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Wearable cardioverter-defibrillator in patients with a transient risk of Sudden cardiac death: the WEARIT-France cohort study

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Aims

We aimed to provide contemporary real-world data on wearable cardioverter-defibrillator (WCD) use, not only in terms of effectiveness and safety but also compliance and acceptability.

Methods and results

Across 88 French centres, the WEARIT-France study enrolled retrospectively patients who used the WCD between May 2014 and December 2016, and prospectively all patients equipped for WCD therapy between January 2017 and March 2018. All patients received systematic education session through a standardized programme across France at the time of initiation of WCD therapy and were systematically enrolled in the LifeVest Network remote services. Overall, 1157 patients were included (mean age 60 ± 12 years, 16% women; 46% prospectively): 82.1% with ischaemic cardiomyopathy, 10.3% after implantable cardioverter-defibrillator explant, and 7.6% before heart transplantation. Median WCD usage period was 62 (37–97) days. Median daily wear time of WCD was 23.4 (22.2–

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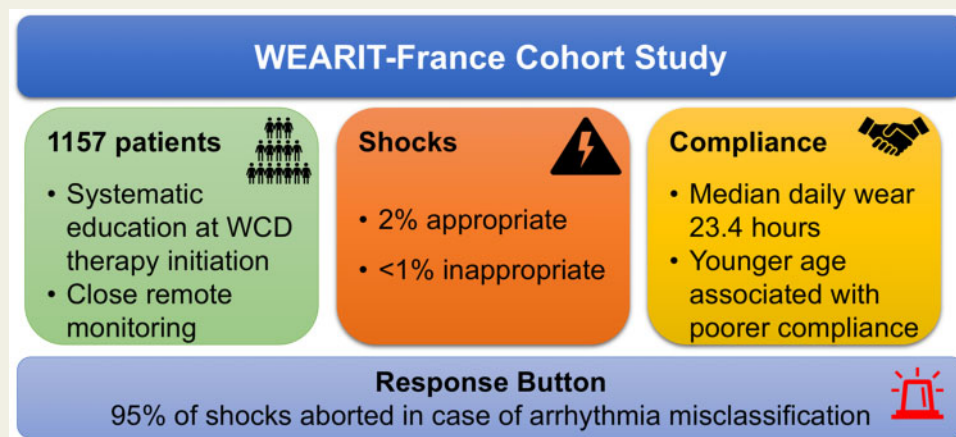
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23.8) h. In multivariate analysis, younger age was associated with lower compliance [adjusted odds ratio (OR) 0.97, 95% confidence interval (CI) 0.95–0.99, $P < 0.01$]. A total of 18 participants (1.6%) received at least one appropriate shock, giving an incidence of appropriate therapy of 7.2 per 100 patient-years. Patient-response button allowed the shock to be aborted in 35.7% of well-tolerated sustained ventricular arrhythmias and in 95.4% of inappropriate ventricular arrhythmia detection, finally resulting in an inappropriate therapy in eight patients (0.7%).

Conclusion

Our real-life findings reinforce previous studies on the efficacy and safety of the WCD in the setting of transient high-risk group in selected patients. Moreover, they emphasize the fact that when prescribed appropriately, in concert with adequate patient education and dedicated follow-up using specific remote monitoring system, compliance with WCD is high and the device well-tolerated by the patient.

Graphical Abstract



Keywords

Education • Sudden cardiac death • Ischaemic cardiomyopathy • Ventricular arrhythmias • Implantable cardioverter-defibrillator • Wearable cardioverter-defibrillator • Remote monitoring • Patient compliance

What's new?

- Two percent of patients received at least one appropriate shock and <1% received an inappropriate shock. Response button, in aborting 95% of shocks in case of arrhythmia misclassification, is a key factor in this very low rate of inappropriate therapies.
- Younger age was associated with lower compliance and this should be considered carefully when educating the patient.
- When prescribed appropriately, in concert with adequate patient education and dedicated follow-up using specific remote monitoring system, compliance with wearable cardioverter-defibrillator is high and the device well-tolerated by the patient.

