

The wearable cardioverter-defibrillator in 2023: current evidence and clinical indications

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Video summary from the author

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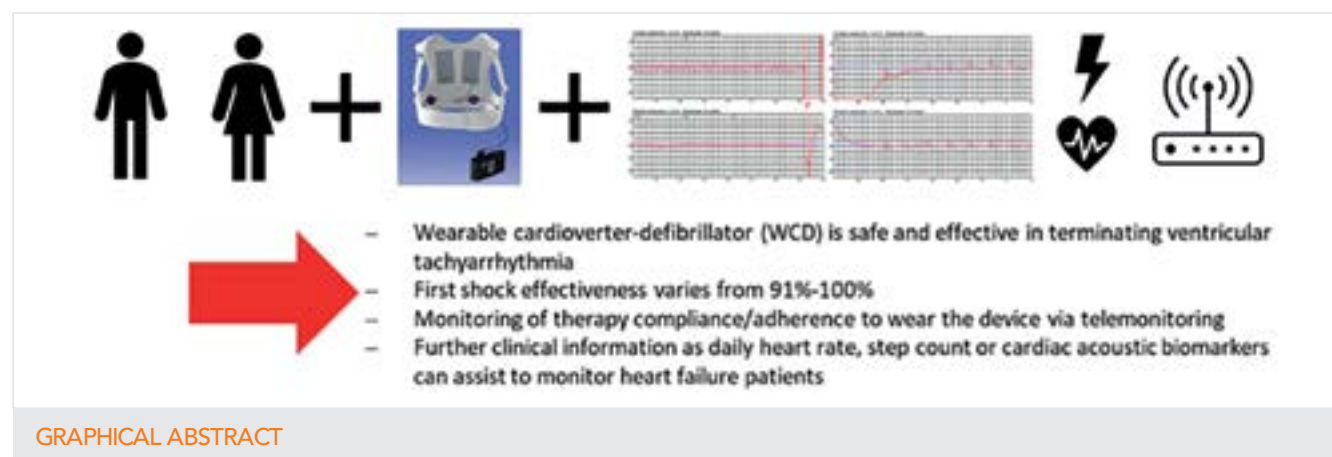
The wearable cardioverter-defibrillator (WCD) consists of a garment containing 3 self-gelling defibrillation patch electrodes, 2 on the back and 1 in the front, and 4 non-adhesive ECG electrodes connected to a monitoring unit (*Figure 1*). Worn around the chest like a vest, the WCD provides continuous ECG monitoring and automatically delivers up to 5 posterior-anterior defibrillation shocks per ventricular arrhythmia (VA) episode. The WCD proved to be both safe and effective in terminating ventricular tachyarrhythmia in various patient cohorts with primary or secondary prevention indication for sudden cardiac death. The first shock effectiveness varies from 91% in the earlier first-in-human studies to 100% in selected patients at-risk. The device is also able to transmit data via telemonitoring concerning arrhythmia and shock discharge, but also information on therapy compliance/adherence to wear the device. Further clinical information as daily heart rate, step count or cardiac acoustic biomarkers are collected that can potentially assist to monitor heart failure patients.

Keywords: Ventricular tachyarrhythmia; VT; VF; wearable-cardioverter defibrillator; sudden cardiac death

Introduction

The wearable cardioverter-defibrillator (WCD) has been approved by the U.S. Food and Drug Administration (FDA) in 2001 (1). The WCD is used for monitoring and immediate treatment of harmful ventricular

tachyarrhythmias (2–7, 9–12). In addition to that, the newest generation of WCD/LifeVest® models including the online telemonitoring platform ZOLL Patient Management Network, allow for heart rate (HR) reports and alerts, and activity and body position reports measured via the ECG electrodes and a 3-axis-accelerometer in



