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Wearable Cardioverter-Defibrillators

Arnon Adler, MD; Amir Halkin, MD; Sami Viskin, MD

Since its introduction >3 decades ago, the implantable cardioverter-defibrillator (ICD) has been used extensively to enhance the survival of patients at high risk for sudden cardiac death resulting from life-threatening ventricular tachyarrhythmias (VTs; ie, sustained VT and ventricular fibrillation [VF]).[1,2] Nevertheless, the invasive nature of the implantation procedure, cost issues, and potential complications related to an in-dwelling intravascular device (eg, inappropriate shocks, infection, thrombosis) have limited the use of ICD therapy to patients whose risk of sudden cardiac death is considered to be both very high and permanent. Consequently, patients undergoing diagnostic workups for underlying causes of VT/VF or those with reversible causes of sudden death frequently remain unprotected against cardiac arrest for time periods of variable duration. Similarly, patients awaiting ICD implantation and those with contraindications to implantation may also go unprotected for significant time periods. The recent emergence of the wearable cardioverter-defibrillator provides a new prophylactic strategy for patients who are at significant risk for VT/VF but are not immediate candidates for ICD implantation. The patient population who is likely to derive the most benefit from the wearable defibrillator remains to be defined. We provide an in-depth review of the evidence base and role of wearable defibrillator therapy and clinical indications for its use.

Device Description

The only commercially available wearable defibrillator to date is the LifeVest manufactured by ZOLL and approved by the Food and Drug Administration (FDA) in 2002. It consists of an elastic belt and shoulder straps (Figure 1) that carry 4 dry, nonadhesive sensing electrodes and 3 defibrillator electrodes. The electrodes exude gel automatically just before delivery of a shock. This way, the discomfort related to the exposure to large amounts of gel during long-term ambulatory use of the wearable defibrillator is avoided. The monitor is worn on a holster around the waist that contains the battery and defibrillator itself, an alarm system, and response buttons. It weighs a total of 600 g. The batteries last for 24 hours and take 2 hours to charge. Typically, 2 batteries are delivered with the LifeVest, allowing uninterrupted use. When receiving the wearable defibrillator, each patient undergoes training, which includes a thorough explanation of exchanging and charging of the batteries.

Besides defibrillation, the device acts as a loop recorder that continuously records and transmits via modem both tachyarrhythmias and bradyarrhythmias. However, to date, it does not have pacing capabilities for backup bradycardia pacing or for antitachycardia overdrive pacing. As with an ICD, the wearable defibrillator may be programmed to different VT or VF zones for which different response times (time from detection to defibrillation sequence activation) and shock energy (between 75 and 150 J, biphasic) may be programmed. The final programming of the device is at the discretion of the treating physician.

Because the wearable defibrillator is not implanted, it has a higher risk of motion-related sensory artifacts than an ICD. Consequently, it is equipped with special algorithms developed for noise reduction and is fitted with an alarm system and response buttons. The alarm system consists of a vibration signal, 2 successive sound alarms (low and high volume), and a verbal warning that a shock is imminent. As long as the response buttons are pressed, the wearable defibrillator withholds therapy. Thus, conscious patients hearing (or sensing) the alarm system may prevent themselves from being shocked inappropriately (as a result of noise artifacts or hemodynamically stable VTs). At the same time, the patient is instructed to sit or lie down to avoid injury in the event of loss of consciousness. In case of a truly life-threatening VT, the patient eventually loses consciousness, the response buttons are thereby released, defibrillation inhibition is withdrawn, and lifesaving shocks are delivered (Figure 2). The total time from VT/VF initiation to shock delivery is <1 minute (unless the response buttons are pressed or the device is intentionally programmed otherwise). This includes arrhythmia detection, alarm system activation, and charging. If the arrhythmia is redetected after defibrillation, the cycle is repeated, and up to 5 shocks can be delivered for a single event. Patients are instructed to seek immediate medical evaluation after receiving a wearable defibrillator shock. Evaluation includes a review of the arrhythmias that trigger the shock, which are automatically recorded and stored. In addition, new electrodes should be provided at this point.

Patient Selection

When trying to determine whether a specific patient is suitable for a wearable defibrillator, 3 aspects need to be considered: device-related issues (efficacy and safety), patient-related factors (compliance, aptitude, and acceptance), and disease-related aspects (possible indications and survival benefit).

Figure 1. The LifeVest wearable cardioverter-defibrillator.

