Cardiovascular Rehabilitation With a WCD—Data From the CR3 Study (Cardiac Rehab Retrospective Review)

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Purpose: Patients at risk for sudden cardiac death may temporarily need a wearable cardioverter-defibrillator (WCD). Exercise-based cardiac rehabilitation (CR) has a class I recommendation in patients with cardiac disease. The aim of this study was to evaluate the safety and feasibility of undergoing CR with a WCD.
Methods: We performed a retrospective analysis of all patients with a WCD who completed a CR in Austria (2010-2020).
Results: Patients (n = 55, 60 ± 11 yr, 16% female) with a median baseline left ventricular ejection fraction (LVEF) of 36 (30, 41)% at the start of CR showed a daily WCD wearing duration of 23.4 (22, 24) hr. There were 2848 (8 [1, 26]/patient) automatic alarms and 340 (3 [1, 7]/patient) manual alarms generated. No shocks were delivered by the WCD during the CR period. One patient had recurrent hemodynamically tolerated ventricular tachycardias that were controlled with antiarrhythmic drugs.

No severe WCD-associated adverse events occurred during the CR stay of a median 28 (28, 28) d. The fabric garment and the device setting needed to be adjusted in two patients to diminish inappropriate automatic alarms. Left ventricular ejection fraction after CR increased significantly to 42 (30, 44)% ($P < .001$). Wearable cardioverter-defibrillator therapy was stopped due to LVEF restitution in 53% of patients. In 36% of patients an implantable cardioverter-defibrillator was implanted, 6% had LVEF improvement after coronary revascularization, one patient received a heart transplantation (2%), two patients discontinued WCD treatment at their own request (4%).
Conclusion: Completing CR is feasible and safe for WCD patients and may contribute positively to the restitution of cardiac function.

Key Words: cardiovascular rehabilitation • sudden cardiac death • wearable cardioverter-defibrillator

KEY PERSPECTIVES:

What is novel?

- A study to investigate patients undergoing exercise-based cardiac rehabilitation (CR) with a wearable cardioverter-defibrillator (WCD) concerning feasibility and safety has not previously been performed.
- This study shows that the number of patients with a WCD being referred to CR is dramatically low and confirms that CR is underutilized in this cohort despite a clear recommendation in guidelines and underlying studies confirming the benefit on patient outcomes.

What are the clinical and/or research implications?

- Referral of patients with a WCD to CR programs needs to be enhanced as numbers are low and the measures can safely be performed by these patients.
- Specific measures may be needed to adjust the fabric garment and/or device settings such as alarm thresholds to decrease the number of alarms and to enhance the patient comfort as well as safety.
- Patients can be sent to CR without a delay and potential adjustments of the garment and the device programming can be easily performed at the CR facility.

The prevalence of heart failure irrespective of its origin is 1-2% in the adult European population.[1] Patients with heart failure and severely impaired left ventricular ejection fraction (LVEF) are at a significant transient or permanent risk to suffer from sudden cardiac death (SCD).[1,2] These patients might be protected by a wearable cardioverter-defibrillator (WCD) if the SCD risk is considered reversible or temporary contraindications for an implantable cardioverter-defibrillator (ICD) are present.[3]

The therapeutic goals for patients with heart failure are SCD prevention, improving cardiac function and functional status to reduce morbidity and mortality and increase quality of life (QoL).[4] In patients with heart failure and reduced LVEF,

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a multiprofessional disease management and exercise-based cardiac rehabilitation (CR) program is recommended in all patients who are able to perform physical activity (class I, level of evidence A). In frail, more severely affected patients with comorbidities, a supervised approach should be considered (class IIa, level of evidence C).[1] The 2020 ESC Guidelines on sports cardiology and exercise in patients with cardiovascular disease set a class I recommendation (level of evidence A) to recommend CR to all patients with coronary artery disease to decrease mortality and the number of hospitalizations soon after discharge and improve QoL.[3,5-7]

Studies have shown that patients with cardiac implantable electronic devices can safely undergo rehabilitation measures and show similar positive effects on exercise capacity and psychological distress levels. In fact, data and studies show decreased total and exercise-related shock rates.[8,9] The purpose of the study was to investigate on feasibility and safety of patients who undergo an exercise-based CR program with a WCD.

