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ORIGINAL PAPER

The wearable cardioverter-defibrillator in a real-world clinical setting: experience in 102 consecutive patients

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Abstract
Background The wearable cardioverter-defibrillator (WCD) is used for temporary protection of patients deemed to be at high risk for sudden death (SCD) not yet meeting indications for the implantable defibrillator (ICD).
Objectives To evaluate the efficacy, safety, and compliance of/to WCD use and subsequent medium-term outcome of patients in a single-center observational study.
Methods A total of 102 consecutive patients were fitted with the WCD from 2012 to 2015 and followed for a mean of 11 months (±8 months).
Results The most common clinical indication for WCD-prescription (63%) was a new diagnosis of severely impaired LV function (LVEF ≤35%). The median wear time of the WCD was 54 days with a daily use of 23 h. Appropriate WCD therapy occurred in four patients (seven shocks for VF, one shock for VT). An ICD was finally implanted in 56 patients (55%). Improvement in LV function was the most common reason not to implant an ICD (HR 0.37; 95% CI 0.19–0.73; $p = 0.004$). Two patients had inappropriate shocks from their WCD due to atrial fibrillation/flutter. Five patients fitted with an ICD after the end of WCD therapy suffered VT/VF episodes. After wearing the WCD, six patients died (five ICD recipients and one non-ICD recipient).
Conclusion WCD therapy was well accepted by patients and provided temporary protection against ventricular tachyarrhythmias in patients at risk for SCD. The WCD may help to avoid unnecessary ICD implantations in a significant proportion of patients.

Keywords Sudden cardiac death · Ventricular arrhythmia · Wearable cardioverter defibrillator · Implantable cardioverter defibrillator · Congestive heart failure

Introduction

Sudden cardiac death (SCD) presumably due to fatal ventricular arrhythmias accounted for 65,000 deaths and with that 30% of all cardiovascular deaths in Germany in 2014 [1]. Implantation of a cardioverter-defibrillator (ICD) is the most effective therapy in preventing SCD and improving survival in carefully selected patients [2–4]. However, risk stratification for SCD is mainly based on LV function assessment and hence is still far from being perfect with many ICD recipients never needing shock therapy [5]. Particularly patients with newly diagnosed congestive heart failure (CHF) or patients soon after myocardial infarction are difficult to handle as LV function may improve within weeks rendering ICD therapy unnecessary [6–11]. For these and for other patient groups (i.e., those with infected ICDs which need removal), the wearable cardioverter-defibrillator (WCD) represents a safety net [6–17]. Before approval of the WCD by health regulators, randomized and non-randomized trials had demonstrated a 99% shock efficacy [13, 14, 17]. Recent published data from large registries demonstrated episodes of sustained ventricular arrhythmia in up to 2% of the patients during the 3 months of WCD use [8, 11]. However, there is still a paucity regarding real-world data on WCD therapy.

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Patients and methods

Patient population

This prospective observational cohort study is based on the data of consecutive patients deemed to be at high risk for ventricular tachycardia/fibrillation (VT/VF) receiving a WCD at the J. W. Goethe University Hospital, Frankfurt and being followed at the same institution. All patients were fitted with a ZOLL® Life Vest™ system (Pittsburgh, USA). The study was approved by the IRB of the J. W. Goethe University and conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

Data collection, follow-up

Data were prospectively collected from the index hospitalization at the time of initial WCD fitting. All patients received optimal medical therapy adhering to current guidelines. Follow-up visits were performed at 6 weeks, 3 and 12 months or when clinically indicated. Data collection included patient characteristics, the initial indication for WCD therapy and left ventricular ejection fraction (LVEF) at the time of WCD fitting and hospitalization (=hospital stay $\geq$24 h) during and after WCD use. Data were also collected from the ZOLL® LifeVest Network™. For missing data, particularly in case of missed follow-up visits, family members, treating physicians, or other hospitals were contacted. In all patients, LV function was determined at the inception of WCD therapy and reassessed 4–8 weeks later. Improvement in LV function was defined as an increase in LVEF of $\geq$5%. If LV function did not increase beyond 35%, primary prevention ICD implantation was considered according to current guideline recommendations [18, 19].