Device-Related Issues

Efficacy

Clinical trials studying the wearable defibrillator have shown that it is very effective in terminating VT/VF. In the first 2 small-scale clinical trials evaluating the efficacy of the wearable defibrillator in terminating rapid VT and VF episodes induced by programmed ventricular stimulation in the catheterization laboratory (the Table), all ventricular arrhythmic events (31 events in 21 patients) were successfully terminated.[3,4] In contrast to ICD trials, no attempt was made to define the defibrillation threshold in these trials. Instead, the wearable defibrillator was programmed to deliver a shock with the same prespecified energy to all patients (230-J monophasic
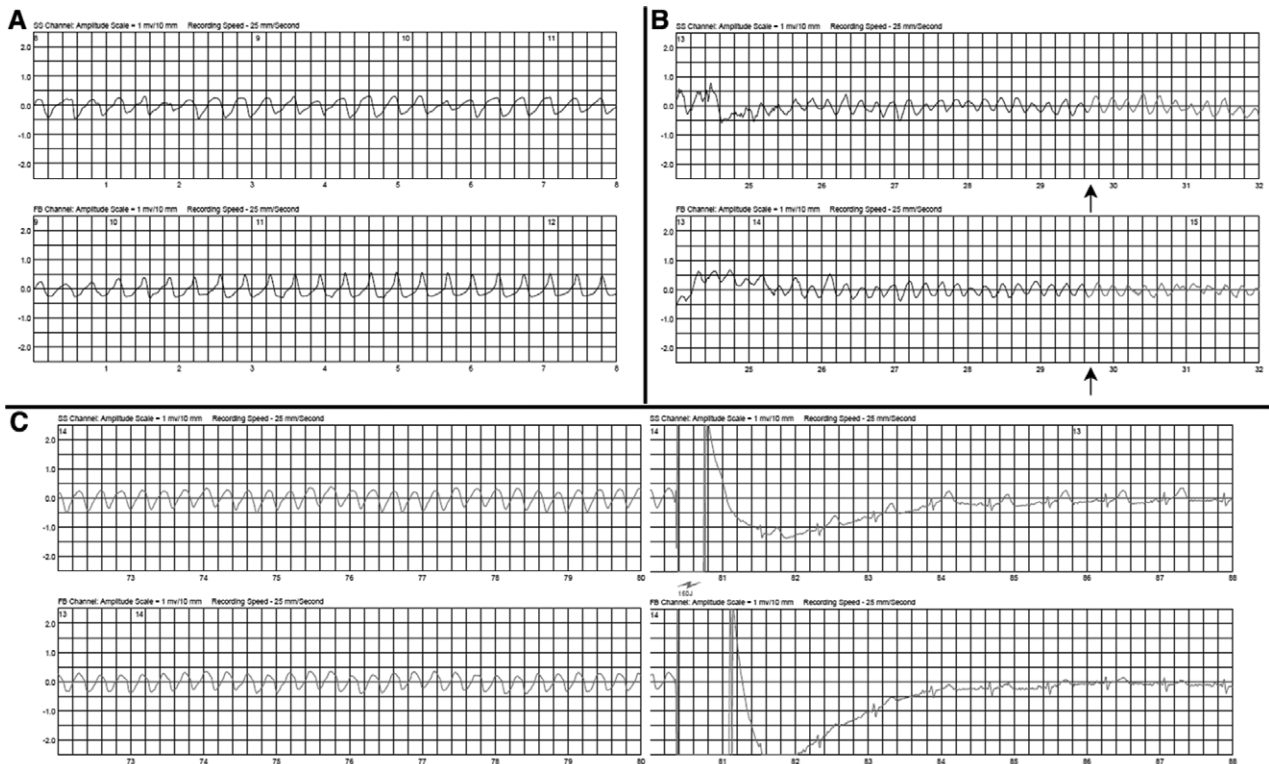

Figure 2. Example of a LifeVest shock report. A recording from a LifeVest of an appropriate shock delivered to a patient with long-QT syndrome. The wearable defibrillator was prescribed after implantable cardioverter-defibrillator (ICD) extraction as a result of infection. All plates show the 2 channels used by the wearable defibrillator. **A**, The LifeVest recognizes a tachyarrhythmia (polymorphic ventricular tachyarrhythmia) and starts recording. **B**, At 30 seconds, the recording turns red, (**arrows**) indicating that the programmed 30-second response time has ended. **C**, At 50 seconds after defibrillation sequence activation, a 150-J shock is delivered with return to sinus rhythm. The patient is alive and well and awaiting ICD reimplantation. FB indicates front to back; and SS, side to side.