GRAPHICAL ABSTRACT

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FIGURE 1. Wearable cardioverter-defibrillator/Zoll Life Vest® (A), (B) Garment with 3 defibrillation electrode pads (apex-to-posterior defibrillation) with 4 sensing electrodes, accelerometer in front defibrillation pad; (C) blue colored gel patches; (D) control box. Adapted from Ref 34

the electrode belt (8). The WCD has been proven to effectively terminate ventricular tachyarrhythmias with a first shock success of 91% in the early studies (13–15) and 95% in the latest studies with newer generations of the WCD (8). The externally placed ECG leads are susceptible to movement artifacts and demonstrated to generate a high proportion of false alarms (>80%) leading to patient discomfort and malcompliance (3, 16). In an observational study with ICD patients wearing the ASSURE WCD (Kestra Medical Technological) with deactivated shock function conducted by Poole and colleagues, the true rate of false alarms was tested with the newest generation WCD (18). In 130 patients, 146 WCD recordings occurred. Only three false-positive shock alarm markers were recorded; one false-positive shock alarm every 1333 patient-days (0.00075 per patient-day, 95% confidence interval: 0.00015–0.00361; $p < 0.001$) (17) making this achilles heel of the WCD probably history. None the less, safety and efficacy of the WCD have been mainly assessed in observational studies and registries (2, 4–17). There is only one randomized-controlled study that evaluated the WCD in patients early after myocardial infarction with LVEF < 35%, the VEST trial, revealing no benefit of the WCD in the primary outcome of arrhythmic death in the intention-to-treat analysis (3).

Therefore, the revised 2022 guidelines on the prevention of ventricular arrhythmias by the ESC recommend the WCD as a class IIb indication level of evidence B for selected patients early after myocardial infarction (18). For patients with secondary prevention indication for sudden cardiac death (SCD), who are temporarily not suitable for ICD implantation, the WCD is currently recommended as a class IIa level of evidence C recommendation (18).

This review sought to summarize the current most common indications for WCD prescription and their corresponding scientific evidence. Gaps of evidence and potential future WCD indications will be described pointing out the need to systematically collect more scientific data on this promising non-invasive technique to prevent SCD in at-risk patients.

Wearable cardioverter-defibrillator (WCD)

The WCD consists of a garment containing 3 self-gelling defibrillation patch electrodes, 2 on the back and 1 in the front, and 4 non-adhesive ECG electrodes connected to a monitoring unit (Figure 1). Worn around the chest like a vest, the WCD provides continuous ECG monitoring and automatically delivers up to 5 posterior-anterior defibrillation shocks per ventricular arrhythmia (VA) episode. The default ventricular tachycardia (VT) and ventricular fibrillation (VF) detection rate thresholds are 150 and 200 beats/min; but can be individually adjusted on therapy initiation and during follow-up. The algorithm also includes a pair of response buttons that allows a conscious patient to respond to the alarm by pressing down on the button preventing an unnecessary WCD shock. The device uses a biphasic shock waveform with programmable energy levels of up to 150 J (Figure 2). The WCD is not able to provide pacing.

Secondary prevention of sudden cardiac death

Most patients with secondary prevention indication for SCD receiving the WCD are temporarily protected