Introduction

Sudden cardiac death (SCD) is a major mode of death accounting for ~600 000 fatalities in Europe every year.¹ Sudden cardiac death constitutes ~50% of all cardiac mortality and delay between cardiac

arrest onset and arrhythmia termination is a major determinant of survival.^{2,3} Since SCD risk may sometimes be transient, the wearable cardioverter-defibrillator (WCD) has been developed as a proposed solution for short-term risk mitigation in such situations.^{4–6}

The Prospective Registry of Patients using the Wearable Defibrillator (the WEARIT-II Registry) and the German National Registry have emphasized the safety and efficacy of WCD in large cohorts of patients.^{7,8} The reported first randomized controlled trial testing the potential benefit of WCD after myocardial infarction (VEST trial) did not show a significant difference in sudden death between the WCD and the control arms but a significant survival benefit was found. The VEST study highlighted the importance of patient compliance with the WCD for it to be effective.⁹ Presently, there are relatively few data on adherence to WCD use and influencing factors, and the extent to which shock interruption by use of the response button by the patient may avoid inappropriate shocks has never been assessed.

The French National Study, WEARIT-France, was designed to evaluate contemporary real-world data on WCD use in France, not only in terms of effectiveness and safety but also compliance and acceptability.

Methods

Study design and patient population

WEARIT-France study (Clinical Trials.gov Identifier: NCT03319160) was comprised of a retrospective and a prospective phase across 88 French cardiology centres. All patients who had already completed the use of a WCD (LifeVest system, ZOLL, Pittsburgh, PA, USA) between May 2014 and December 2016 were invited to participate in the retrospective part. The prospective phase was carried out between January 2017 and March 2018. Patients receiving a WCD during a clinical appointment were offered participation in the prospective part of the study. This study complies with the Declaration of Helsinki and an ethics committee has approved the research protocol. All patients who agreed to participate were entered into the study after having given their informed consent.

According to French Social Security and healthcare reimbursement, the criteria for WCD prescription were one of the following: implantable cardiac-defibrillator (ICD) removal due to device infection, bridge to heart transplantation, and ischaemic cardiomyopathy with left ventricular ejection fraction (LVEF) <30% in the settings of early post-myocardial infarct or after a recent coronary revascularization.

The wearable cardioverter-defibrillator

The WCD technology used in the WEARIT-France study is a commercially available external defibrillator (LifeVest, Zoll Systems, PA, USA), guided by an algorithm to detect ventricular tachyarrhythmia events. The functioning of WCD has been already described.⁴

The LifeVest Network

During the index hospitalization when WCD therapy was initiated, the treating physician systematically assessed the appropriateness of WCD prescription and educated the patient regarding the transient risk for SCD, functioning of the WCD, and benefits expected from the device. Additionally, just before discharge, a technical expert from the WCD company imparted a practical education to the patient, encompassing the nature of the disease, indication for WCD, alarm management, battery recharging, and remote transmission.

Collected data and study endpoints

At the time of enrolment, medical history, comorbidities, symptoms, and other baseline characteristics were collected in addition to the indication for WCD. Device information extracted included wear time, therapies delivered with associated EGMs, and response button utilization. Stored EGMs related to the utilization of the response button were reviewed by the independent adjudication committee, and categorized as episodes of well-tolerated sustained ventricular arrhythmia or inappropriate ventricular arrhythmia detection. Only sustained (i.e. ≥ 30 s) ventricular tachycardia (VT)/ventricular fibrillation (VF), atrial fibrillation, atrial flutter, supraventricular tachycardia, bradycardia, and asystole (heart rate <10 b.p.m. during 16 s) were automatically collected.

The main endpoints were centrally adjudicated by an independent clinical events committee composed of three experts who adjudicated the events, by analysing the EGM data independent of each other and blinded to any additional information. The primary endpoint was appropriate therapy, which was defined as shocks delivered for adjudicated sustained (>30 s) VT or VF episodes. Inappropriate shocks were defined as shocks delivered for all episodes other than sustained VT or VF. The incidence

was calculated as the number of appropriate or inappropriate shocks/100 patient-years.