Table.   Summary of Wearable Cardioverter-Defibrillator Clinical Trials and Registries

Authors	Inclusion Criteria	Patients, n	Mean WCD Use Time, d	Appropriate Shocks, No. VT or VF Events/No. Patients	First-Shock Success Rate, %	Inappropriate Shock, No. Events/No. Patients	Mortality,* %
Auricchio et al[3]	Patients undergoing EPS because of SCA[†]	9	…	…	100	…	**…**
Reek et al[4]	Patients undergoing EPS because of VT	12	…	…	100	…	**…**
Rao et al[9]	CSHD	43	27	0	…	0	**5**
	IA	119	29	3/2	100	7/4	**2**
Saltzberg et al[10]	PPCM	107	124	0	…	0	**0**
	NIDCM (women only)	159	96	2/1	100	0	**7**
Feldman et al[5] (WEARIT/BIROAD)	Symptomatic HF and EF ≤30% or high risk of sudden death after MI/CABG	289	93	8/6	75	6/6	**4**
Klein et al[6]	All comers	354	106	21/11	95	3/NA	NA
Chung et al[7]	All comers	3569	53	80/59	99	NA/67	**1**

CABG, coronary artery bypass graft; CSHD, congenital structural heart disease; EF, ejection fraction; EPS, electrophysiological testing; HF, heart failure; IA, inheritable arrhythmia; MI, myocardial infarction; NIDCM, nonischemic dilated cardiomyopathy; PPCM, peripartum cardiomyopathy; VF,ventricular fibrillation; VT,ventricular tachycardia; WCD, wearable cardioverter-defibrillator; and WEARIT/BIROAD, Wearable Defibrillator Investigative Trial and Bridge to ICD in Patients at Risk of Arrhythmic Death.

* Mortality during wearable defibrillator use period.

†All episodes were VF induced during the EPS, and the WCD was used only during the EPS.

shock in the first trial[3] and either a 70- or a 100-J biphasic shock in the trial of the second generation of the LifeVest[4]).

The first outpatient evaluation of the wearable defibrillator consisted of the parallel Wearable Defibrillator Investigative Trial and Bridge to ICD in Patients at Risk of Arrhythmic Death (WEARIT/BIROAD) studies.[5] These 2 trials, united into 1 trial at the request of the FDA, included a total of 289 patients either with advanced heart failure and a left ventricular ejection fraction (LVEF) <30% or at high arrhythmic risk after a myocardial infarction (MI) or recent coronary artery bypass grafting (the Table). All patients were ineligible for ICD implantation, would have had to wait several months for implantation, or refused to undergo the procedure. In this study, 8 VT/VF events in 6 patients were appropriately detected and automatically treated. Moreover, all but 2 shocks were successful. The only 2 shock failures were attributed to technical errors in the electrode placement. As a result, in the most recent version of the LifeVest, an alarm sounds if the electrodes are not connected properly.

High success rates of VT/VF termination were also reported by Klein et al.[6] In this series of 354 patients in Germany, 20 of 21 VT/VF events were successfully terminated (95% success rate). Finally, in the largest and most recent wearable defibrillator registry published to date[7] that includes 3569 patients, the first-shock success rate was 100% for unconscious patients (76 of 76) and 99% for all patients (79 of 80). The only patient in whom the first shock failed pressed the withhold-therapy response buttons for 10 minutes before allowing himself to be shocked. Survival after VT/VF was also very high in this registry (72 of 80 patients). All 8 patients with fatal outcomes were initially successfully treated by their wearable defibrillator but died of recurrent arrhythmias. These cases included 4 patients found alive by emergency medical personnel who eventually died of recurrent VT/VF despite advanced life support. Thus, only 4 deaths occurred as a result of failure of the

device to defibrillate recurrent events. Reasons for defibrillation failure included displacement of sensing electrodes in 2 patients who fell during the first successfully treated arrhythmic event, deliberate withholding of therapy by a patient's spouse during recurrent VF, and prevention of VF detection by unipolar pacing artifacts from an implanted pacemaker in 1 patient.[8] It is now recommended that pacing artifact be kept <0.25 mV to prevent such a scenario.