WCD programming and arrhythmic events

The WCD programming was individually adapted to the patients underlying heart disease and electrocardiographic patterns. For most patients the VT zone was programmed at a heart rate of 150 bpm with a VT response time of 60 s and the VF zone at a rate of 200 bpm with a VF response time of 25 s. To avoid inappropriate alarms or therapies, the VT zone was adjusted to 180 bpm in young and active patients [5]. First shock energy was set at 150 J in all patients. An arrhythmia episode included an onset and a conversion in a slower rhythm/sinus rhythm. Any arrhythmia episode was considered as a separate episode when occurring with a minimum delay of 3 min from the previous one. Each individual episode was reviewed and classified into seven categories: (1) sustained VT (lasting 30 s or longer) or VF with WCD shock therapy, (2) sustained VT with no WCD shock delivered as the patient inhibited therapy through activation of the response button, (3) non-sustained VT (lasting less than 30 s), (4) supraventricular arrhythmias (5) bradycardia of 30 beats per minute or less, (6) asystole and (7) artifact episodes. Inappropriate WCD therapy was classified as a non-VT/-VF episode treated by WCD shock.

Statistics

Statistical analysis was performed using SPSS version 23 program (IBM, USA). Baseline characteristics were compared by the Wilcoxon Mann–Whitney U test or H test of Kruskal and Wallis for continuous variables and the χ^2 test or Fisher's exact test for categorial variables. Survival analysis was performed using Kaplan–Meier analysis and the Cox proportional hazard analysis. Survival curves were compared using the Log Rank test. Hazard ratios (HR) with 95% confidence intervals were calculated using Cox regression model. Only two-sided tests were used and p values $p < 0.05$ were considered statistically significant.

Results

Patient population

A total of 124 patients received a WCD of whom 102 were regularly followed in our outpatient clinic and form the basis of this analysis. The median WCD wear time was 54 days (1–166 days) and the mean post WCD follow-up time was 11 $\pm$ 8 months. The leading indication for WCD-prescription was newly diagnosed heart failure (mean LVEF of 30 $\pm$ 11%, mean NYHA functional class 2.2 $\pm$ 1.0). Ischemic ($n = 27$) and non-ischemic cardiomyopathy ($n = 33$) represented the most often encountered structural heart disease. A total of 16 patients had received recent coronary revascularization (PCI in 8 patients, CABG in 8 patients). In 25 patients, a previously implanted ICD had been removed because of device infection. Of these patients, 56% ($n = 14$) had survived a prior cardiac arrest. The remainders were patients with myocarditis of unknown duration ($n = 9$), patients with congenital arrhythmias or channelopathies ($n = 4$) or patients with other heart diseases like peripartum cardiomyopathy ($n = 2$) or Tako-Tsubo cardiomyopathy ($n = 2$) (Table 1; Fig. 1).

Clinical course during WCD therapy

During WCD therapy LVEF improved in 51% of the patients ($n = 52$). Patients with newly diagnosed heart failure were more likely to improve LV function and

Table 1 Patient characteristics at baseline/WCD fitting

Variables	ALL, $n = 102$	Ischemic heart disease, $n = 27$	Dilative cardiomyopathy, $n = 33$	Myocarditis, $n = 9$	Channelopathy/Cong. HD, $n = 4$	Device infection, $n = 25$
Age mean (years)	59 ± 11	66 ± 12	57 ± 14	54 ± 20	28 ± 16	61 ± 16
Male gender, *n* (%)	73 (73)	23 (85)	25 (76)	6 (67)	1 (25)	18 (72)
Prior SCD, *n* (%)	21 (21)	2 (7)	1 (3)	1 (11)	3 (75)	14 (56)
Recently diagnosed heart failure	45 (44)	11 (41)	32 (97)	2 (22)	0 (0)	0 (0)
Atrial fibrillation, *n* (%)	25 (25)	5 (19)	11 (30)	1 (11)	0 (0)	8 (32)
Left bundle branch block, *n* (%)	19 (19)	8 (29)	4 (12)	1 (11)	0 (0)	6 (24)
Right bundle branch block, *n* (%)	13 (13)	1 (4)	5 (15)	0 (0)	2 (50)	5 (20)
Betablocker, *n* (%)	92 (90)	26 (96)	33 (100)	9 (100)	3 (75)	21 (84)
Amiodarone, *n* (%)	14 (14)	5 (19)	3 (9)	0 (0)	2 (50)	4 (16)

