RESEARCH LETTER

Optimizing sudden cardiac death prevention: a promise of wearable cardioverter-defibrillator

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Introduction Wearable cardioverter defibrillator (WCD) is a device with proven effectiveness in terminating life-threatening ventricular arrhythmias, that is, ventricular tachycardia (VT) and ventricular fibrillation (VF). The 2022 European Society of Cardiology (ESC) guidelines[1] state that this solution should be considered as secondary prevention of sudden cardiac death (SCD) in patients in whom, for various reasons, implantable cardioverter-defibrillator (ICD) cannot be used. A classic example are patients who had their ICD removed due to infectious complications, who require several weeks of antibiotic therapy, and who are still at a significant risk of SCD. Other indications include acute myocarditis and primary prevention indications during pregnancy. WCD use may also be considered in selected patients in an early phase after myocardial infarction (MI), although scientific evidence supporting this approach is of lower quality.[1] Considering that this type of device has become available relatively recently in Poland, a summary of WCD use experience from a reference center in cardiac electrotherapy seems valuable.

Patients and methods A retrospective, single-center study included all consecutive patients (n = 18) who received WCD (LifeVest, ZOLL, Pittsburgh, United States) therapy from February 1, 2020 to September 30, 2023, in the Department of Cardiology and Electrotherapy, Medical University of Gdansk. The analysis included demographic data, comorbidities, pharmacologic treatment, and data on the use of WCD from the manufacturer's information technology system. The Bioethics Committee for Scientific Research at the Medical University of Gdansk bioethics committee approved the study (KB/616/2023).

Statistical analysis A *P* value below 0.05 was assumed significant for all comparisons and calculations. Numerical variables were expressed as median and interquartile range (IQR). Categorical data were expressed as numbers and percentages. The Wilcoxon test was used to compare the baseline and final left ventricular ejection fraction (LVEF) values. When appropriate, categorical variables were compared using the χ^2 or Fisher exact test. Correlations between selected quantitative variables were assessed using the Spearman rank correlation test. The data were analyzed using the STATISTICA 13 software (TIBCO Software Inc., Palo Alto, California, United States).

Results The study group included 18 patients at a median (IQR) age of 40 (33–53) years, with male predominance (n = 15; 83%). Descriptive characteristics of the study group and the outcomes of the WCD application are presented in **TABLE 1**. The most prevalent indication for the use of WCD in the analyzed group was myocarditis with de novo heart failure (HF) and/or VT/VF (n = 8; 44.4%). The most common comorbidities were HF (n = 15), hypertension (n = 6), and atrial fibrillation (n = 6). Median (IQR) LVEF was 26% (20%–38%) at the time of WCD application, and 45% (30%–50%) after the monitoring was completed; however, this change was not significant (*P* = 0.06).

Median (IQR) monitoring time of the WCD use was 77 (52–95) days, and it is still ongoing at the time of publication of this article for 4 patients. Median (IQR) daily monitoring time was 23.5 (22.4–23.8) hours. No deaths were reported during the WCD use. The results of the WCD monitoring are shown in Supplementary material, *Figure S1*.

During monitoring, sustained VTs (sVTs) were observed in 2 patients. In 2 other patients, nonsustained VTs (nsVT) were registered (Supplementary material, *Figure S2A* and *S2B*). No therapy was delivered for the abovementioned ventricular arrhythmias, as the patients deferred the therapy due to good tolerance of arrhythmia.

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TABLE 1 Descriptive characteristics of patients with wearable cardioverter-defibrillator outcomes