Safety

Induction of VF by an inappropriate shock or acceleration and deterioration of VT to VF by an appropriate shock might occur during wearable defibrillator use but have not been reported in the clinical trials performed so far. The only serious complication of the wearable defibrillator reported is inappropriate shocks. Fortunately, this has been a rare event. Several series (including 43–354 patients with a mean wearable defibrillator use time of 27–124 days) have reported this complication to occur in 0% to 3% of patients (the Table). In the largest registry published, the occurrence was 1.9% (1.4%/mo).[7] Because the device is equipped with response buttons that withhold therapy, an inappropriate shock can occur only as a result of a combination of false detection and failure of the patient to respond. The main reasons for false detection as reported in this registry were artifacts (68%) and rapid supraventricular tachycardia (26%). Other reasons included loss of signal, double counting of normal complexes, and nonsustained VT. Main reasons for failure of the patient to respond were sleep, forgetting training, and mental or physical inability to respond. Only a minority of patients failed to recognize activation of the alarm system.[7]

Patient-Related Issues

Compliance

One of the main concerns about the wearable defibrillator was that compliance would be low. This concern was largely

refuted in several series that examined the actual time the device was worn by patients (this information is automatically collected by the device). The registry published by Chung et al[7] showed that 71% of patients wore the wearable defibrillator >80% of the assigned time and that 52% wore it almost continuously. In the German registry, 72% of patients wore it >90% of the time, and the vast majority reported that it was easy to handle after sufficient training.[6] Smaller series have reported compliances rates of 70% to 91%.[9,10] Furthermore, only 14% stopped using the wearable defibrillator altogether, mainly because of weight and size issues.[7]

Because the use (or lack of thereof) of the wearable defibrillator may be monitored online, it is possible to confront noncompliant patients in real time. Alternative modes of therapy (like ICD implantation, hospitalization, or home monitoring combined with external automatic defibrillator for home use[11]) may then be discussed.

Aptitude

Another potential concern with the wearable defibrillator is the ability of patients to use the device correctly. Examples of incorrect use include mainly errors in placing the electrodes and refraining from pressing the response buttons by conscious patients. As mentioned, the former error is avoided in the latest LifeVest model by an appropriately timed alarm. Training of patients and family members/caregivers is crucial because as many as 10% of patients receiving inappropriate shocks report having forgotten the instructions for use as the reason for not pressing the response buttons.[7] Accordingly, cognitive function should be carefully evaluated in postresuscitation patients with a history of anoxic brain damage. It is estimated that 5% of patients will be unable to use the device correctly.[6]

Acceptance

No methodical studies on the psychological impact of using the wearable defibrillator have been published. However, Klein et al[6] interviewed 60 patients in their series and reported favorable results in this aspect. First and foremost, almost all patients reported that, despite some discomfort associated with its use, the wearable defibrillator provided them with a sense of security that was more important. In fact, about a quarter of the patients interviewed stated that they preferred a wearable defibrillator over an ICD. On the other hand, about half reported sleep disturbances, mainly caused by false alarms. It was calculated that such alarms occur, on average, once every 13 days. In general, these alarms were not a major concern for most patients. All in all, it was estimated that only 5% of patients will discontinue use because of comfort issues.[6]

Disease-Related Issues

Indications

Although anecdotal cases of long-term use of a wearable defibrillator have been reported (up to 7 years in 1 case[6]), the LifeVest is intended as a temporary solution. Thus, the main indications for its use are as a bridge to ICD implantation or until the arrhythmic risk subsides. These indications may be divided into 4 categories. The first category is made up of patients with accepted indications for ICD implantation who also have (usually temporary) contraindications for such a procedure. The typical example is the patient in need of prolonged antibiotic treatment after extraction of an infected ICD. The second category comprises patients under investigation for a disease with a high risk of arrhythmic death pending definitive diagnosis. This category includes mainly patients suspected of having an inheritable arrhythmic disorder who are awaiting results of confirmatory testing or survivors of a cardiac arrest of unclear (and potentially treatable or reversible) origin. The third category is made up of patients with severe heart failure awaiting transplantation. The last category comprises patients having a condition that temporarily places them at high risk of an arrhythmic death. This category includes patients with a low LVEF resulting from potentially reversible condition such as a newly diagnosed dilated cardiomyopathy (that could be due to transient myocarditis) or an ischemic cardiomyopathy in the early period after revascularization or in the early period after a MI. The latter clinical setting may yet prove to be the most frequent indication for wearable defibrillator prescription and is therefore discussed separately in a subsequent section of this article.

