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Single-center experience with wearable cardioverter-defibrillator as a bridge before definitive ICD implantation

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ABSTRACT

Background: The wearable cardioverter-defibrillator (WCD) has been approved for patients with poor left ventricular ejection fraction (LVEF) who are at risk of sudden arrhythmic death for a limited period but are not candidates for a definitive implantable cardioverter-defibrillator (ICD). The present study sought to retrospectively analyse our single-centre experience.

Methods and results: All consecutive WCDs applied between April 2017 and September 2018 in our centre were enrolled. An exercise test was performed in all patients in order to evaluate the absence of false detection of ventricular arrhythmias by the device. A total of 16 patients (57.7 ± 14.8 years old; 75% males) were taken into consideration for the analysis. Mean LVEF was 32 ± 11% at diagnosis and 42 ± 10% at last follow-up (mean, 3.1 ± 1.7 months; median, 3 months). At the end of the "wearing period" 11/16 patients (69%) did not have ICD implant indications and only 5 (31%) underwent ICD implantation. Neither appropriate nor appropriate shocks occurred during the follow up.

Conclusions: The WCD represents a useful tool to bridge a temporarily increased risk for sudden cardiac death. The proportion of patients with an improvement of LVEF> 35% beyond the WCD-application period was considerable.

1. Introduction

Nowadays, the implantable cardioverter-defibrillator (ICD) is the gold standard for the prevention of sudden cardiac death due to ventricular tachyarrhythmias [1,2]. Current guidelines recommend ICD implantation for secondary and primary prevention in patients with an established high risk of sudden cardiac death (SCD) [3,4]. However, in selected patients, the risk of SCD may be increased only temporarily or cannot be immediately determined. The wearable cardioverter-defibrillator (WCD) has been approved for clinical practice in 2001 to bridge a period of presumed high risk of SCD [5,6]. The 2015 guidelines of the European Society of Cardiology give a IIb, level of evidence C indication for WCD in case of patients with poor left ventricular systolic function who are at risk of sudden arrhythmic death for a limited period but are not candidates for an ICD (i.e. bridge to transplant, bridge to transvenous implant, peripartum cardiomyopathy, active myocarditis, and arrhythmias in the early post-myocardial infarction phase) [4]. The present study sought to retrospectively analyse our single-centre experience with a relatively small sample of patients treated with WCD.

2. Methods

The current study is a retrospective analysis based on all consecutive WCDs applied between April 2017 and September 2018 in our centre to those patients at risk of sudden arrhythmic death for a limited period and without an immediate indication to ICD implantation.

All patients were fitted with the device, trained in its use, and instructed to wear the device continuously for 3 months (except while bathing). According to the PROLONG study [7], those patients who presented an increase in left ventricular ejection fraction (LVEF) ≥5% or from 30% to 35% received a prolongation of WCD application. Sites were alerted if a participant wore the device for

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less than 15 h in a 24-h period (monitored through the device itself).

The database collection includes demographic information, customer call reports and device data, such as reason, compliance and duration of WCD use. Incidences of shock therapy and asystole (defined as ECG signal amplitude below 100 μV for at least 16 s) were reviewed from ECG recordings. Sudden cardiac arrest included both sustained (lasting 30 s) ventricular tachycardia (VT) or ventricular fibrillation (VF), as detected through programmed rate criteria. An exercise test was performed in all patients in order to evaluate the absence of false detection of ventricular arrhythmias by the device.

Compliance with device use for each patient was calculated by averaging the hours used per day of wear. The time to deliver therapy was programmed as follows: 60 s for VT and 25 s for VF. The VT and VF zones were programmed, respectively, >150 bpm and >200 bpm in all patients except one, who received a more conservative programmation (VT and VF zone respectively >170 and > 220 bpm).

A detailed description of the WCD (LifeVest® device, ZOLL, Pittsburgh, PA, USA) has been provided in prior publications and reviews [7,8]. In case of sensed ventricular arrhythmic episodes, the WCD is able to deliver a treatment shock through three self-gelling defibrillation electrodes. The WCD stores data on device usage and all ECGs associated with arrhythmia detection, which are then uploaded to the company server to be reviewed and evaluated by the treating physician.