METHODS

This was a multicenter, retrospective, observational cohort study of patients prescribed with a WCD (LifeVest, ZOLL CMS GmbH) between 2010 and 2020 and completed CR in the CR facilities Hochegg, Grossgmain, and St Radegund of the Austrian Pension Insurance (PVA) following the current recommendations.[5,10] All patients either signed informed consent (48/55) or were deceased at follow-up (7/55). The Austrian WCD registry[11,12] was screened for patients who met the following inclusion criteria: partial (>50%) or full completion of CR when wearing the WCD; and ≥18 yr and able to give informed consent.

Baseline characteristics, complete CR data, outcomes, and follow-up data, as well as WCD-derived data, were collected from these patients. Data recorded by the WCD such as automatically and manually recorded ECG, as well as wearing time, were collected. Data derived from WCD were accessible on the online network provided by the WCD manufacturer for physicians to access events and WCD data. An institutional review board approval has been granted by the local ethics committee for entire Austria, and the study was registered at ClinicalTrials.gov (NCT04675957). Detailed information about the Austrian WCD registry has been published before.[11,12]

CR REFERRAL AND SETUP

This cohort represents the typical CR referral and setup in Austria: Patients in Austria are mainly referred to CR during their index hospitalization and CR starts on average 36 d after the index event. Phase II CR can be either outpatient or inpatient. The majority (96%) of patients, and especially the reported high-risk cohort, complete inpatient CR in Austria.[13] Times are changing and the outpatient setting is growing faster, so a proportional turnaround in this matter is expected within the next few years. Nevertheless, inpatient and outpatient CR have the same amount of therapeutic units (1800 min in 3 wk for inpatients as well as for outpatients in 6 wk).

Each therapeutic unit has a duration of either 25 or 50 min and consists of aerobic training on a treadmill or bicycle with continuous ECG monitoring or resistance training. At the beginning of CR, a thorough medical examination and a bicycle ergometry are performed to assess the functional capacity in metabolic equivalents and to set the goals that need to be reached during CR. A detailed explanation about CR in Austria was published by Niebauer.[13] The staff consists of medical doctors, mainly specialists in internal medicine or cardiology or general practitioners, working together with nurses and therapists (psychologists, diabetologists, physiotherapists, and ergotherapists).

WCD DIAGNOSTICS AND TREATMENTS

Electrocardiogram (ECG) recordings during different alarms either triggered by an automatically working algorithm with predefined detection limits or those manually recorded by the patient him-/herself were reviewed in the online network.

The treating physicians set the heart rate thresholds for ventricular tachycardia (VT) and ventricular fibrillation (VF) detection, with the default programming being 150 bpm for VT and 200 bpm for VF. These automatically detected ECGs triggered an alarm so that the patient could react to avoid inappropriate WCD shocks for hemodynamically tolerated ventricular arrhythmia (VA) or due to ECG artifacts. When VAs were captured but the WCD treatment was aborted by the patient, these arrhythmias were counted as hemodynamically stable VA unless the correlated medical records disagreed.

Patients who felt symptoms of arrhythmia could trigger a manual alarm by pressing a button on the WCD. This led to documentation of a surface ECG at time of symptoms for further diagnostic use and notification of the treating physician in the online network.

The appropriateness of WCD recordings was assessed by three members of the working group independently assessing the blinded ECG strips. Sustained VT (>30 sec), VF, torsade de pointes were adjudicated as appropriate alarms. Asystole, bradycardia, artifacts, pacemaker and T-wave oversensing, sinus tachycardia, atrial fibrillation with rapid ventricular response, or nonsustained ventricular tachycardia (nsVT, <30 sec) triggered alarms were categorized as inappropriate.

FOLLOW-UP

All available medical reports and additional information from telephone follow-ups by the treating physicians were reviewed. Data concerning arrhythmic events like WCD treatments, VA, SCD, or cardiovascular death/death from any cause were documented in the registry as well as clinical follow-ups after WCD termination.

DATA ANALYSIS

Continuous variables are presented as mean ± SD, or median (IQR). Categorical variables are presented as n (%). The *t* test was used for normally distributed data and the Wilcoxon rank-sum test as a nonparametric test. Normal distribution was assessed with the Kolmogorov-Smirnov test. Analyses were performed using SPSS 27 (IBM).