To date, no randomized, controlled trials studying the survival benefit with a wearable defibrillator for a specific indication have been conducted. Thus, guidelines for its use are quite general (as is elaborated later), and its prescription often relies on expert opinion. This may explain the difference in the frequency of various indications reported by Chung et al[7] in the United States and Klein et al[6] in Germany (Figure 3).

Survival Benefit

The registry published by Chung et al[7] is currently the only study large enough to allow speculation on the survival benefit potentially afforded by the wearable defibrillator. During a mean use time of 53 days, the overall survival was 99.2% and survival after VT/VF was 90%. Although robust conclusions cannot be drawn from registry data, this report provides some insight into the benefit from the wearable defibrillator in specific indications. For instance, 5.2% of patients after ICD explantation experienced sustained VT/VF while using the wearable defibrillator, but only 0.3% died of these events. During the same time period, 1% of these patients died suddenly as a result of nonshockable rhythms (asystole or pulseless electric activity). Another group with a relatively high risk of arrhythmic events consists of patients in the early post-MI period with LVEF ≤35%. Three percent of these patients experienced VT/VF while using a wearable defibrillator, but only 0.6% died of these events, whereas 2% died suddenly as a result of asystole or pulseless electric activity. In the same registry, 1.4% of patients awaiting first ICD implantation experienced VT/VF, but only 0.2% died. No other events were recorded in this group. Importantly, none of the 104 patients with recent MI and LVEF >35% had arrhythmic events. Therefore, it seems that patients awaiting implantation or reimplantation of an ICD represent a group that is at a relatively high risk of life-threatening arrhythmias and thus have the most robust indication for a wearable defibrillator. This is not surprising when we take into account the fact that these patients already had a clear indication for an ICD. As for other clinical settings, further studies are needed to establish the role of the wearable defibrillator in their treatment.
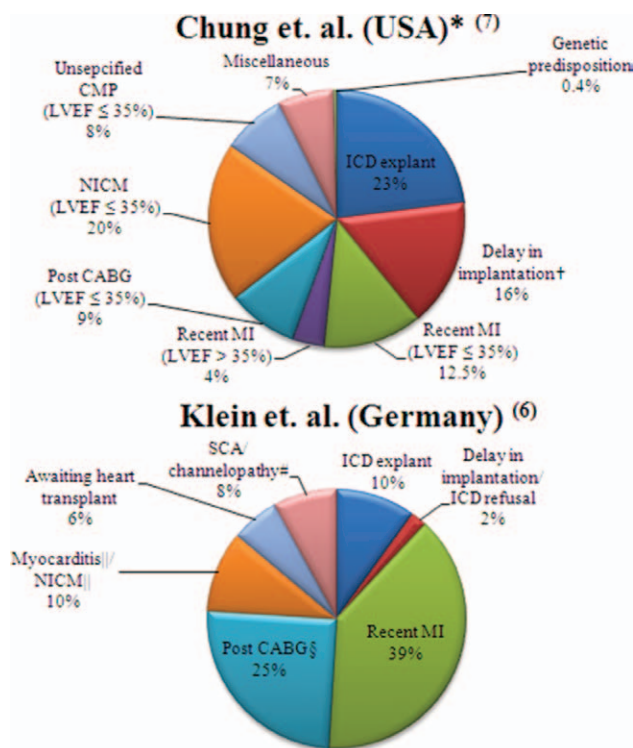
Figure 3. Relative frequencies of wearable defibrillator indications in Germany and the United States. * Patients with known indication only (77% of the patients in the registry). †After a ventricular tachyarrhythmia/ventricular fibrillation (VT/VF) event. ‡Complicated by left ventricular ejection fraction (LVEF) ≤35%, early (≤24 hours) aborted VT/VF, or advanced acute pulmonary congestion (Killip class III/IV). §Associated with poor left ventricular function, difficult postoperative hemodynamic recovery, or early postoperative life-threatening VTs. ‖With syncope. #Newly detected long-QT syndrome or Brugada syndrome. CABG indicates coronary artery bypass graft; CMP, cardiomyopathy; ICD, implantable cardioverter-defibrillator; MI, myocardial infarction; NICM, nonischemic cardiomyopathy; SCA, sudden cardiac arrest; and WCD, wearable cardioverter-defibrillator. Adapted from Klein et al[6] with permission from the publisher. Copyright © 2010, John Wiley and Sons, Inc.