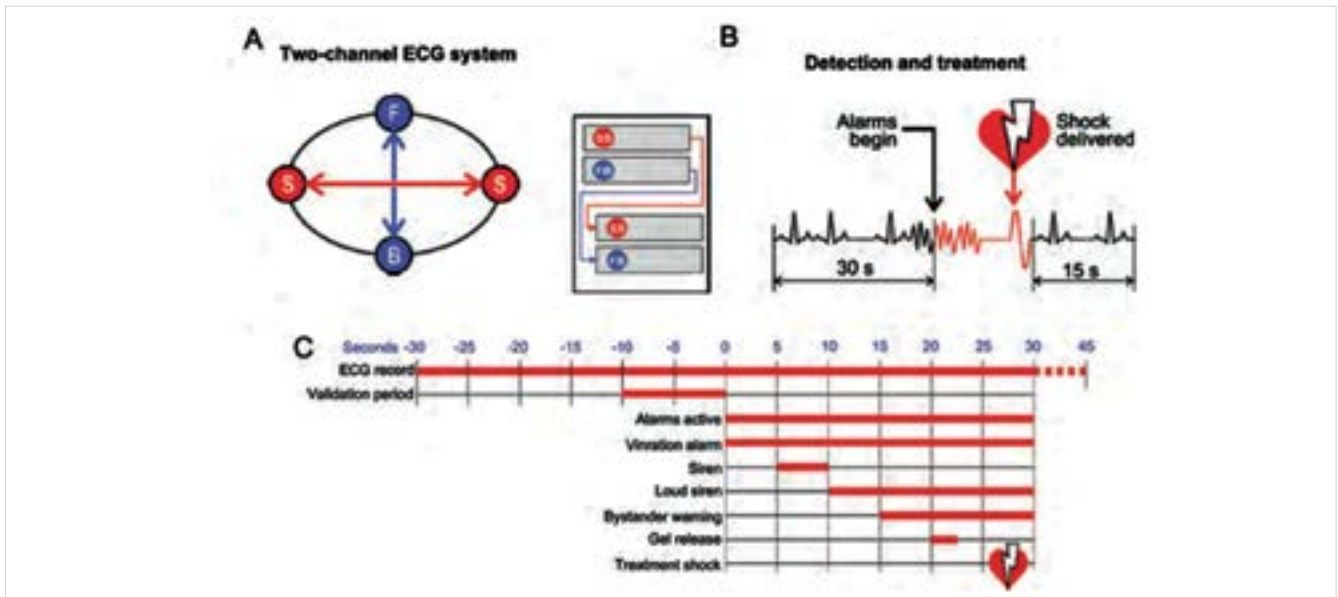


FIGURE 2. The LifeVest detection, treatment, and alarm system. (A) two channel ECG (front-back, FB; site-site, SS recording); (B) detection time, shock delivery, and ECG after shock delivery; (C) the time sequence of alarms with vibration, two siren tones, and a warning voice. Adapted from Ref. 34

due to an infected implantable defibrillator system as a bridging therapy. In the “Aggregate National Experience with the Wearable Cardioverter-Defibrillator” a total of 3,569 patients were retrospectively evaluated, thereof 638 (23.4%) after ICD explantation. In this subgroup, the occurrence of shocked VT/VF while wearing the device (mean WCD use duration 52.6 ± 69.9 days), was highest in this patient group compared to all subgroups (49 events in 33 patients) (19). This finding was recently confirmed by a large multicenter German study focusing on post-heart surgery patients receiving the WCD either for LVEF $\leq 35\%$ and/or after ICD explantation (20). Again, patients after ICD explantation had the highest WCD appropriate shock rate with 2.9% compared to an overall shock rate of 1.5%. Further, median LVEF was initially the lowest among patients after explant compared to all subgroups (median 27% IQR 20.00–45.00%) and most likely not to recover during the follow-up period of 3 months (median 31% IQR 25.00–45.00% at WCD end of use) (20). Interestingly, patients after sternotomy showed a good therapy adherence none the less (23.4 hours per day) (20). To give an example for a potential secondary prevention patient entity, patients with cardiac sarcoidosis have been studied (21). This data of 46 patients fitted with the WCD for median one month have been extracted from the manufacturer’s database. In 41% of the patients, ventricular arrhythmias have been documented before WCD therapy initiation. With an adequate shock rate of 22% and a first shock success rate of 100% this patient cohort seems to derive substantial benefit from WCD therapy while undergoing further diagnostic evaluation (21).