RESULTS

Within 896 patients in the Austrian WCD registry, 55 (6%) completed CR (age 60 ± 11 yr, 16% female patients). Underlying cardiac disease was ischemic cardiomyopathy (CMP) in 27 (49%) patients, dilatative CMP in 15 (27%) patients, and inflammatory CMP in 10 (18%) patients. One patient had valvular CMP, one patient had Takotsubo CMP, and one patient had an aborted SCD without known structural disease, suggesting a primary electrical disease (each 2%, Figure 1). Apart from the underlying disease, patients had different reasons for a WCD prescription, for example, to bridge the time to a delayed ICD implantation (18%), due to a temporary contraindication to ICD

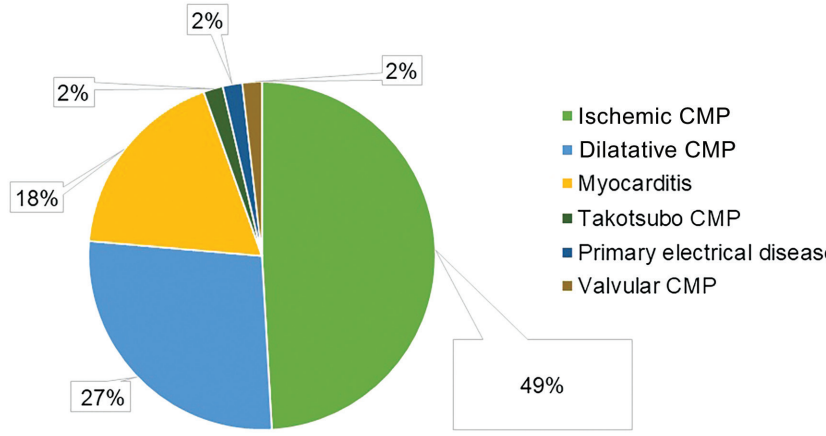

Figure 1. Underlying cardiac disease as a reason for wearable cardioverter-defibrillator prescription in 55 patients: 27 (49%) with ischemic cardiomyopathy, 15 (27%) with dilatative CMP, 10 (18%) with myocarditis, and each one patient with Takotsubo CMP, primary electrical disease, and valvular CMP (6%).[1] Abbreviation: CMP, cardiomyopathy. This figure is available in color online (www.jcrpjournal.com).

implantation (15%) or because of an expected restitution, or during the process of establishing a diagnosis, or during risk stratification for SCD (67%).

Forty (72%) patients received their WCD as primary prophylaxis and 15 (27%) patients experienced VA earlier. Preexistent VAs were VT in four patients, VF in nine patients, and two patients had both VT and VF. The median baseline LVEF at the start of CR was 36 (30, 41)%. Several comorbidities were present such as arterial hypertension or vascular disease in this population (see Table 1).

CARDIAC REHABILITATION

Concerning CR referral and referral rates in the Austrian WCD population, 55 (6%) WCD patients completed CR. All patients completed CR in an inpatient setting. Five (9%) did complete <50% of the scheduled CR duration. The majority of patients (841, 94%) were not referred to CR during their WCD prescription period. There was no difference in referral rate concerning sex (P = .24), age (P = .92), body mass index (P = .94), LVEF at WCD prescription (P = .46), or comorbidities such as arterial hypertension (P = .47). Patients with diabetes (P = .013), patients with a WCD due to risk stratification with a potential reversible cause (P = .03), or patients with coronary artery disease after percutaneous coronary intervention or coronary artery bypass grafting (P = .01) were more likely to be referred to CR. Patients awaiting a therapeutic procedure like ICD implantation, heart transplantation, or catheter ablation were less likely to be referred to CR (P = .008).

At the beginning of CR, baseline parameters were collected to detect modifiable cardiovascular disease risk factors and to set goals for CR measures. At the beginning of CR, 76% of patients were overweight or obese. Baseline blood pressure was systolic 126 ± 18 mm Hg and diastolic 79 ± 11 mm Hg. Exercise testing was performed in 48 (87%) patients; 42 (76%) performed a classical bicycle stress test. They reached 100 ± 33 W and 65 ± 17% of the individually calculated target W. Six (11%) performed a simple walking test. In seven patients (13%) exercise testing was not performed due to the preexisting severe left ventricular (LV) dysfunction.