Compliance was evaluated through daily use, defined as hours per day of use during the wearing period. Adherence to WCD and the health status of patients was assessed in 202 (38%) patients of the prospective cohort, at 30 days using a questionnaire, developed specifically to evaluate the acceptability of WCD therapy.¹⁰ Items on the survey asked the patient to indicate their agreement using the five-point Likert agreement response scale (Strongly agree, Agree, Neither agree nor disagree, Disagree, Strongly disagree) with respect to the following topics related to their use of the WCD: peace of mind, worry, sleep quality, confidence in returning to activities of daily living, confidence to exercise or perform cardiac rehabilitation, taking their disease condition seriously, improved self-care, change in lifestyle modification, and whether they would recommend the WCD to other patients.

Statistical analysis

Preparation of this report was carried out in accordance with the STrengthening the Reporting of Observational studies in Epidemiology (STROBE) statement.¹¹ Data collection and analysis were conducted independent of the WCD manufacturer by ClinSearch (Paris, France) and CRI (Munich, Germany). Descriptive statistics were used to report major clinical characteristics, incidence, and frequency of appropriate and inappropriate shocks. Continuous variables were expressed as mean and standard deviation when normally distributed and compared using the Student's *t*-test; and expressed as median and interquartile range, when not normally distributed, and compared using Wilcoxon–Mann–Whitney non-parametric test. Nominal variables were expressed as number and percentage and compared using the Pearson's χ^2 test or Fisher's exact test, as appropriate. Sensitivity analyses were performed according to the period of inclusion (retrospective vs. prospective).

For analysis of WCD compliance, daily wear duration was arbitrarily categorized as < or ≥ 20 h. Logistic regression was used to identify significant factors associated with non-compliance. Analyses were performed using R software (version 3.5.3). All statistical tests performed were two-sided. A *P*-value of <0.05 was considered statistically significant.

Results

Baseline patient characteristics

A total of 1157 patients were included in the WEARIT-France study. Among them, 628 (54.3%) were retrospectively included and 529 (45.7%) were prospectively enrolled. Indication for WCD was ischaemic cardiomyopathy with LVEF <30% in 950 (82.1%) patients, post-ICD extraction in 119 (10.3%) patients, and waiting for heart transplant in 88 (7.6%) patients (Figure 1). Clinical baseline characteristics of the patients are listed in Table 1. The mean age was 60.0 ± 11.5 years, 974 (84.2%) were males, and mean LVEF was $27.3 \pm 8.9\%$. New York Heart Association (NYHA) status was Class I or II in 671 (58%) patients and Class III or IV in 486 (42%) patients. When looking across the different groups NYHA 3–4 was present in 42% of ischaemic cardiomyopathies, 31% of ICD extraction, and 66% of heart transplantation. A total of 90 patients (7.8%) had renal disease requiring therapy, 119 (10.3%)