Primary prevention of sudden cardiac death with the WCD

Patients with ischemic cardiomyopathy

In the VEST trial (3), the first randomized-controlled multicenter study on the WCD, 2,302 patients early after myocardial infarction (MI) with LVEF of $\leq 35\%$ were randomly assigned in a 2:1 fashion to receive either the WCD for a follow-up period of 90 days as well as medication for heart failure according to guidelines or heart failure guideline-directed medication alone. The primary analysis plan was to perform an intention-to-treat analysis (ITT) and a secondary weighted sensitivity analysis excluding patients who could not be clearly classified. Initially, total mortality has been defined as the primary endpoint. Due to slow patient enrolment, the endpoint was later changed to “death by sudden cardiac death or VT”. Total mortality remained a secondary endpoint. The primary endpoint, arrhythmic death, occurred in 1.6% of patients in the WCD group and 2.4% of patients in the control group. The secondary endpoint of total mortality was significantly reduced in the WCD group, with a 36% relative risk reduction: 3.1% (WCD) versus 4.9% (control group) ($P=0.04$), and an absolute reduction of 1.8%. This study had several limitations: (1) Unpermitted crossover from the control to the WCD group was recorded in 2.6% of patients who received a WCD. (2) 5.7% of the control group received ICD implantation during the follow-up period (4.4% as protocol deviations). In the WCD group, 4.4% underwent ICD implantation (2.8% outside the protocol). The average WCD wear time in an intention-to-treat analysis was very low (14 h per day). (3) Only 12 of the 48 patients (25%) who died in the group randomized

to WCD were actually wearing the device at the time of death. Of note, an initial, pre-specified as-treated analysis compared event rates per person-month between patients who were wearing the WCD and patients not wearing the WCD, independent of the randomization. This approach showed a significant relative risk reduction of the primary end point "arrhythmic death" by approximately 50% ($P=0.03$). Both secondary endpoints "total mortality" (reduced by $\sim 75\%$, $P<0.001$) and "non-arrhythmic mortality" (reduced by almost 90%, $P<0.001$) showed a relative risk advantage for wearing the WCD during the waiting period after myocardial infarction. As high wear time appears crucial for WCD effectiveness, these factors should be considered when selecting patients expected to benefit from WCD prescription post-myocardial infarction.

This data is inconsistent with the existing real-world data (RWD) on WCD patients with HF r EF and ICM (2, 22, 23). For instance, Epstein and colleagues describe a post-MI cohort of 8,453 patients with LVEF $\leq 35\%$ (2). A total of 133 patients (1.6%) received 309 appropriate shocks; 91% were resuscitated from ventricular tachyarrhythmia. The median time from the index MI to WCD therapy was 16 days. Of the treated patients, 75% received treatment in the first month, and 96% within the first 3 months of use. Shock success resulting in survival was 84% in nonrevascularized and 95% in revascularized patients (2). *Zishiri and colleagues* published a cohort of 4958 patients either being interventional or surgically revascularized after MI with LVEF $\leq 35\%$ (22). 809 patients were protected with the WCD and compared to 4149 patients without WCD. Early mortality hazard was higher among 4,149 patients discharged without a defibrillator compared to 809 patients with WCD (90-day mortality post-coronary artery bypass graft surgery 7% versus 3%, $P=0.03$; post-PCI 10% versus 2%, $P<0.0001$). WCD use was associated with adjusted lower risks of long-term mortality in the total cohort (39%, $P<0.0001$) and both post-coronary artery bypass graft surgery (38%, $P=0.048$) and post-PCI (57%, $P<0.0001$) cohorts (mean follow-up, 3.2 years). In propensity-matched analyses, WCD use remained associated with lower mortality (58% post-coronary artery bypass graft surgery, $P=0.002$; 67% post-PCI, $P<0.0001$). The authors concluded that mortality differences were not attributable solely to therapies for ventricular arrhythmia. Only 1.3% of the WCD group had documented appropriate therapy (22). After WCD use, ICD implantation rates were 32% (PCI) and 30% (CABG), respectively (22). A smaller German study on 100 patients being discharged with WCD after cardiac surgery, mostly after CABG (59%) reported an appropriate shock rate of 3% (first shock success 100%), with ventricular tachyarrhythmia documented in a total of 13 patients (23). During a median WCD use of 60 days, no patient died. In 25% an ICD was implanted after WCD use; the reason not to implant an ICD was mainly LVEF

recovery (LVEF $28.9\pm 8\%$ after surgery and during follow-up $36.7\pm 11\%$; $P<0.001$) (23).

In conclusion, patients early after MI with HF r EF are a vulnerable group susceptible to (any) cardiac and non-cardiac complication with the paradoxon of a higher mortality when early implanted with a defibrillator as seen in the DINAMIT pivotal trial (35). Cardiac arrhythmic death might be withheld with WCD protection in suitable, compliant patients.