The duration of CR was 28 (28, 28) d compared with a total WCD prescription duration of 94 (84, 151) d. The daily wearing duration was 23.4 (22, 24) hr. The majority of patients (41, 76%) started the inpatient CR period with a WCD being prescribed a median 43 (55) d before admission and stopped the WCD after the CR period. These cohorts completed the regular CR period with a WCD. Twelve (22%) got their WCD before CR but the therapy was stopped during CR due to recovery of LVEF after 13 (7, 56) d of CR. Two patients (4%) were admitted to CR without a WCD and got a WCD prescribed during CR due to newly diagnosed severe LV dysfunction. One WCD was prescribed after the first day at the initial echocardiographic evaluation and the other one after 23 d of CR.

ALARMS

There were 2848 automatic alarms (8 [1, 26]/patient) and 340 manual alarms (3 [1,7]/patient) generated. Automatic alarms were frequently motion artifacts (2826 [99.2%]). Nonsustained VA or non-VA such as atrial fibrillation triggered inappropriate alarms (18 [0.6%]). Appropriate shocks for sustained VA appeared in only two patients, thus account for 0.14% of all automatic alarms (see Table 2).

Two patients had recurrent stable VT. One patient had a VT that was slower than the programmed detection heart rate (130 vs 150 bpm threshold) detected during CR as an incidental finding on a Holter ECG. The other patient aborted the WCD alarms and consecutively the treatment during the timespan before CR. Both were treated with antiarrhythmic drug therapy and none of them received an ICD thereafter.

Table 1

Baseline Characteristics[a]

Age, yr	60 ± 11
Sex, female	9 (16)
Arterial hypertension	38 (69)
Atrial fibrillation/flutter	11 (20)
Diabetes mellitus	19 (35)
Vascular disease	31 (56)
Prior percutaneous coronary intervention	28 (50)
Prior stroke	4 (7)
Body weight, kg	82 (74, 90)
Body mass index, kg/m^2	28 (25, 31)

[a]Data are presented as mean ± SD, n (%), or median (IQR).

Table 2

Overview of Automatically and Manually Recorded Alarms and Underlying Heart Rhythm and Shocks for VT/VF Events[a]

Category	Number	Patients
Automatically recorded alarms	2848	44 (80)
Artifacts	2826	44 (80)
Sustained VTs without shock	4	2 (4)
Tachycardic atrial fibrillation	12	3 (6)
Nonsustained VT	2	2 (4)
Shocks	4	2 (4)
Shocks for VT	3	1 (2)
Shocks for VF	1	1 (2)
Inappropriate shocks	0	0 (0)
Manually recorded alarms	340	5 (9)
Sinus rhythm	340	5 (9)
Ventricular arrhythmia	0	0 (0)

Abbreviations: VF, ventricular fibrillation; VT, ventricular tachycardia.
[a]Data presented as n or n (%).

Within this cohort two patients (4%) had four (0, 0) shocks for VT/VF during prescription, but all occurred before CR (1 and 13 d after WCD prescription and 48 and 1 d before CR). One VF event was successfully terminated with the first shock in one patient. Another patient had three VT events that were also terminated with the first WCD shock. No inappropriate shock was delivered in this cohort.

ADVERSE EVENTS

Three patients had a reported syncope during CR. All events were associated with clinically documented hypotension and without evidence of an underlying arrhythmia in the WCD ECG. One patient had an ambulatory check-up at the device clinic because of an increase in false automatic alarms due to artifacts. At the check-up, a relevant weight loss through CR measurements seemed to result in a loose fabric garment of the WCD. He was provided with a smaller size of the vest, and this intervention resolved artifact detection due to poor skin contact of ECG electrodes. One patient needed a reprogramming of detection rates due to recurrent alarms for sinus tachycardia during exercise training (see Table 3).

FOLLOW-UP

The reassessed LVEF at the end of CR showed an increase of 11 ± 12.4% ($P < .0001$; see Figure 2). More than half of all patients (29 [53%]) had an improvement in cardiac function to an LVEF > 35% through guideline-directed medical therapy (GDMT) and CR without further ICD indication. Another three patients (6%) had an LVEF restitution after CR and coronary revascularization. Twenty (36%) patients were implanted with an ICD after the WCD prescription period and rehabilitation. One 28-yr-old patient (2%) with myocarditis underwent a heart transplantation. One patient had the intrinsic desire to stop wearing the WCD and one patient (each 2%) had a terminal carcinoid syndrome and the WCD was stopped in consent with the patient.