Patient	Sex	Age, y	Etiology	Main comorbidities	LVEF at WCD application, %	Time of WCD use, d	sVT/nsVT during WCD use	LVEF at WCD completion, %	Result at the end of WCD application
OJ	M	40	Myocarditis	HF, FAP	42	160	sVT	28	T-ICD
NK	F	33	Myocarditis	HF, PAF, DM	32	84	None	45	No further indications for ICD
KB	M	71	Myocarditis	HF, CAF, AH, DM, CKD	10	95	None	55	No further indications for ICD
GM	M	36	Myocarditis	HF	27	93	None	33	S-ICD
KA	F	41	HCM + pregnancy + nsVT	None	54	77	None	52	Lack of patient consent to ICD implantation
HA	M	64	CDRIE	HF, AH	20	69	None	HTx	HTx
GM	M	53	Myocarditis	HF, AH, ICM	25	60	None	47	No further indications for ICD
ZJ	M	14	CPVT	None	68	74	None	65	No further indications for ICD
PM	F	38	Myocarditis	None	52	179	nsVT	50	S-ICD
MD	M	53	Myocarditis	HF, PAF	33	83	None	45	No further indications for ICD
AF	M	28	Myocarditis	HF, CKD	22	94	None	30	Lack of patient consent to ICD implantation
HM	M	33	CHF + bridge to HTx	HF, AH	15	12	None	HTx	HTx
GS	M	54	CHF + bridge to ICD due to infection	HF, AH, DM, ICM	15	33	None	20	T-ICD
ZP	M	40	ACS + de novo HF	HF, PAF, ICM	38	56	sVT	41	T-ICD
JK	M	66	CDRIE	HF, CAF, CKD	27	95 (ongoing)	nsVT	n/a	Ongoing WCD use
TB	M	49	DCM + de novo HF	HF	20	52 (ongoing)	None	n/a	Ongoing WCD use
ZM	M	28	DCM + de novo HF	HF, CKD	10	39 (ongoing)	None	n/a	Ongoing WCD use
RA	M	52	DCM + de novo HF	HF, AH, DM	20	38 (ongoing)	None	n/a	Ongoing WCD use

Abbreviations: ACS, acute coronary syndrome; AF, atrial fibrillation; AH, arterial hypertension; CAF, chronic atrial fibrillation; CDRIE, cardiac device–related infective endocarditis; CHF, chronic heart failure; CKD, chronic kidney disease; CPVT, catecholaminergic polymorphic ventricular tachycardia; DCM, dilated cardiomyopathy; DM, diabetes mellitus; F, female; HCM, hypertrophic cardiomyopathy; HF, heart failure; HTx, heart transplant; ICD, implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; M, male; n/a, not applicable; nsVT, nonsustained ventricular tachycardia; PAF, paroxysmal atrial fibrillation; S-ICD, subcutaneous implantable cardioverter-defibrillator; sVT, sustained ventricular tachycardia; T-ICD, transvenous implantable cardioverter-defibrillator; WCD, wearable cardioverter-defibrillator

The recorded arrhythmia episodes in the other 6 patients were artefacts (Supplementary material, *Figure S2C*). The number of artefacts correlated positively with the patient age ($P = 0.02$). No inappropriate shocks were recorded, as the patients manually deferred the therapy using the device's control panel, or the episodes were too short to be classified as sustained arrhythmias. Tolerance of WCD use was very good. We found no dermatologic complications, and we did not note a single case of WCD discontinuation due to discomfort of its use.

After discontinuation of WCD use, indications for ICD implantation remained valid in 7 out of 14 patients with completed observation. Of those, 3 patients received transvenous ICD, subcutaneous ICD (S-ICD) was implanted in 2 patients, and 2 other patients did not consent to ICD implantation. In the remaining 7 patients (50%), there were no indications for using ICD after the completion of WCD monitoring due to improved LVEF.

Discussion Although WCD was first used 25 years ago, this method is still not widely available in Europe, as indicated by the results of the European Heart Rhythm Association survey.[2,3] Despite the evidence mentioned above, presenting WCDs as a valuable therapeutic option for patients at a risk of SCD, access to these devices remains limited, also in Poland, and seems insufficient in relation to demand.[4]

The indications for WCD use are constantly evolving. According to the ESC guidelines,[1] this

device could be considered in patients with low LVEF immediately after MI to prevent sudden arrhythmic death. Meanwhile, VEST (Vest Prevention of Early Sudden Death Trial),[5] in which patients with recent MI and LVEF of 35% or less were randomized to WCD therapy or standard care, showed that WCD did not significantly lower the rate of the primary outcome of arrhythmic death in comparison with control. In our pilot study, the dominant indication for WCD was myocarditis (44.4% of the patients). A significantly lower representation of patients with an indication for WCD after MI was mainly due to the profile of our center, which deals primarily with cardiac arrhythmias.