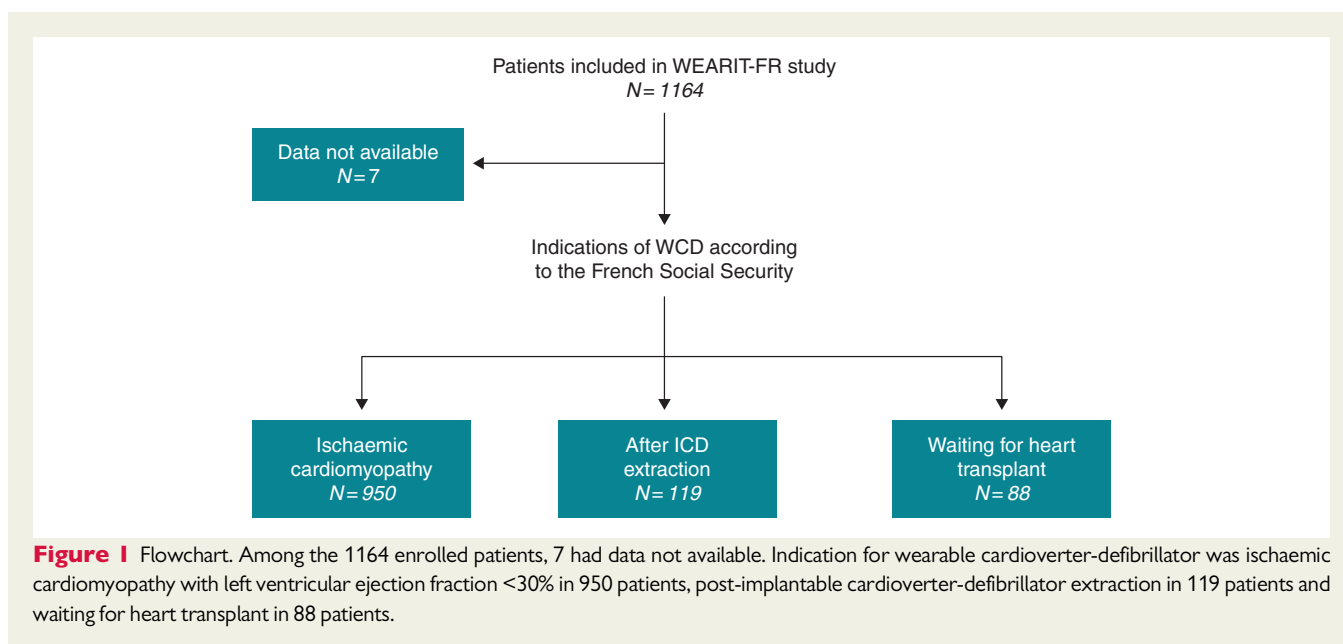


Table 1 Clinical characteristics of patients at WCD initiation (n = 1157)

Variables	
Age (years)	60 ± 12
Female sex	183 (16%)
Left ventricular ejection fraction (%)	27 ± 9
Heart failure	685 (59%)
Renal disease	90 (8%)
Atrial fibrillation	119 (10%)
Stroke	78 (7%)
Cardiac arrest or resuscitation	154 (13%)
Syncope	66 (6%)
Medical therapy	
Beta-blockers	1038 (89%)
Amiodarone	189 (16%)
ACE-I/ARBs	1004 (86%)

ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

patients had history of atrial fibrillation, 78 (6.7%) had previous stroke. Regarding medical therapies, 1038 (89.7%) patients were prescribed beta-blockers, 1004 (86.8%) angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and 189 (16.3%) amiodarone. Sensitivity analyses were performed according to the period of inclusion (retrospective vs. prospective), and no significant differences were found in baseline characteristics and outcomes (data not shown).

Median WCD usage period was 62 (37–97) days in the overall patient population and differed among patients according to WCD indication with a median period of 64 (38–98) days for patients with ischaemic cardiomyopathy, 44 (27–70) days for patients after ICD extraction, and 77 (43–108) days for pre-transplant patients ($P < 0.001$).

Adherence to wearable cardioverter-defibrillator and impact on perceived health status

The median daily WCD wear time was 23.4 (22.2–23.8) h in the overall population (Figure 2). A total of 162 patients (14.0%) wore the WCD for <20 h per day. In univariate analysis age was significantly lower in patients who wore the WCD <20 h compared to those who wore the WCD ≥20 h (55.7 ± 11.2 vs. 60.8 ± 11.4 years; $P < 0.001$). After multivariable analysis, only younger age was associated with lower compliance [odds ratio (OR) 0.97, 95% confidence interval (CI) 0.95–0.99; $P < 0.01$] (Table 2); WCD indication and sex category were not associated with poor compliance.

Overall, the use of WCD was generally positively associated with health and lifestyle benefits (Figure 3). The two items that patients most agreed with were: 'Wearing the LifeVest makes me take my condition seriously' and 'I follow life style modification recommendations from my physician' with respectively 88.2% and 92.3% of patients responding 'Strongly agree' or 'Agree'. The two items that users least agreed with were: 'I sleep significantly better knowing I am protected by the LifeVest' and 'LifeVest has given me the confidence to perform exercise or cardiac rehabilitation' with respectively 52.5% and 49.2% of patients responding 'Strongly agree' or 'Agree'.

Appropriate, inappropriate therapies, and response button use

During follow-up, a total of 73 arrhythmic events occurred in 55 patients: 42 sustained ventricular tachyarrhythmias (in 36 patients, 3.1%), 24 supraventricular tachycardias/atrial fibrillation or flutter (in 12 patients, 1.0%), and 7 bradycardia or asystole (7 patients, 0.6%). No significant difference was observed according to WCD indication.