Non-ischemic cardiomyopathy

Patients with non-ischemic cardiomyopathy and HF r EF represent a relatively heterogenic group. The largest patient cohort with non-ischemic cardiomyopathy (NICM) fitted with a WCD is to be found in the German Experience with WCD and was published in 2016 by Wäßnig and colleagues (5). Of 6,043 patients, 2,220 were classified as DCM and 735 as NICM with relatively low appropriate WCD shock rates (1.3% and 1.0% respectively, incidence per 100 patient-years 9.7 and 4.6). Daily WCD wear hours were excellent with mean values of 23.0 and 23.1 hours per day (5). Further real-world evidence stems from the US WEAR-IT II cohort, that incorporated 927 patients with NICM (46% of the total cohort $n=2000$) (4). During a median WCD use of 90 days, only 1% of NICM patients received appropriate WCD treatment, the lowest appropriate shock ratio among the total patient cohort ($P=0.02$) (4).

In the PROLONG study, *Duncker and colleagues* describe 156 patients with newly diagnosed heart failure (mixed indications) with LVEF $\leq 35\%$ protected with the WCD during uptitration of heart failure medication (12). The WCD was initially prescribed for 3 months, but prescription was prolonged instead of ICD implantation if: (1) LVEF at 3-month visit increased from 30% to 35%; (2) increase in LVEF of $\geq 5\%$ compared to the last visit; and (3) nonoptimized heart failure medication. Mean LVEF was $24\pm 7\%$ at diagnosis and $39\pm 11\%$ at last follow-up (mean, 12 ± 10 months). Whereas 88 patients presented with primary preventive ICD indication (LVEF $\leq 35\%$) at 3-month follow-up, only 58 showed a persistent primary preventive ICD indication at last follow-up. This delayed improvement in LVEF was related to nonischemic origin of cardiomyopathy, New York Heart Association functional class at baseline, heart rate, better LVEF after 3 months, and higher dosages of mineralocorticoid receptor antagonist (12). In a subgroup analysis of patients with NICM ($n=117$) in the PROLONG study, 12 ventricular tachyarrhythmias occurred in 10 (9%) patients (6 DCM, 4 PPCM). Nine appropriate WCD shocks for hemodynamically unstable VT/VF in 8 (7%) patients were observed. Two patients presented with sustained hemodynamically stable VT for >30 minutes detected by the WCD, but withheld WCD therapy. Of note, two adequate shocks were observed during the extended WCD prescription period (>90 days) (24). As this study has been conducted at Hannover Heart Center, which

is also known for their experience in peri-/post-partum cardiomyopathy (PPCM), an unusual large amount of PPCM patients was included in the PROLONG study (24). Indeed, PPCM patients are ideal candidates for WCD therapy as the risk for ventricular tachyarrhythmia is potentially high (12%) (25). In a German multicentre registry 49 patients from 16 German centres with newly diagnosed PPCM and LVEF $\leq 35\%$ receiving a WCD were included in this retrospective analysis. Mean follow-up was 15 ± 10 months. At diagnosis, mean age was 33 ± 5 years, parity was 2.1 ± 1.6 , LVEF was $21 \pm 7\%$, NYHA functional class was 3.4 ± 0.7 . Six (12%) patients presented eight ventricular tachyarrhythmias during WCD period: five episodes of VF, two sustained ventricular tachycardia (VT) and one non-sustained VT occurred (26). In this patient group, the WCD seems not only to be suitable for temporary treatment of ventricular tachyarrhythmia, but also for arrhythmia screening and documentation.

