular death, particularly SCD, has been described.48 Besides the known cardiovascular risks in advanced renal disease, other factors may contribute to the increased incidence of SCD with declining kidney function.49 Dialysis patients have the highest risk of SCD at the end of the long inter-dialysis interval.50 Implantable cardioverter-defibrillator implantation in haemodialysis patients is controversial, particularly with multiple co-morbidities, and is not without risks.51 Therefore, ICD implantation should be restricted only to patients with an assessed high risk of SCD. Wearable cardioverter-defibrillator monitoring for some months may be helpful to identify patients who clearly need an ICD, particularly, in the initial phase of haemodialysis treatment.

Another field of future interest for the use of the WCD may be the chemotherapy-induced cardiomyopathy.52 The incidence of SCD in patients with cardiomyopathies, induced by several chemotherapy compounds, such as anthracycline, is not well established. Cardiotoxicity may occur early after initiation of chemotherapy or can induce cardiomyopathy long thereafter.

Onset, outcome and clinical symptoms are often unpredictable. The overall benefit of ICD therapy may be assessed over several months by the WCD.

Some drugs bear a risk of QT prolongation, which can lead to TdP arrhythmic events. The list of compounds with potentially dangerous QT prolongation contains antiarrhythmic drugs, antibiotic compounds, antipsychotic- and antidepressant drugs, some antihistaminic and doping compounds.53 In some cases with suspicious susceptibility to QT prolongation, the WCD may be helpful to protect patients in the event of life-threatening TdP episodes or SCD.54

Figure 9 LifeVest® electrocardiogram recording (recorded only one channel ‘SS’) of an asystole event, 61-year-old male with severe left ventricular dysfunction (left ventricular ejection fraction 12%) with removed implantable cardioverter-defibrillator, waiting for heart transplantation. The patient died 5 months after beginning of wearable cardioverter-defibrillator wearing without ventricular tachycardia /VF event. Short episode of atrial flutter before sinus arrest and asystole.
Advantage and shortcomings of the wearable cardioverter-defibrillator

Compliance of uninterrupted wearing of the WCD correlates with the cognitive function and understanding, as well as thorough teaching and training of the patient by the hospital nurse or technician responsible for the ‘WCD outpatient clinic’. Not all patients in whom the WCD is indicated are suitable for appropriate use of the device. These are mostly elderly patients with mental or physical disability or young individuals, unwilling to accept the necessary compliance to wear the garment and monitor unit. In our experience, this problem accounts for ~5% of all potential WCD candidates.23

The WCD wearing time per patient varied between 2 to 4 months (mean 106 days). In >70% of all patients, the daily use of the device ranged between 22 to almost 24 h. The US experience showed a slightly shorter mean daily wearing time of 19.5 h, and mean length of wearing was 53 days. About 14% of the US patients discontinued prematurely use of the WCD.24

The WCD provides continuous ECG monitoring, wearing time information, and event history interrogation via Internet. ECG analysis allows precise QT interval measurements, identification of rhythm characteristics prior to an arrhythmic event, and yields useful information after spontaneous tachycardia termination or after shock delivery.25 An overview of the current and potential future application of the WCD is listed in Table 2.23

The indications for WCD use in recent years in Germany are shown in Figure 10.23

Of 354 patients wearing the WCD for little >3 months, 27 patients (7.6%) experienced VT/VF episodes, terminated by the first shock within 45–65 s with programmed shock energy of 150 J. Only one patient needed two discharges for one VF episode. Two patients died after successful VF termination, both suffered from advanced heart failure. Asystole events occurred in two patients (0.5%); both patients died after bradycardia alarm of the WCD. Of all the patients included in our retrospective analysis, 153 (43%) underwent ICD implantation thereafter.23

The US WCD analysis of 3569 patients24 showed that 8 of 59 patients with 80 VT/VF episodes died after successful VT/VF termination, half of them due to frequently recurring VT/VF events (electrical storm); four patients died due to technical or device mismanagement, one of them had a unipolar pacemaker.14

Of 23 patients (0.6%) who had asystole events while wearing the WCD, 17 died shortly thereafter. Three patients had pulseless electrical activity without developing VT/VF.24