A total of 18 participants (1.6%) received at least one appropriate shock: 10 patients for VT and 8 for VF, giving an incidence of appropriate shock of 7.2 (95% CI 3.9–10.5) per 100 patient-years in the overall population (Table 3). According to WCD indication

subgroups, the incidence rate of appropriate therapy was 7.3 (95% CI 3.6–10.9) per 100 patient-years in the ischaemic heart disease group, 6.9 (95% CI –0.9 to 14.8) per 100 patient-years in the post-ICD

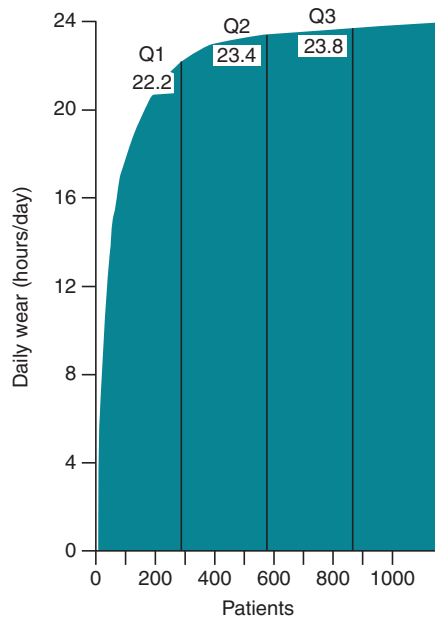


Figure 2 WCD compliance. This figure represents the distribution of average daily wearable cardioverter-defibrillator use, in hours per day. Bars represent separation between quartiles. Quartile 1 corresponds to 22.2 h, meaning that one-quarter of the population is actually wearing the vest <22.2 h. Quartile 3 is 23.8 h, meaning that one-quarter of the population is wearing the vest >23.8 h. The median daily wearable cardioverter-defibrillator wear time was 23.4 h. WCD, wearable cardioverter-defibrillator.

explantation group and no appropriate therapy was delivered in the pre-transplant group (*P*-value not calculable). All patients who had shock delivery had their VT/VF episode successfully terminated after a mean number of 1.05 ± 0.22 shocks; only one patient (5.6%) required two shocks to terminate the arrhythmia episode.

Cumulative probability of sustained VT/VF by patient subgroup showed that ventricular tachyarrhythmias occurred preferentially during the first month of use. During the first 30 days of use, 26 ventricular arrhythmias (61.9% of all ventricular tachyarrhythmias) occurred and led to 11 shocks in 10 patients. Between Day 30 and Day 90, 12 ventricular tachyarrhythmias (28.6%) led to 7 shocks in 7 patients.

Eight inappropriate shocks occurred in eight patients (0.7%), giving an incidence rate of 3.2 (95% CI 1.0–5.4) per 100 patient-years. Among the eight inappropriate shocks, six were because of electrocardiogram (ECG) artefact, one because of supraventricular tachycardia and one because of sustained VT that self-terminated just prior to shock.

No inappropriate shock occurred when the deviation button was used. Summary of events, appropriate and inappropriate shocks, and shocks aborted during WCD use are reported in Table 4. A total of 42 patients (159 episodes) aborted \geq one shock by pressing the patient-response buttons during an alarm. Analysis of EGMs revealed that 31 patients (144/151 episodes) pressed the response button because of VT/VF misclassification and that 11 patients (15 episodes) aborted shocks for well-tolerated VT/VF (out of 42 VT/VF episodes, 35.7%).