At the end of CR, the mean body weight showed no significant difference ($P = .13$). The initial mean body weight was 82 ± 15 kg and it was 81 ± 15 kg at the end of CR. Mean blood pressure was systolic 117 ± 17 mm Hg and diastolic 72 ± 12 mm Hg, with a mean reduction of 11±17/7±13 mm Hg ($P < .001$). Final exercise testing via bicycle ergometry was performed in 49% (27) patients. These patients reached 130 ± 45 W and 75 (63, 92)% of the calculated target W. Thus, the median improvement was 15 (0, 26) W and +9 (0, 13)% of the calculated target W ($P < .001$). Three patients (5.5%) underwent a walking test, and 25 (45%) did not undergo any exercise testing. Cardiac rehabilitation centers stated in 36 patients (65%) that the individually set goals were fully reached, in 33% (18) partly fulfilled, and in one patient goals were not reached at all.

DISCUSSION

There are only case reports of patients wearing the WCD during CR,[14] while our CR3 study is the first to demonstrate that no severe WCD-related adverse events were observed during exercise-based CR in a cohort of 55 patients. These results should support and promote a higher referral rate of patients with a cardiac disease and with a WCD to exercise-based CR to improve patient outcomes.

Specific recommendations for CR in patients with a cardiac implantable electronic device are to consider exercise testing to see whether arrhythmias might be provoked and to potentially consider reprogramming the device. The detection rate of arrhythmias should be higher than the targeted exercise heart rate to avoid inappropriate shocks for sinus tachycardia or atrial arrhythmia (class IIa, level of evidence C).[5,15] Oversensing and consecutive inhibition through myopotential is scarce in cardiac implantable electronic devices, especially in bipolar leads.[5,16,17] However, recommendations for CR with a WCD is missing.

This study confirms that only few patients are referred to CR while guideline-driven indications would suggest higher rates of CR referrals. In publications about the worldwide number of CR referrals, underutilization in patients with a cardiac disease is common. In the United States, around 50-60% of patients after myocardial infarction have been referred to CR compared with 40-50% of patients in Europe.[18-20] Moreover, only 29% of patients with any cardiovascular CR-eligible event in the United States are enrolled in CR, with only four states achieving a rate >50% in 2017.[21] These numbers are still almost 10 times higher than the reported referral rate of around 6% in this study.

Reasons for underutilization seem to be multifactorial: time and logistic barriers on the patient side, as well as not perceiving the need for CR. A study of US patients being referred to CR identified that electronic referral, a strong physician recommendation, patients who are nonsmokers or former smokers, high school or higher education, and/or a preserved LVEF as factors to positively influence CR participation. The study also reports male sex as a positive factor with only 31% female patients in the all-over cohort.[22] On the hospital and physician side, the missing information about CR, potential benefit, and missing knowledge about the process of referral are listed. Also, rehabilitation centers seem to have concerns about WCD treatments or complications associated with the WCD. Costs seem to play a role depending on the local health insurance system.[18] Furthermore, insufficient rates of attendance at CR programs pose another problem. This problem mainly exists in countries with outpatient CR programs while 96% of patients in Austria attend inpatient programs.[13] Reasons for nonattendance or premature discontinuation are reported to be motivational or perceptive reasons, as patients state a lack of need for supervised training or CR in general. Similar influencing factors concerning referral, male sex, and higher education as well as low distance to CR centers seem to be

Table 3

Patients With Adverse Events

No.	Event	Age, yr	Underlying Disease or Condition	LVEF, %	Sex	Intervention	Outcome
1	Symptomatic hypotension	56	Dilatative cardiomyopathy	25	Male	Reduction of sacubitril/valsartan	Resolved without sequelae
2	Symptomatic hypotension	79	Dilatative cardiomyopathy	40	Male	Dose reduction of valsartan	Resolved without sequelae
3	Symptomatic hypotension	64	NSTEMI, VF, CPR	50	Male	Dose reduction of lisinopril	Resolved without sequelae
4	High number of WCD alarms	63	STEMI	30	Female	Ambulatory check-up at device clinic, reprogramming of VT/VT thresholds	Resolved without sequelae
5	High number of WCD alarms	77	STEMI, CPR	50	Male	Ambulatory check-up at device clinic, smaller fabric garment for WCD to improve skin-electrode contact	Resolved without sequelae