Cong. HD congenital heart disease, *SCD* sudden cardiac death

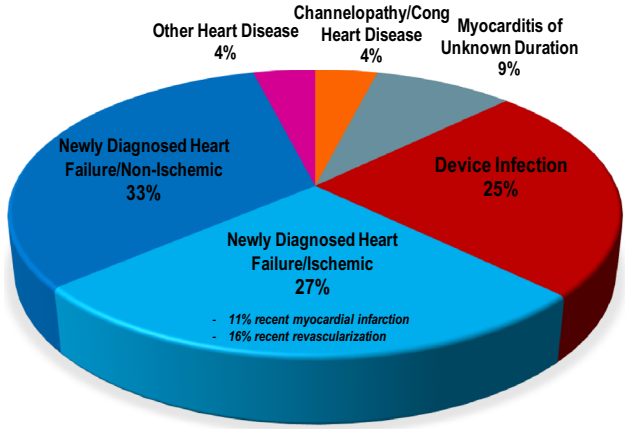

Fig. 1 Indications for WCD therapy in the study collective

NYHA status compared to patients with device infection (both $p = 0.001$). NYHA functional class decreased during WCD wear time in 31% of the patients ($n = 32$) by at least one class compared to the initial status. A total of 48 patients experienced 157 arrhythmic events during WCD wear time (Figs. 2, 3). Nineteen episodes of sustained ventricular arrhythmias occurred in six patients. Of these, four patients were adequately shocked for ventricular fibrillation (seven episodes) or for ventricular tachycardia (one episode).

Twenty-eight percent of patients experienced atrial arrhythmias, either sinus tachycardia or atrial fibrillation/flutter. Episodes of sinus bradycardia ($n = 2$) or asystole ($n = 5$) were rare (Fig. 2).

Hospitalization

Information on hospitalizations due to cardiac causes was collected during and after WCD use. During WCD use, 13 patients had to be admitted to hospital. Of these, 7 (54%) had device-related problems such as adequate WCD therapy ($n = 3$), inadequate WCD therapy ($n = 1$), WCD alarms due to sustained VT without shock therapy ($n = 1$), syncope due to asystole ($n = 1$) or allergic skin reactions due to nickel hypersensibility ($n = 1$). After WCD therapy, 16 patients (16%) were admitted to hospital. There was no statistical difference between admission rates during and after WCD therapy ($p = 0.88$).

Unwanted WCD effects

Two patients were inadequately shocked because of atrial fibrillation/flutter with rapid ventricular conduction. Although hemodynamically stable, both patients did not press the inhibition button to abort WCD therapy. In one patient with inappropriate WCD shock, LVEF was found to be 41%. Hence, WCD therapy was terminated. In another patient with inappropriate WCD shock therapy and highly impaired LV function, treatment with the life vest was continued. Over half of the patients (57%) experienced "false alarms" (vibration/siren/bystander warning) due to missensed ECG episodes, defined as artifacts upon review. Most artifacts were induced by impaired ECG electrode–skin contact mainly in skinny and/or active patients. In nine patients, small QRS amplitudes provoked artifacts and WCD alarms. One of these patients could not be protected with the WCD because of persistent ECG missensing. Two patients developed allergic skin reactions due to nickel hypersensibility which could not be controlled with local or systemic steroid therapy, and forced us to end WCD therapy.