Overall mortality, specific causes of death, and care path at the end of the wearable cardioverter-defibrillator period

Of the 1157 patients who had the WCD, 24 (2.1%) died during the period of WCD use. Among these patients, in nine who wore the

Table 2 Univariate and multivariate logistic regression on factors associated with compliance (daily wear duration ≥ 20 h)

	Univariate analysis			Multivariate analysis		
	Odds ratio	95% CI	<i>P</i> -value	Odds ratio	95% CI	<i>P</i> -value
Reference: female gender						
Male gender	0.54	0.31–0.93	0.03	0.54	0.28–1.01	0.07
Younger age	0.96	0.95–0.98	<0.001	0.97	0.95–0.99	<0.01
Body mass index	0.99	0.96–1.03	0.81	1.01	0.96–1.05	0.90
Reference: ischaemic WCD indication						
Post-extraction WCD indication	0.63	0.38–1.03	0.07	0.76	0.38–1.53	0.44
Pre-transplantation WCD indication	0.44	0.26–0.75	0.003	0.82	0.41–1.68	0.59
Reference: NYHA class I						
NYHA class II	0.66	0.35–1.24	0.19	0.63	0.33–1.21	0.16
NYHA class III	0.59	0.31–1.12	0.11	0.59	0.29–1.17	0.13
NYHA class IV	0.98	0.42–2.30	0.96	0.87	0.36–2.11	0.75
Left ventricular ejection fraction	0.99	0.98–1.02	0.96	1.02	0.99–1.05	0.22

NYHA, New York Heart Association; WCD, wearable cardioverter-defibrillator.

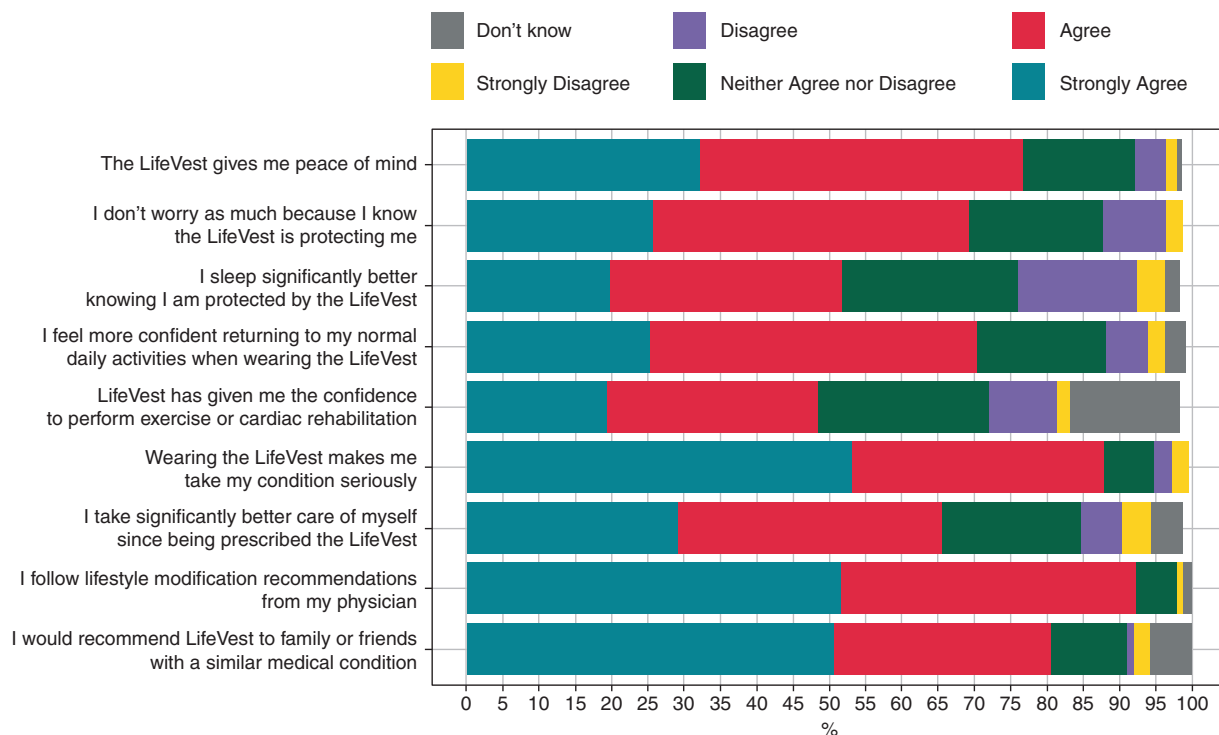


Figure 3 Questionnaire to evaluate WCD therapy acceptability. Five-point Likert agreement response scale assessed patient agreement regarding nine items related to their use of the wearable cardioverter defibrillator ($N = 202$).¹¹ The item that patients most agreed with was: 'I follow life style modification recommendations from my physician' and the item that users least agreed with was: 'I sleep significantly better knowing I am protected by the LifeVest'. WCD, wearable cardioverter-defibrillator.

