

Wearable defibrillator use in patients with high risk of sudden cardiac death: a brief report from a single center

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Abstract

Devices such as implantable cardioverter defibrillators (ICDs) and wearable cardioverter defibrillators (WCDs) have opened up new paths in the treatment of Sudden Cardiac Death. Guidelines advocate ICD placement for primary prevention after at least three

months of optimal medical therapy following the first diagnosis of heart failure with reduced FE from any cause, and at least 40 days after an acute myocardial infarction with FE 35% notwithstanding medication. In these and other cases documented in the guidelines, the use of a wearable defibrillator (WCD), a noninvasive device that guards against malignant arrhythmias while waiting for arrhythmic risk to be defined and medication therapy to be optimized, may be considered. In our Cardiology/Utic Department, we treated 26 patients with a preliminary indication for ICD implantation: the use of the WCD allowed us to swiftly put them in clinical safety, avoiding potentially fatal arrhythmias while waiting for pharmacological therapy to be optimized. At the end of the periodic follow-up, FE had normalized in ten patients, allowing them to avoid ICD. Only 10 of the 26 participants with WCD had a proven indication for final implantation. There were no fatalities or problems in any of the patients.

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Introduction

Sudden cardiac death (SCD) is a potentially fatal clinical event that requires the use of urgent interventions such as defibrillation. Over the past decade, the development of devices such as implantable cardioverter defibrillators (ICDs) and wearable cardioverter defibrillators (WCDs) has provided new avenues in the management of SCD.¹

Among the affected population, males are at higher risk of MCI than females, and depending on the age group, the type of disease predisposing to SCD differs from fixed anatomic events to transient triggering events.¹ Channelopathy, cardiomyopathy, structural heart disease, and myocarditis are predominantly found in the younger population. Pathologies such as coronary artery disease, valvular disorders, and heart failure intervene more often in the elderly. Ventricular fibrillation (VF) and ventricular tachycardia (VT) are the most common arrhythmias associated with MCI.¹ The management of these life-threatening arrhythmias involves the use of various interventions ranging from medical to invasive strategies such as the ICD.

The ICD represents the most effective option in the treatment of malignant ventricular tachyarrhythmias; however, implantation is an invasive procedure, it costs, and has early and late post-procedure complications such as infections, inappropriate shocks, and device malfunction. However, there are conditions in which the risk of sudden death is relatively high, but with possible transience of the risk itself: recent acute myocardial infarction (AMI) with left ventricular systolic dysfunction, heart failure with reduced ejection fraction (FE) of first diagnosis. European and American guidelines recommend ICD implantation in primary prevention after at least three months of optimal medical therapy

since the first diagnosis of heart failure (HF) with reduced FE of any etiology, and at least 40 days after an AMI with global contractile function remaining, despite therapy, below 35%.² In all these conditions, the use of the wearable defibrillator (WCD), a noninvasive device that allows the patient to be protected from malignant arrhythmias while waiting to define the arrhythmic risk and possibly optimize drug therapy, can be considered. Likewise, WCD is appropriate in patients who have undergone ICD explanation.³⁻⁷ However, there are also other indications for the use of WCD: i) other nonischemic cardiomyopathies: myocarditis is the most common cause of nonischemic heart failure;⁸ others include peripartum cardiomyopathy and Tako-Tsubo cardiomyopathy. These are acute forms, even severe ones, with a good chance of functional recovery but in acute cases, they have a high risk of life-threatening arrhythmias;^{3,4,6,7} ii) patients with toxic-based systolic dysfunction, induced by drugs and toxic substances such as chemotherapeutics;⁹ iii) patients with genetic cardiomyopathies: suspected Brugada syndrome, suspected long QT syndrome;^{4,5} iv) patients with transient contraindications to ICD implantation such as acute infection, endocarditis, and peripheral ulcers in patients with arteriopathy obliterans, abscesses, and intracardiac thrombosis;¹⁰ v) patients awaiting heart transplantation or with implanted ventricular assist device.¹⁰

The wearable defibrillator can be used by each patient for a period ranging from 1 to 6 months, allowing them to be discharged home and to lead an essentially normal daily life, with the security of being protected from fatal arrhythmic events.

The only automatic wearable defibrillator on the market is the LifeVest® device manufactured by the Zoll Manufacturing Corporation.¹¹ It is a kind of belted bodice, easily worn and removable independently by the patient, which can promptly recognize any malignant arrhythmias and immediately deliver external defibrillation up to 5 consecutive times.¹² The WCD continuously monitors the patient's heart rhythm and uses an arrhythmia detection algorithm based on two frequency ranges (VT zone and FV zone) and several parameters that can discriminate between ventricular tachyarrhythmias, supraventricular tachyarrhythmias, and noise episodes. When an arrhythmia is identified, the WCD emits a series of vibrational, acoustic, visual, and vocal alarms that seek the patient's response to establish the patient's degree of consciousness. The patient, therefore, has the option of delaying the shock by pressing the response buttons. If those buttons are not pressed, the device releases a blue gel that can optimize the electrical impedance between the pads and the skin, it issues a vocal warning to bystanders that the shock is imminent and delivers defibrillation therapy. All recordings and information about proper use are then made available through an automated remote monitoring system on an Internet site which is accessible only to prescribers.¹²

Materials and Methods

We performed a retrospective, single-center observational study, analyzing patients in the Cardiology Unit/Cardiology Intensive Care Unit of the Sarno Hospital between April 2019 and September 2021 for whom LifeVest® was indicated. This is a heterogeneous patient population by cardiac pathology, but all with a prior indication for ICD implantation.