Wearable cardioverter-defibrillator effectiveness during 1 year in 2105 patients reported 54 appropriate shocks, accounting for 1.58 shocks/100 patient-months. Sustained VT was the cause for shock delivery in 56%, fast VT or VF in 44%. Inappropriate shock delivery occurred in 0.9%/100 patient-months. Main causes for false shock delivery were ECG signal interference (signal disturbance, electrode movement, or non-cardiac electrical signals) in 47% and supraventricular tachyarrhythmias in 29%.26

The current WCD can provide a bradycardia alarm with ECG recording, but no bradycardia back-up pacing. However, the need for life-saving bradycardia pacing after shock delivery is rare, and could be handled by backup pacing.23

Table 2 Current and potential future indications for the use of the wearable cardioverter-defibrillator

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AMI, acute myocardial infarction; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; CA, cardiac arrest; CABG, coronary artery bypass grafting; LVAD, left ventricular-assist device.

Figure 10 Current experiences (percentage of indications) of the LifeVest® in Germany. AMI, acute myocardial infarction; CABG, coronary artery bypass grafting; DCM, dilative cardiomyopathy; CHF, congestive heart failure; HTX, heart transplantation; LVAD, left ventricular-assist device; inherited, inherited arrhythmia syndromes; explant, ICD removed due to infection or lead dysfunction.
external bradycardia pacing may run the risk of re-inducing VF by inappropriate sensing after shock delivery.

Currently, there is no cost-effectiveness analysis for the WCD available. Results of a cost-effectiveness analysis will mainly depend upon the selected indication and WCD wearing time.

In the US, Medicare covers most WCD indications. In European countries with WCD experience, the prescribed WCD system is rented from the LifeVest® Company for the planned patient’s wearing period and will be reimbursed by most healthcare insurance companies, sometimes only after detailed explanation of the patient’s medical condition.

Potential limitations and shortcomings of the WCD should not be neglected. The WCD garment and belt fitting is crucial for ECG signal analysis and appropriate shock delivery. The inconvenience of continuously wearing the monitor unit and disturbing noise alarms, particularly at night, may limit daily activity and can cause sleep disturbance. A smaller WCD system that fits for young children (below the age of 12 years) is still missing.

The WCD does not compete with the automatic external defibrillator (AED). The home automatic defibrillator external defibrillator trial (HAT study) did not show reduced overall mortality compared with the emergency medical service performing cardiopulmonary resuscitation at home in case of cardiac arrest.57

The reason for the failure of the AED concept at home is obvious, since half of all sudden cardiac arrest episodes occurred unwitnessed. Even when witnessed, time to deliver life-saving shocks from the AED is often long, compared with WCD shock delivery within 1 min.

Prospective randomized trials with the WCD will be difficult to perform. However, prospective observational studies or registries for specific WCD indications are mandatory, or have been launched already.

In summary, ICD therapy requires careful risk assessment prior to device implantation. The WCD offers the possibility to assist with risk assessment as long as necessary to either justify or deny ICD implantation. During the time of risk assessment, the WCD protects the patient from dying suddenly (Figure 11).

Available data prove that the WCD is safe and demonstrate that VT/VF episodes are terminated successfully in almost 100% of all episodes. Inappropriately delivered shocks are relatively rare, and with full compliance of the thoroughly trained patient, the WCD complication rate is low.

Conclusion
The WCD represents a safe and effective approach for patients known to be at high risk of sudden arrhythmic death, yet do not fulfill accepted criteria for immediate ICD implantation. The WCD provides useful long-term ECG monitoring and delivers immediate shock therapy for VT/VF unless the conscious patient withholds shock delivery. The WCD system is used in patients when risk stratification needs more time for final therapy decision; it helps to avoid unnecessary ICD implantation and may replace ICD therapy when ICD implantation is not without risk. The WCD protects the patient during the time of temporary interruption of ICD therapy and bridges the time when ICD implantation needs to be postponed.

**Figure 11** Overview of the role of the wearable cardioverter-defibrillator to improve implantable cardioverter-defibrillator therapy by better risk stratification. AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; N-DCM non-ischaemic dilative cardiomyopathy; CM, cardiomyopathy; HTX, heart transplantation; LVEF, left ventricular ejection fraction; LVAD, left ventricular-assist device.
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