Table 3 Incidence of ventricular and supraventricular arrhythmias

Events	Patients, N (%)	Events (N)	Event rate per 100 patient-years
Any sustained VT/VF	36 (3.1%)	42	14.4
Appropriate shock for VT/VF	18 (1.6%)	19	7.2
Shock deviation for well-tolerated sustained VT/VF	11 (1.0%)	15	4.4
Sustained and self-terminating VT	7 (0.6%)	8	2.8
Supraventricular arrhythmia, atrial fibrillation and flutter	12 (1.0%)	24	4.8

VF, ventricular fibrillation; VT, ventricular tachycardia.

WCD at the time of death, non-arrhythmic death was the cause of death in seven, and electrical storm in two. Of the 18 patients who received an appropriate shock and admitted alive, all survived to hospital discharge.

At the end of WCD use, 586 patients (50.6%) were implanted with an ICD. The reasons for non-implantation were 376 (32.5%) LVEF improvement, 69 (6.0%) patient refusal, 20 (1.7%) heart transplantation, 24 (2.1%) death, and 82 (7.1%) other reasons. Among the 950 (82%) patients with WCD indication for ischaemic cardiomyopathy with LVEF <30%, 443 (46.6%) had LVEF improvement $\geq 35\%$, with no further need for ICD implantation. During

WCD wearing time, 17 (1.5%) patients underwent bypass surgery, 12 (1.0%) patients had implantation of a left ventricular assist device, and 37 (3.2%) patients underwent percutaneous coronary intervention.

Discussion

Our real-life findings reinforce previous studies on the efficacy and safety of the WCD in the setting of transient high-risk group in selected patients. Moreover, they emphasize the fact

Table 4 Summary of events, appropriate and inappropriate shocks, and shocks aborted during WCD use

	Patients (N)	Events (N)	Appropriate shock, N of event (%)	Inappropriate shock, N of event (%)	Response button pressed, N of event (%)
Ventricular arrhythmias					
Ventricular fibrillation	9	11	9 (82%)	–	2 (18%)
Ventricular tachycardia	27	31 ^a	10 (32%)	1 (3%) ^b	13 (42%)
Supraventricular arrhythmias and artefacts					
ECG artefact	49	303 ^c	–	6 (2%)	133 (44%)
Atrial fibrillation and flutter	4	9	–	–	–
Supraventricular tachycardia	8	15 ^d	–	1 (7%)	11 (73%)

ECG, electrocardiogram; N, number; WCD, wearable cardioverter-defibrillator.

^aSeven episodes of VT were sustained but self-terminated before shock or pressure on the response button.

^bOne patient had VT and presented an inappropriate shock because the arrhythmia self-terminated just before the shock.

^cOne hundred and sixty-four episodes of artefact were sustained but self-terminated before shock or pressure on the response button.

^dThree episode of supraventricular tachycardia was sustained but self-terminated before shock or pressure on the response button.

that when prescribed appropriately, in concert with adequate patient education and dedicated follow-up using specific remote monitoring system, compliance with WCD is high and the device well-tolerated by the patient.