ICD implantation

After WCD use, 56 patients (55%) were implanted with an ICD. Patients with a primary preventive ICD indication

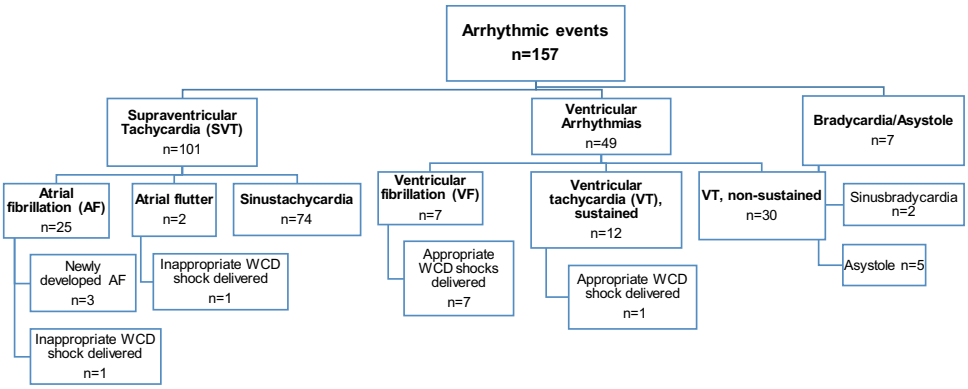

Fig. 2 Flow-chart showing all arrhythmic episodes occurring during WCD wear time

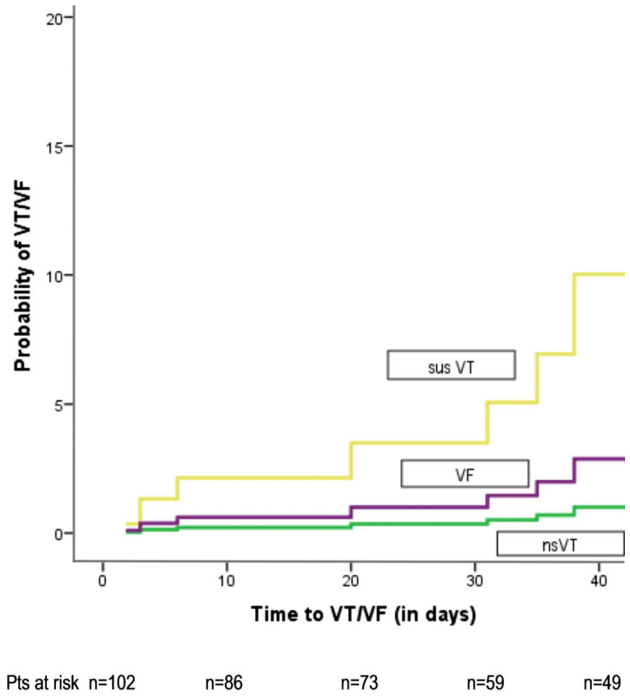

Fig. 3 Kaplan-Meier analysis comparing events of ventricular arrhythmia (VF/sustained VT/non-sustained VT) occurring during WCD use

received a device if their LVEF remained ≤35%. Patients with channelopathy/congenital heart disease and patients with device infection showed the highest ICD implantation rates compared to the other patient groups ($n = 3$; 75%; $n = 23$; 92%; p overall = 0.001) (Table 2). Improvement of LVEF was the most common reason to skip ICD implantation (HR 0.37; 95% CI 0.19–0.73; $p = 0.004$).

Follow-up post WCD therapy

After WCD therapy all 102 patients were followed for a mean of 11 ± 8 months. VT/VF episodes were documented in six ICD recipients (11%) of which three (5%) were appropriately treated by the device. Two ICD recipients suffered from cardiac arrest necessitating resuscitation. Wearing the WCD, none of our patients died. After WCD use, more ICD recipients died compared to non-recipients ($n = 5$; 9% versus $n = 1$; 2%), three due to progressive heart failure, one due to sustained slow VT, one due to non-cardiac causes (all ICD-group) and one in the non-ICD group during surgery (Table 3).

Discussion

Main findings

This single-center experience confirms that the WCD is able to protect patients deemed to be at risk for sudden cardiac death. The WCD terminated ventricular arrhythmias in four patients. Two patients were inadequately shocked because of ECG missensing of atrial fibrillation and flutter.