Categorical variables are expressed as absolute and relative frequencies. Continuous variables are expressed as mean+SD or median and range as appropriate. Statistical analysis was performed using SPSS 20.0.0 (IBM Inc., Armonk, New York, USA).

3. Results

A total of 16 patients (57.7 ± 14.8 years old; 75% males) were enrolled in the study. The characteristics of the study population are listed in Tables 1 and 2. As Fig. 1 shows, the underlying reasons for WCD application were: dilated cardiomyopathy with impairment of LVEF following myocardial infarction (n = 4; 25%), myocarditis (n = 4; 25%), chemotherapy (n = 2, 12%), alcohol abuse (n = 1, 6%), and related to unknown causes in 3 patients (19%); in addition, 2 patients (12%) were recruited because of ventricular arrhythmias under diagnostic definition. The patients wore the device for a mean time of 3.1 ± 1.7 months (median: 3 months) and for a mean daily time of 22.3 ± 1.9 h (median 23.3 h). The mean wear time was 91.2 ± 44.1 days.

Table 1
Clinical characteristics and medical therapy of the study population.

Clinical features	
Age (years)	57.7 ± 14.8
Male gender	12 (75%)
Hypertension	5 (31%)
Dyslipidemia	4 (25%)
Diabetes	5 (31%)
Medical therapy	
ACE inhibitors/sartans	10 (62%)
Beta blockers	14 (87%)
Amiodarone	6 (37%)
Sacubitril/valsartan	2 (12%)
Diuretics	13 (81%)
MRAs	12 (75%)
Statins	8 (50%)

ACE: angiotensin-converting enzyme; MRA: mineralocorticoid receptor antagonist.

No patients presented sustained ventricular arrhythmias during the observation period; neither appropriate nor inappropriate shocks were delivered by the device. Of note, in 3 patients (19%) the WCD reported episodes of high ventricular rates which the medical review actually labelled as sinus tachycardias. Two patients (12%) had already a story of persistent atrial fibrillation and another one (6%) had a paroxysmal episode of atrial fibrillation during the hospital stay. Of note, 11 patients (69%) exhibited non sustained ventricular tachycardias before WCD application.

Mean LVEF was 32 ± 11% at diagnosis and 42 ± 10% at last follow-up (mean, 3.1 ± 1.7 months; median, 3 months). At last follow up and after the clinical re-evaluation, 11 patients (69%) did not have indication for a definitive ICD. Five patients (31%) underwent ICD implantation, 3 of them received a single-chamber device, another one received a biventricular device and the fourth one a subcutaneous ICD. Finally, one patient (6%) showed a marked reduction in ventricular arrhythmias under therapy with amiodarone and a loop recorder implantation was decided to monitor the patient during the follow up.

4. Discussion

Although the present cohort study is limited by the relatively low number of patients and, subsequently, the absence of malignant arrhythmic events, the following observations can be drawn: (1) no inappropriate shocks released by the device occurred; (2) the mean wear time per day was high; (3) the rate of patients who did not present indications for ICD at last follow up was high, especially for those patients who received a prolonged WCD application period.

Some studies reported the occurrence of inappropriate shock delivered by WCD. Olgin et al. [9] reported a rate of 0.6% of inappropriate shock (9/1524) in a recente, large, randomized and prospective study investigating the usefulness of WCD in the early phase after acute myocardial infarction. In the PROLONG study [7], Duncker et al. did not report any inappropriate shocks in 156 patients with newly diagnosed LVEF≤ 35%. Our patient population did not experience any inappropriate shock but this finding is limited by the very small number of patients. However, in our protocol an exercise test was systematically performed in all patients in order to evaluate the absence of false detection of ventricular arrhythmias by the device. This might have hypothetically been useful to avoid inappropriate shocks during the follow-up period.