Post-MI Patients

As stated previously, patients in the early post-MI period with an LVEF ≤35% warrant specific attention.[12] This group of patients is known to be at high risk of arrhythmic death, particularly during the first months after the infarction, as indicated by the Valsartan in Acute Myocardial Infarction Trial (VALIANT).[13] However, in the Defibrillator in Acute Myocardial Infarction Trial (DINAMIT), which recruited patients with a recent MI (6–40 days previously) and high-risk characteristics (including LVEF ≤35% and cardiac autonomic dysfunction) and randomized them to either an ICD or standard therapy, there was no overall survival benefit.[14] The practical consequence of the "VALIANT/DINAMIT conundrum" is its impact on the guidelines of the major professional societies. These guidelines recommend a 40-day waiting period before an ICD is implanted for the primary prevention of sudden cardiac death in patients with low LVEF after an acute MI.[2,15] Moreover, in the United States, ICD implantation is not reimbursed if performed within this time period. Whether a wearable defibrillator is a solution

for this "dangerous gap" in these patients is still unknown. This question will, we hope, be answered by the ongoing Evaluating the Effectiveness of the LifeVest Defibrillator and Improving Methods for Determining the Use of Implantable Cardioverter Defibrillators (VEST/PREDICTS)[16] and Vest Prevention of Early Sudden Death trials,[17] which randomize patients with LVEF ≤35% up to a week after discharge as a result of MI to either a wearable defibrillator or standard care.

Guidelines in Perspective

When the FDA approved the LifeVest in 2002, it did so on the basis of a single clinical study, WEARIT/BIROAD,[5] which included only 289 patients with 8 VT/VF events. Obviously, the noninvasive nature of this device led the FDA to adopt a more lenient approach than that taken during the approval of the ICD.[18] Since then, as described above, only several registries have been published that include different patient populations and vary in times of use and follow-up (the Table). No randomized, controlled trials have been completed. This gap in knowledge prevents any conclusive recommendation to be given. Nevertheless, several major societies have included the wearable defibrillator in their guidelines:

1. The 2006 joint American and European cardiac societies (American College of Cardiology/American Heart Association/European Society of Cardiology) guidelines quote the FDA approval of the wearable defibrillator 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 implanted defibrillator for antibiotic therapy."[15]
2. The Heart Rhythm Society published an expert consensus that recommends the consideration of a wearable defibrillator after device extraction because of infection.[19]
3. The International Society of Heart and Lung Transplantation 2006 guidelines give a Class I indication (Level of Evidence C) for wearable defibrillator prescription as follows: "An implanted or wearable ICD should be provided for Status 1B patients who are discharged home given that the wait for transplantation remains significant."[20]

Limitations and Gaps of Knowledge

1. The lack of completed randomized trials of wearable defibrillators should be emphasized, particularly when discussing its use for patients in the "waiting period" soon after MI. In the DINAMIT trial, which randomized high-risk patients shortly after MI to ICD versus conservative therapy, a significant number of patients received appropriate ICD shocks for spontaneous life-threatening arrhythmias, but a significant effect on total survival could not be demonstrated for the study group. Similar results were reported in the Immediate Risk-Stratification Improves Survival (IRIS) trial.[21] The wearable defibrillator was not subjected to such rigorous trials, and it is not clear whether this device will significantly decrease total mortality (and not merely arrhythmic death) in patients with recent MI.

2. The number of wearable defibrillators used is rapidly increasing. As opposed to ICDs, which are generally implanted by arrhythmia specialists, the wearable defibrillator may be prescribed by physicians less experienced in the management of arrhythmias. This could lead to an increased number of complications related to wrong patient selection or suboptimal device programming.

Conclusions

The available evidence, which includes preclinical studies evaluating the performance of the device during induced arrhythmias in the electrophysiological laboratory and clinical registries, suggests that the wearable defibrillator does what it is meant to do (automatically detect and terminate rapid ventricular arrhythmias) with a very high efficacy. Specifically, in all the clinical studies combined, the total number of events of sustained rapid VT or VF that required defibrillation was 114, and 110 of these events were appropriately treated by the wearable defibrillator. Nevertheless, when the prescription of a wearable defibrillator is being considered, it should be kept in mind that there are no randomized, controlled studies showing that it provides survival benefit.

The wearable defibrillator should be considered for patients capable of using it who are considered to be at high risk of VT/VF and need temporary protection from these arrhythmias. It can also be considered as a long-term solution in unique cases with contraindications for an ICD.

Disclosures

None.

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