Appropriate and inappropriate therapy

Appropriate therapy incidence in the present study was relatively similar to what has been observed in WEARIT-II (5 shocks/100 patient-years) and the German registry (8.4 shocks/100 patient-years), although our population did not include non-ischaemic dilated cardiomyopathies (in accordance with French Social Security Criteria for reimbursement).^{7,8} Nevertheless, the appropriate therapy incidence was much lower compared with a recent meta-analysis and more specifically in the post-ICD extraction (6.9 per 100 patient-years) group when compared with the German registry (19.3 per 100 patient-years) which included more than 6000 patients, through old studies which enrolled very high-risk patients.^{8,12} On the other hand, WCD was associated with a remarkably low inappropriate therapy rate in the present study (3.2/100 patient-years). Inappropriate shocks by the WCD occur only when there is a combination of a sustained inappropriate classification by the device algorithm and the absence of patient response. In terms of comparison with another device using external ECG discrimination, incidence of inappropriate shocks with the subcutaneous defibrillator is 4.7 per 100 patient-years.^{13,14} Although subcutaneous defibrillator and WCD detection algorithms are different, the possibility of shock abortion in the WCD by the patient seems an effective way to reduce inappropriate therapy without an increased risk for untreated VT/VF episodes. Specialized healthcare providers educate patients on how to properly wear the device and how to disable shock delivery using the response buttons. Patient interaction with WCD is useful to avoid inappropriate therapy resulting from supraventricular arrhythmia and artefacts but also to avoid shocks in case of haemodynamically well-tolerated VT which accounted for 35.7% of all sustained VT/VF in our study.

Adherence and impact on perceived health status

Proper patient education is of paramount importance to ensure optimal efficacy of the device. Compliance was very high, with a median wear time of 23.4 h, similar to US and German observational experiences. These results contrast with the highly debated VEST trial in which average wear time was 14 ± 9.3 h per day.^{9,15,16} Possible reasons for this difference may be (i) better patient education; (ii) a closer follow-up through the LifeVest Network telemonitoring platform, with a phone reminder if necessary; (iii) in addition, the context may have played a role—in the current real-life French setting, patients considered WCD to have a clear additional value, since it is reimbursed by the national health French system, contrary to the setting of the VEST trial where the usefulness of WCD was being tested. We found a younger age to be associated with lower compliance. Our results contrast with the recent publication of Olgin¹⁷ which identified ethnicity, marital status, prior percutaneous coronary intervention, and history of cardiac arrest to be associated with adherence. Nevertheless, even if the number of patients enrolled in the present study is lower, we assessed a different population, in which compliance was much better. Lower compliance in younger patients might be explained by several factors, including a more active life incompatible with the WCD. Efforts should be made to improve compliance in this group when delivering WCD. Structured and personalized education, enabling guided patient empowerment, help in improving adherence to WCD.

Overall, users reported a positive experience in the patient questionnaire regarding the WCD. Patients self-reported that using the WCD resulted in taking their disease condition more seriously, which could have a positive impact on their disease management and overall outcome. Indeed, the VEST trial showed that, despite the absence of a statistically significant effect on sudden death, all-cause death was significantly lower in the WCD group.⁹

Care path at the end of the wearable cardioverter-defibrillator period

Patients with LVEF <30% early after myocardial infarction are a difficult group for decision-making, due to possible transient nature of

risk for SCD and also because very late ventricular arrhythmia occurrence.¹⁸ A significant proportion (almost half in our study) of these patients were not implanted with an ICD after optimization of pharmacological therapies, due to their recovery of LVEF. The WCD offers an opportunity for a bridge to recovery or to ICD implantation. Wearable cardioverter-defibrillator allows physicians to correctly evaluate their patients, provide time to achieve optimal pharmacological therapy, thereby improving patient's management and avoiding unnecessary ICD implantation, which may be associated with significant long-term complications.^{4,19,20}

Limitations

This study has certain limitations due to its observational nature and lack of a control population. Unfortunately, the population was not large enough to identify subgroups at higher risk for appropriate therapies which may help refine candidate selection for the WCD. This call for collaborative studies on WCD in order to test this hypothesis. Moreover, it did not enrol patients with non ischaemic dilated cardiomyopathy according to French reimbursement regulation.

Conclusion

Our observational findings reinforce existing data on efficacy and safety of WCD and furthermore emphasize the high level of patient compliance with WCD in France when specific patient education and remote monitoring are incorporated. Compliance is crucial in ensuring meaningful results from WCD use, and our study's finding of younger age being associated with poorer compliance, points to the need for additional efforts in this area. Finally, this study also demonstrates the extent to which the use of response button plays a crucial role in the observed low rates of inappropriate WCD shock.

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Data availability

The data underlying this article will be shared on reasonable request to the Zoll.

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