Patients with myocarditis are a subgroup of non-ischemic heart disease etiology that warrant careful screening for arrhythmias. Real-world evidence stems from two retrospective studies from university hospital Charité, Berlin (27, 28). In the first study by *Tscholl and colleagues*, 59 patients were diagnosed with myocarditis by histology. The mean age was 46 ± 14 years, and 11 patients were women (19%). The mean WCD wearing time was 86 ± 63 days, and the mean daily use was 20 ± 5 h. During that time, two patients (3%) had episodes of sustained ventricular tachycardia (VT; four total) corresponding to a rate of 28 sustained VT episodes per 100 patient-years. Consequently, one of these patients underwent rhythm stabilization through intravenous amiodarone, while the other patient received an implantable cardioverter defibrillator. Two patients (3.4%) were found to have non-sustained VT (27). In the second study by *Blaschke* 76 patients (mean age 48.9 ± 13.7 years; 84.2% male) were prescribed the WCD for clinically suspected myocarditis (28). Based on the results of the endomyocardial biopsy and, where available cardiac magnetic resonance imaging, 39 patients (51.3%) were diagnosed with myocarditis and impaired LVEF and 37 patients (48.7%) with dilated cardiomyopathy (DCM) without evidence of cardiac inflammation. The main immunohistopathological myocarditis subtype was lymphocytic myocarditis in 36 (92.3%) patients, and four patients (10.3%) of this group had an acute myocarditis. VT occurred in seven myocarditis (in total 41 VTs; 85.4% non-sustained) and one DCM patients (in total one non-sustained ventricular tachycardia). Calculated necessary WCD wearing time until ventricular tachycardia occurrence is 86.41 days in myocarditis compared with 6.46 years in DCM patients (28). This data beautifully illustrates the susceptibility for ventricular tachyarrhythmias in myocarditis patients depending on the amount of inflammation and not only on LVEF impairment.

The WCD in selected populations (young patients, old patients, female patients)

Young patients

There is scarce data evaluating WCD use in pediatric patients. In a retrospective US study, 455 patients with a median age of 15 years (IQR 3–17) were identified with a median WCD wear time of one month (29). The study population was divided into children with an ICD problem (e. g. infection, lead fracture etc.) ($n=63$) and nonimplantable defibrillator problem ($n=392$). A total of 6 patients (1.3%) received adequate WCD shock treatment and survived, but 7 patients (1.5%) died while not wearing the device (29). This expands to a substantial problem not only in pediatric patients but also in young adults, as they tend to have lower compliance rate with significantly shorter daily wear time (>20 hours vs. <20 hours) in patients aged 14–51 years compared to patients aged 73–91 years (68% vs. 88%; $P<0.001$) as described in a multicenter, multinational WCD population comprising 708 consecutive patients (30).

Old patients

Concerning older patients, data from the Prospective Registry of Patients using the Wearable Defibrillator (31) divided the study cohort of 1,732 patients in two subgroups: patients with age ≥ 65 years (41.7%) and 1,010 patients with age <65 years (58.3%). Daily WCD wear time was longer in the older population (median 22.8 h/d (IQR 21.5–23.2) vs. 22.3 h/d (IQR 19.5–23.0); $P<0.001$). Patients with age ≥ 65 years experienced higher event rates, per 100 patient-years, for any sustained ventricular tachycardia/ventricular fibrillation (31.95 vs. 9.82; $P=0.027$) and VT/VF treated with WCD shock (6.92 vs. 2.37; $P=0.034$), particularly with ischemic cardiomyopathy. Younger patients experienced a trend toward a higher event rate for atrial arrhythmias with nonischemic cardiomyopathy (150.07 vs. 74.86; $P=0.055$). At the end of WCD use, ICD implantation was more frequent in older patients (41.8% vs. 36.5%; $P=0.034$) (31). Therefore, the WCD might be an appropriate risk stratification tool in older patients considered to be at-risk for SCD.

Women with WCD

By epidemiologic nature of SCD, women are underrepresented also in WCD trials, e. g. the VEST trial (3). In this trial, only 27% women were randomized in the interventional group and 25% women in the control group (3). Lacking further scientific evidence, analysis of big data can be helpful to answer relevant clinical questions surrounding women at risk for SCD using the WCD. Data from the manufacturer's database was used to evaluate efficacy and safety of WCD in women receiving adequate WCD therapy (8). A total of 572 female patients (mean age 63 ± 15 years) were identified who