In our study the mean wear time per day was high when compared with the literature; for instance, the PROLONG study [7] and Olgin et al. [9] reported a mean wear time per day of 21.7 ± 4 and 14.0 ± 9, respectively. The latter did not find a significant lower rate of arrythmic death or total mortality in patients with WCD compared with those without WCD. However, the authors interestingly reported in the as-treated analysis that patients who chose to wore the device, having a better compliance and higher mean wear time per day, presented a significant reduction both in arrhythmic death and in total mortality (respectively, $p = 0.03$ and $p < 0.001$). Therefore, the compliance and the mean wear time might probably be crucial for the decrease of arrhythmic and overall mortality. In our study the compliance and mean wear time per day were satisfactory; however, as no arrhythmic events occurred in our patient population, any inference about these aspects and malignant arrhythmic episode and mortality could not be done.

The rate of patients who did not implant ICD at the end of the WCD period was high (69%); these data are in line with the findings of the PROLONG study [7], which reported that 63% of initial patients with LVEF <35% experienced a significant improvement in the left ventricular systolic function and avoided a permanent ICD

Table 2
Characteristics of the study population.

Patient	Age	Gender	Indications	WCD application time (months)	Daily average of use (hours)	Medical therapy	LVEF before (%)	LVEF after (%)	Outcome
#1	73	male	Ischemic DCM	3	23.9	ACEi, BB,D,AA,statin	35	35	ICD implantation
#2	57	male	Post-myocarditis DCM	2	23.9	BB,S/V,D,AA,statin	29	54	no ICD
#3	57	male	Idiopathic DCM	2	23.6	BB,amio, D,AA,statin	31	46	no ICD
#4	67	male	Ischemic DCM	3	23.7	ACEi,BB,D,statin	30	35	ICD implantation
#5	56	female	Post-chemotherapy DCM	5	21.4	ACEi,BB,amio,D	26	42	no ICD
#6	14	male	Ventricular arrhythmias	1	19.4	none	60	60	no ICD
#7	56	male	Post-myocarditis DCM	8	19.1	ACEi, amio,D,AA	18	30	ICD implantation
#8	59	male	Post-myocarditis DCM	3	23.8	ACEi,BB,D,AA,statin	34	37	no ICD
#9	60	female	Post-myocarditis DCM	2	23.1	ACEi,BB,D,AA	25	25	CRT implantation
#10	76	female	Ischemic DCM	2	23.9	ACEi,BB,amio,D,AA, statin	30	42	no ICD
#11	63	male	Ventricular arrhythmias	3	22.2	BB,amio	58	58	ICD implantation
#12	45	male	Ischemic DCM	4	22.7	ACEi,BB,D,AA,statin	30	36	no ICD
#13	53	female	Post-chemotherapy DCM	1	20.6	BB,amio,AA	30	45	no ICD
#14	79	male	Idiopathic DCM	3	23.5	ACEi,BB,D,AA	30	38	no ICD
#15	52	male	Idiopathic DCM	4	23.7	BB,S/V,D,AA	30	45	no ICD
#16	56	male	DCM related to alcohol abuse	3	18.2	ACEi,BB,D,AA,statin	23	40	no ICD

WCD: wearable cardioverter-defibrillator, LVEF: left ventricular ejection fraction, DCM: dilated cardiomyopathy, ACEi: angiotensin converting enzyme inhibitors. BB: beta blockers, D: diuretics, AA: anti-aldosteronics, ICD: implantable cardioverter-defibrillator, S/V: sacubitril/valsartan, amio: amiodaron, CRT: cardiac resynchronization therapy.