Data regarding ventricular arrhythmia rates and the number of appropriate shocks in WCD patients vary in different studies. This is primarily due to different criteria of patient inclusion. Among cardiac surgery patients with LVEF equal to or below 35% or after ICD explantation, 9.1% exhibited VT.[6] A total of 93.2% of the episodes occurred within the first 3 months of observation. In the WEARIT-France (LifeVest Safety and Efficacy in Real Life Settings in France) cohort study, 1.6% of patients received at least 1 appropriate shock, while the Swiss experience shows a rate of 2.6%.[7,8] In the paper by Rosenkaimer et al,[9] adequate WCD therapies were found in 4% of patients. In the WEARIT-II registry[10] involving patients with ischemic cardiomyopathy (n = 805; 40%), nonischemic cardiomyopathy (n = 927; 46%), or congenital / inherited heart disease (n = 268; 13%), the authors showed a higher burden of ventricular arrhythmic events in women than in men (30 vs 18 events per 100 patient-years; $P = 0.02$). Data from a multicenter registry of patients with myocarditis treated with WCD indicate the incidence of nsVT at 9.7% and sVT at 6.5%.[11] Subsequently, 2.4% of the patients experienced an appropriate WCD shock. Interestingly, the authors of this study suggest that in this population prior ventricular arrhythmia might be a better risk predictor than reduced LVEF below 35%. In our dataset, we recorded 2 episodes of sVT registered by WCD; however, due to good arrhythmia tolerance, WCD therapy was manually deferred by patients.

We did not observe any inappropriate WCD shocks in our group, which is consistent with the current literature reporting an infrequent rate of inadequate arrhythmia detection. In one study, 1 false-positive shock alarm was recorded every 1333 patient-days of WCD use.[12] In the WEARIT-France cohort study, inappropriate therapy occurred in 0.7% of patients.[7] In the Swiss registry of 456 patients, no inappropriate WCD interventions were found.[8]

As expected, after initiation of optimal medical treatment of de novo HF, LVEF could increase within WCD monitoring time. In a study by Nägele et al[13] involving 436 patients, a significant improvement in LVEF, from 25% to 40%, was found during guideline-directed medical therapy. We observed a comparable trend in our study (an increase of LVEF from 29% to 41%).

Notably, a bridge therapy with WCD allows for withdrawal from ICD implantation in up to 58%–76% of patients.[9,14] In our study, this percentage was slightly lower (50%), which may be primarily due to the small size of the study group. The difference may also be due to significant discrepancies in the indications for WCD in the referenced studies and our material. In the cited works,[9,14] a significantly larger group of patients (37% and 44%) were those with ischemic cardiomyopathy, in whom early percutaneous coronary intervention was probably also responsible for the improvement in LVEF. In our study, only 1 patient (6% of the study group) was a post-acute coronary syndrome individual with de novo HF. In addition, 4 patients (22%) included in our study are still secured with WCD, which may affect the above results.

The side effects of WCD application primarily include symptoms related to the discomfort of WCD use and dermatologic symptoms, such as itching, which occurs in 5.9% of patients using WCD.[15] Other dermatologic complications are also uncommon, for example, incidence of contact dermatitis in one study was 1.7%.[16] We did not find such complications in our patients, and treatment tolerance was very good.

Good tolerance of WCD is further evidenced by its high daily use rate. The available literature shows it is most commonly used for 21.2–23.4 hours per day.[7,17-19] The duration of WCD use per day was equally high even after cardiac surgery requiring sternotomy.[6] Our data are consistent with the literature (median time of monitoring 23.5 h per day).

Based on literature data and the results of our pilot study, it seems that WCD therapy has some clinical benefits; moreover, it could be economically justified.[20] All the arguments mentioned above could encourage the administration of to WCD treatment as in the case of other state-of-the-art technologies in electrotherapy (S-ICD, leadless pacemakers).

Conclusions WCD is a safe, well-tolerated solution for patients at a risk of SCD, in whom a decision to qualify for ICD implantation should be postponed. With optimal medical treatment and WCD protection, nearly 50% of the patients may avoid unnecessary ICD implantation.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/paim.

ARTICLE INFORMATION

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