To the best of our knowledge, this is the first study with continued patient follow-up after WCD therapy, irrespective of subsequent ICD implantation. Following WCD therapy, ICD implantation could be avoided in almost half of the patients.

Efficacy of WCD therapy

Prior to FDA approval, several studies demonstrated safety and efficacy of the WCD in terminating ventricular arrhythmia with a first shock success rate of up to 100% [13, 14, 17]. Further studies showed successful application of WCD therapy in patients with channelopathies or congenital heart disease [16] or with new-onset heart failure [7–11, 15]. One of the largest studies comprised 8453 patients early after myocardial infarction with a LVEF ≤35%. The WCD aborted SCD in 1.6% of the patients during the recommended waiting period prior to ICD implantation [9, 18]. A total of 75% of the patients received treatment in the first month, and 96% within the first

Table 2 Clinical developments during WCD wear time

Variables	ALL, $n = 102$	Ischemic heart disease, $n = 27$	Dilative cardiomyopathy, $n = 33$	Myocarditis, $n = 9$	Channelopathy/ Cong. HD, $n = 4$	Device infection, $n = 25$
LVEF baseline mean	30 ± 11	28 ± 6	24 ± 7	28 ± 11	46 ± 13	38 ± 13
LVEF follow-up mean	39 ± 14	39 ± 11	36 ± 15	39 ± 13	56 ± 18	39 ± 13
Improvement	52 (51)	19 (70)	22 (67)	4 (44)	2 (50)	5 (20)
NYHA-Class baseline mean	2.2 ± 1	2.4 ± 1	2.6 ± 1	2.3 ± 1	1.8 ± 1	1.7 ± 1
NYHA-Class follow-up mean	1.8 ± 1	2.0 ± 1	2.0 ± 1	1.6 ± 1	1.8 ± 1	1.8 ± 1
Improvement	32 (31)	9 (33)	18 (55)	4 (44)	0 (0)	1 (4)
NT-pro BNP baseline median (min–max)	2481 (104–64,584)	2916 (240–7406)	2703 (210–11136)	6475 (592–64,584)	908 (104–1987)	1892 (109–4668)
NT-pro BNP follow-up median (min–max)	825 (56–30,153)	1817 (185–30,155)	892 (105–13,018)	1431 (215–10,685)	461 (432–490)	597 (56–4520)
Improvement	43 (42)	9 (33)	21 (63)	6 (67)	1 (25)	6 (24)
Wear time (min–max)						
Overall (days)	54 (1–166)	54 (1–121)	61 (1–166)	61 (5–164)	17 (5–45)	54 (1–131)
Per day (h)	23.0 (7–24)	23.0 (12–23.9)	22.6 (7–24)	22.7 (15–24)	23.3 (17.2–23.9)	23.7 (16.8–24)
ICD, *n* (%)	56 (55)	13 (48)	13 (39)	4 (44)	3 (75)	23 (92)
Death, *n* (%)	6 (6)	2 (7)	1 (3)	0 (0)	0 (0)	3 (12)

Cong. HD congenital heart disease, *LVEF* left ventricular ejection fraction, *NYHA-Class* New York Heart Association Classification (for symptomatic heart failure), *BNP* brain natriuretic peptide, *ICD* implantable cardioverter-defibrillator

Table 3 Arrhythmic events post WCD therapy and cause specific mortality [21]

Events post WCD therapy	ICD recipients, $n = 56$	Non ICD recipients, $n = 46$
Any VT/VF, *n* (%)	6 (11)	0 (0)
ICD shock, *n* (%)	3 (5)	0 (0)
Arrhythmia requiring CPR, *n* (%)	2 (4)	0 (0)
Death, *n* (%)	5 (9)	1 (2)
Cardiac arrhythmic, *n* (%)	1 (2)	0 (0)
Cardiac non arrhythmic, *n* (%)	3 (5)	0 (0)
Non cardiac, *n* (%)	1 (2)	1 (2)