received appropriate WCD shock therapy. The most frequent indications for WCD prescription were newly diagnosed cardiomyopathy (n=309; 54%), impaired left ventricular function early after acute myocardial infarction (n=133; 23%), or documented ventricular arrhythmia (n=58; 10%). During a median period of WCD use of 59 days (range: 1 to 845 days), with excellent compliance (median daily wear time 20.5 h), 1,043 WCD shocks (median time to first shock 20 days from first wear date) occurred for ventricular tachycardia (VT) (n=325 of 1,043; 31%) or ventricular fibrillation (VF) (n=718 of 1,043; 69%). The first shock was successful in 95% of patients (n=541). Most first WCD events with shocks occurred within the first month (351 of 572; 61%); however, 39% of shocks occurred between 30 days and the end of WCD use (8). Further, 24-hour survival was 89% in this patient group (8). A subgroup analysis from the US WEAR-IT II registry directly compared men versus women using the WCD (9). Among these, 30% were female (n=598) and 70% were male (n=1,402). Better therapy compliance could be confirmed (21.4 h/d vs. 20.7 h/d; P=0.001). Of note, burden of ventricular tachycardia or ventricular fibrillation was higher in women, with 30 events per 100 patient-years compared with 18 events per 100 patient-years in men (P=0.017), with similar findings for treated and non-treated VT/VF. Recurrent atrial arrhythmias/sustained ventricular tachycardia was also more frequent in women than in men (167 events per 100 patient-years vs. 73 events per 100 patient-years; P=0.042). However, ICD implantation rate at the end of WCD use was similar in both women and men (41% vs. 39%; P=0.448) (9) confirming the ununderstood paradoxon that ICD therapy is underused in women who already presented with an indication for SCD prevention (31). Nonetheless, it has been proved that women derive the same benefit from ICD therapy even in a primary prevention setting as men (32).

Future indications

Newer generations of the WCD are not only more comfortable concerning daily use and prevention of inadequate shock therapy (17), but it is also possible to gain further relevant clinical information about the patient using the device (7, 10). For instance, in the HEAR-IT study, 671 patients with newly diagnosed heart failure with LVEF \leq 35% were protected with the WCD for 3 months (7). WCD therapy was directly initiated at hospital discharge. Using acoustic cardiography, an algorithm amongst including heart rate as one parameter, was developed. This algorithm was able to detect HF events 30 days in advance of the event. Therefore, integrating cardiac acoustic biomarkers (CAB) technology into clinical practice may prevent HF rehospitalizations (7). Further, the WCD garment also contains

an accelerometer able to collect data on body position and step count (10). In a retrospective data analysis of commercial data, 120 women who received an appropriate WCD shock, presented quadratic relationship between time and activity prior to shock. Physical activity increased starting at the beginning of the 30-day period up until day -16 (16 days before the ventricular arrhythmia) when activity begins to decline (10). These data suggest that through thorough clinical supervision, patients at-risk could potentially be prevented from experiencing heart failure events or even lethal ventricular tachyarrhythmia. That is why the authors of this literature review recommend considering WCD therapy also for patients at unknown risk for SCD (e. g. hemodialysis patients, patients after cardiotoxic chemotherapy, patients on QT prolonging drugs, patients undergoing familial SCD screening, patients after VT-ablation). Currently, there is no better risk stratification tool available that is both non-invasive and wearable and provides a considerable amount of relevant clinical information.

Conclusion

The wearable cardioverter-defibrillator proved to be both effective and safe in terminating ventricular tachyarrhythmia in various patient cohorts at-risk for malignant arrhythmias. Besides, the WCD is able to collect relevant clinical data relating to heart rate monitoring, documentation of arrhythmias as well as activity data and early clinical signs of cardiac decompensation with acoustic cardiography. As both a temporary wearable defibrillator and diagnostic screening tool, individualized therapeutic concepts can be established.

Conflict of interest statement

Julia W. Erath reports receiving consultant fees, travel support and lecture fees from ZOLL Medical, travel grants from Bayer Vital, St. Jude Medical/Abbott, Novartis and lecture fees from Servier, Medtronic and Bayer Vital. She is a fellow of the Biotronik International Fellowship Program and was a fellow of the Boston Scientific heart rhythm fellowship program.

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