We recruited 26 patients selected with the following inclusion criteria: i) heart failure patients with FEVS < 35%; ii) patients with recent episodes of ventricular tachycardia with preserved FE; iii) patients with post - AMI left ventricular failure with FE < 35%; iv) patients with recent cardiac arrest in VF.

Outcomes

The effectiveness of WCD was evaluated using all-cause mortality and disease-related mortality as primary outcomes. Secondary outcomes, on the other hand, were TV/FV incidence, avoided ICD implantation, health-related quality of life HRQoL,¹³ satisfaction, and compliance. For the assessment of WCD safety, adverse events (AEs) and serious adverse events (SAEs) were selected as outcomes.

Results

In the 26 patients observed between April 2019 and September 2021 in our study, the average LifeVest® utilization was two months for confirmation of possible ICD use. The effectiveness of WCD was evaluated using all-cause mortality and disease-related mortality as primary outcomes. Secondary outcomes, on the other hand, were VT/FV incidence, avoided ICD implantation, health-related quality of life (HRQoL), hospitalization rate, satisfaction, and compliance. Adverse events (AEs) and serious adverse events (SAEs) were selected as outcomes for the safety assessment of WCD. All patients were discharged home and underwent medical therapy and periodic follow-up. Ten patients experienced gradual normalization of FE and avoided ICD. Of the 26 subjects who had LifeVest® applied, only 10 were confirmed indications for ICD implantation. No fatal events or reportable complications occurred in any patient. Compliance with the wearable device was good, with satisfactory mean HRQoL scores.

Discussion and Conclusions

The aim was to put patients in a clinically safe condition quickly, averting possible malignant arrhythmias, pending optimization of drug therapy and/or possible performance of cardio - MRI, in several cases essential in the indication for definitive implantation. The ability to use the LifeVest® allowed us to discharge patients early, reducing hospital stay time, a need which is even more pressing when considering the onset of the SARS-CoV2 pandemic. In our analysis, we did not record any deaths in lifewest patients, although this is a small cohort and there are still little data on large cohorts in the literature. We performed an extensive literature search on this device, consulting recent literature. The LifeVest® in Europe obtained the CE mark for the first model in 2000 and then in 2011 for the latest generation model, the fifth. Since then, the experiences carried out in European and Italian treatment centers have gradually expanded, allowing the collection of quite significant data. However, the heterogeneity of the target population, given the variability of the clinical indication, and the bias related to patient's adherence to the device, do not allow us to draw a unique model of cost-benefit analysis.

In the VEST study, the Intention to Treat analysis showed that WCD was highly effective in returning VT/VF patients to sinus rhythm, reducing all-cause mortality but not sudden cardiac death mortality. The subsequent Per Protocol secondary analysis of the same study showed that the significance of the reduction in sudden cardiac death had been affected by low adherence to therapy or wearing less than the 90 days required by the protocol. With this new analysis, the authors of the VEST Per-Protocol concluded that the use of the wearable defibrillator allows an important and significant reduction in both all-cause mortality and sudden cardiac death mortality.¹⁴

As early as 1998 and 2003, Auricchio *et al.*¹⁵ and Reek *et al.*¹⁶ demonstrated that WCD could intercept and terminate ven-

tricular tachyarrhythmias in all cases. In the prospective studies, WEARIT-II, WEARIT-II-Europe (WEARIT I and II studies), and the study by Röger *et al.*,¹⁷⁻¹⁹ compliance in WCD use, event rate, and the final need for an ICD were analyzed. At the end of WCD treatment, the ICD was implanted in only 51% of patients for FEVS improvement >35%. During the 18-month follow-up following WCD discontinuation, no VT/VF events with the need for treatment or SCD were documented in patients who did not undergo ICD implantation. The authors concluded that WCD allows a safe “bridge” to ICD implantation or improvement in left ventricular function.¹⁸ In the WEARIT-II registries of 2000 patients with ICM (40%), NICM (46%), or congenital heart disease (13%), it was found that 2% (41 patients) experienced VT/VF that required WCD treatment in 54% of cases.¹⁶ An ICD was implanted in only 42% of patients. Compliance averaged 22.5 hours per day. The rate of inappropriate shocks was 0.5%. No deaths from FV/TV were documented during WCD use (3 deaths from asystole occurred).¹⁸

On the other hand, a perhaps under-explored aspect is the cost-effectiveness of WCD, especially when compared with ICD implantation and prolonged hospitalization.

Recently, a health technology assessment (HTA) on the use of WCD was published in the prestigious journal *Pharmaceutical Economics and Therapeutic Pathways*.²⁰ This HTA, prepared by the Research Centre on Public Health (CESP) of Bicocca University in Milan together with key opinion leaders from AIAC, is based on the construction of an economic model centered on the Italian national health care system: the aim was to investigate the economic impact of WCD for arrhythmic risk stratification and protection from sudden cardiac death for high-risk patients.

In a population of patients with the recent acute coronary syndrome, waiting 90 days at home with WCD versus medical therapy alone demonstrated a much lower ICER (Incremental Cost-Effectiveness Ratio) per QALY (Quality-Adjusted Life Years): this is a cost-effective finding.

In addition, according to this analysis, in post-transplant patients, the use of WCD reduces management costs. WCD is also advantageous when potential confounders such as hospitalization in a high-intensity facility, incidence of mortality, incidence of complications given by the implantation of invasive devices, and battery life are considered.

As far as our analysis is concerned, the small sample size and heterogeneity among patient indications may be a limitation. However, the data collected so far, placed in a larger context, nevertheless allow us to draw some conclusions: the use of the wearable defibrillator may result not only in improved clinical management of the patient but also in more efficient use of health system resources, to the extent that this type of noninvasive strategy may become the first choice in selected patients.

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