3 months of use [9]. This data corresponds to our findings. All episodes of ventricular arrhythmia ($n = 49$) occurred within the first 42 days after WCD fitting (3–42 days) with the majority being self-terminating during the programmed extended detection period. In four of our patients WCD shock therapy was needed with a first shock success rate of 100%. All of these sustained arrhythmia episodes occurred in patients with device infection, channelopathy/congenital heart disease or myocarditis. Kutiyfa et al. found 120 episodes of sustained ventricular arrhythmia in the WEAR-IT II registry amongst 2000 patients, mainly in patients with ischemic cardiomyopathy and congenital/inherited heart disease occurring in the first 3 months after WCD fitting [8]. Hence, the current European guidelines recommend WCD therapy as a class IIb indication for patients with poor LV function at risk for sudden cardiac death after removal of an infected defibrillator for antibiotic therapy, for patients with peripartum cardiomyopathy, myocarditis, arrhythmias in the early post-MI phase and as a bridge to transplant [19, 20].

Safety of WCD therapy

Two patients received inappropriate WCD shocks due to rapidly conducted atrial fibrillation and flutter. Both patients were unable to inhibit WCD therapy through activation of the response button. According to reassessment of LV function at this time, WCD therapy was discontinued in one patient and continued in the other patient. Feldman reports a similar number of inadequate WCD

shock therapy in the WEARIT/BIROAD collective with 6/289 heart failure patients with LVEF ≤35% being shocked for non-ventricular arrhythmias [14].

Other frequent unwanted effects were "false alarms", often audible as siren or bystander warning, resulting from ECG missensing of artifacts upon ECG review. A small QRS complex amplitude provoked artifacts in 9% of the patients and made WCD therapy impossible in one case because of persistent ECG missensing. Two other patients developed a proved nickel hypersensibility during WCD wear time which forced us to end WCD therapy. Feldman described in the WEARIT/BIROAD collective a "rash and/or itching" that led to interruption of WCD therapy in 6% of the patients ($n = 17$), but did not provide any information about the etiology of the skin irritation [14].

Medium-term outcomes

After WCD use, 56 patients (55%) were implanted with an ICD. The most common reason not to implant with an ICD was improvement in LV function. These data correspond to other studies which reported LVEF improvement rates from 40 to 57% [8, 15]. Furthermore, the WCD as a diagnostic tool helped to detect newly developed atrial fibrillation in three patients (2%) and initiate stroke preventive therapy.

Our study is one of the first to provide clinical information beyond WCD therapy. After a WCD wear time of median 54 days, ICD recipients ($n = 56$) and non-ICD recipients ($n = 46$) were followed for a mean of 11 months. ICD recipients had more ventricular arrhythmias (11%), ICD shocks (5%) or arrhythmias requiring CPR (4%) compared to non-ICD recipients (all 0%). None of our patients died while wearing the WCD. Thereafter, more patients with an implanted defibrillator died mostly due to progressive heart failure.

Conclusions

The WCD provides a reliable temporary safety net for patients at risk for SCD. Its application represents a useful tool to avoid unnecessary ICD implantation in clinical practice.

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Compliance with ethical standards

Funding There was no funding of this study.

Conflict of interest Dr. Julia W. Erath reports receiving lecture fees and travel support from Zoll Medical and is a fellow of the Boston Scientific heart rhythm fellowship program, outside the submitted work. Dr. Mate Vamos reports receiving lecture fees from Bayer and Pfizer and travel support from Bayer, Pfizer and SJM, outside the submitted work. Dr. Abdul Sami Sirat has no conflict of interest. Professor Dr. Stefan H. Hohnloser reports receiving consulting fees from Bayer Healthcare, Boehringer Ingelheim, Gilead, J&J, Medtronic, Pfizer, St. Jude Medical, Sanofi-Aventis, Zoll Medical; and lecture fees from Boehringer Ingelheim, Bayer Healthcare, Bristol-Myers Squibb, Pfizer, St. Jude Medical, Sanofi-Aventis, and Cardiome, outside the submitted work.

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