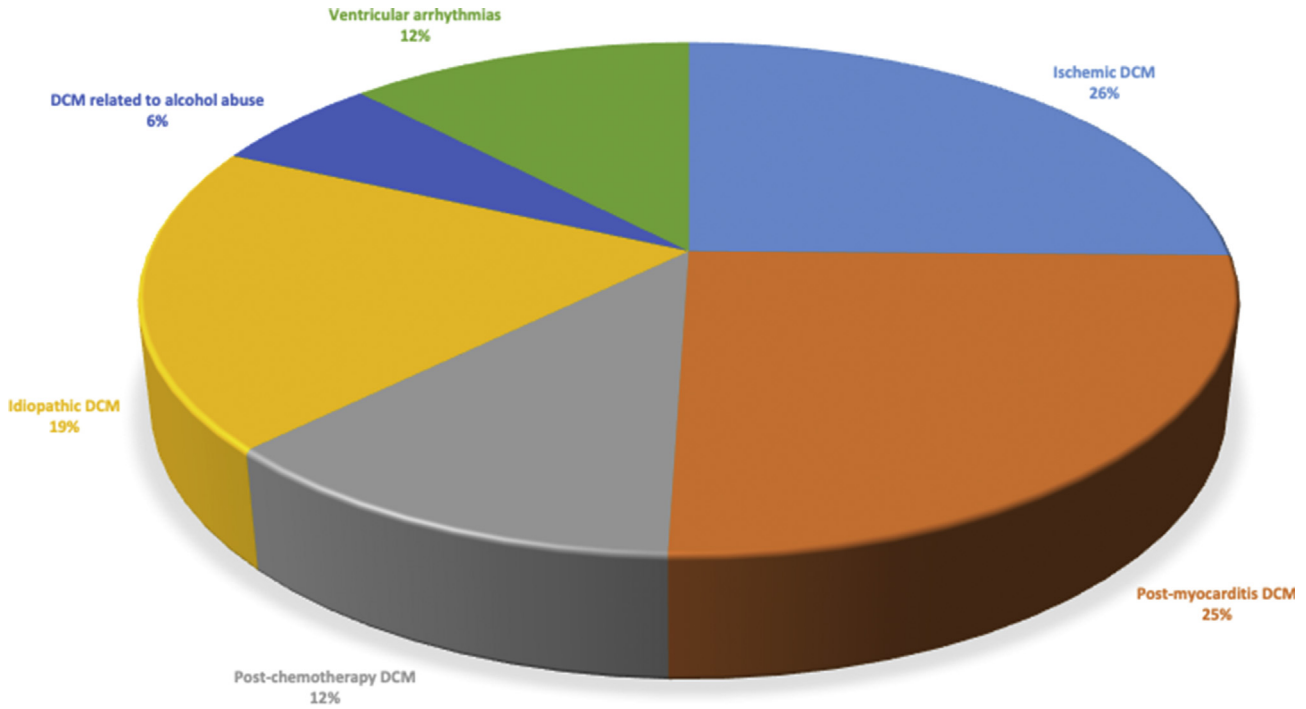

Fig. 1. The picture shows the underlying conditions for wearable cardioverter-defibrillator application. DCM: dilated cardiomyopathy.

implantation. Of note, the prolongation of WCD period >3 months because of initial increase of LVEF resulted in an higher proportion of patients with a recovery of LVEF >35%. In the present study, 4 patients received WCD for >3 months because of a partial increase of LVEF; as shown in Tables 1 and 3 of them (75%) presented an improvement of LVEF over 35% and indications for ICD implantations faded out in these patients. Finally, the WCD might also be an helpful tool for the detection of supraventricular arrhythmias during the follow up of these patients.

It should be specified that although the current practice accepts a LVEF cut off of 35% is based on MADIT II [10] and SCDHeFT [11] trials, the arrhythmic risk is not binary but it is present through the entire continuum of LVEF with a reverse trend, the more the LVEF increases the more arrhythmic risk decreases but it never abolishes [12].

The relative small number of patients and heterogeneity of the

underlying aetiologies represent important limitations. Moreover, another limitation is that patients did not receive a further arrhythmic risk stratification beyond the LVEF assessment.

In conclusion, the WCD may represent a useful tool for patients with poor LVEF who are at risk of sudden arrhythmic death for a limited period but are not candidates for a definitive ICD. The present study reports an optimal profile of compliance after adequate training of the patient; neither arrhythmic death nor inappropriate shock occurred. The proportion of patients with an improvement of LVEF> 35% beyond the WCD period was considerable as already shown by previous studies. However, as the present study includes a small population and no arrhythmic events occurred during the follow period, no conclusions about arrhythmic detection and treatment of this device can be drawn. Larger, randomized, controlled studies are needed to confirm the effectiveness of this technology and to identify the subgroup of patients who might benefit from this technology.

Declaration of competing interest

The authors report no relationships that could be construed as a conflict of interest.

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