Abbreviations: CPR, cardiopulmonary resuscitation; NSTEMI, non-ST-elevation myocardial infarction; STEMI, ST-elevation myocardial infarction; VF, ventricular fibrillation; WCD, wearable cardioverter-defibrillator.

positively influencing completion rates. The authors suggest a home-based and more personalized CR approach and a better patient education to enhance their motivation and adherence to CR programs.[23]

Our data from the CR3 study confirm underutilization of CR measures while no severe adverse events would confirm a hazard from the device itself. The WCD may serve as a tool for prolonged CR measures in an outpatient setting, as former studies have tested the device to surveil a 6-min walking test.[24,25] Integrated in the WCD, accelerometers can detect not only the step count and the average heart rate, but also the body position during day and night already tested in studies.[26-28] Data from an ICD cohort during the COVID-19 pandemic confirmed the need for telemedically controlled home-based exercise training programs.[29] These data could help to confirm the success of CR measures and guide ambulatory or home-based post-CR exercise training to enhance CR success and increase CR attendance rates.

ALARMS, MALIGNANT ARRHYTHMIAS

The percentage of alarms in general and the distribution into inappropriate alarms is comparable to those in literature.[12,24,30-32] However, the high number of alarms did not seem to reduce wearing compliance that was overall very high.

Analogously to ICD cohorts during CR, no severe adverse events such as fatal inappropriate shocks were captured in this cohort. An advantage of the wearable device is that alarms precede an imminent shock. Patients can abort an inappropriate treatment if necessary. Only two patients needed adjustments to lower the number of inappropriate alarms, while in ICD patients an adjustment of the detection rate should be considered recommended in every patient after documentation of the exercise heart rate.

Furthermore, reprogramming of device settings does not need a specific programming device like one would need for an ICD. A trained technician could reprogram the device according to the CR physician advice at the CR facility.

Moreover, a benefit of the WCD could also be that there is no need for a CR delay after an acute event and the time-point of referral to CR compared with a patient with an implantable device with electrodes that need several weeks to settle.

OUTCOMES

The results suggest that patients in CR with a WCD resulted in improved modifiable risk factors like body weight, body mass index, blood pressure, and exercise capacity without specific hazards. The device itself did not seem to prevent patients from exercise training. Left ventricular dysfunction was a frequently mentioned reason why for example exercise-based testing was not performed. Early increased physical activity is associated with improved survival and is a goal that should be sought.[9]

While this analysis is the first of its kind to document CR in all patients with a prescribed WCD in a country over a period of 10 yr, its limitations lie in its retrospective design. No randomization or control group was established because the goal was to investigate the

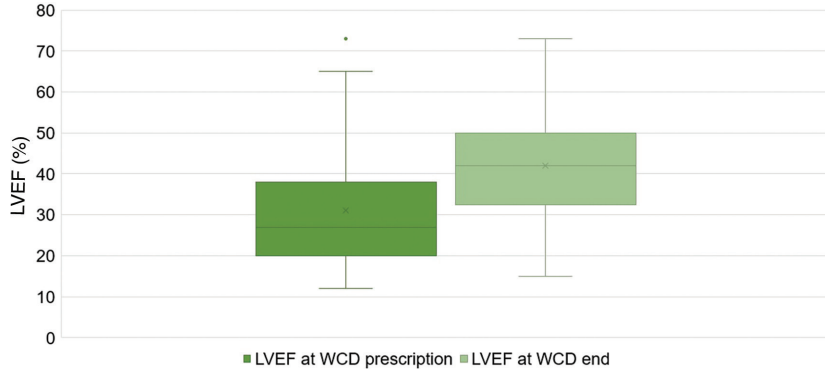

Figure 2. Increase in LVEF from the time point of prescription (median LVEF 36% [11]) compared with LVEF at the end of WCD wearing period (median 94 d [67], median LVEF 42% [12]); ($P < .0001$).[1] Abbreviations: LVEF, left ventricular ejection fraction; WCD, wearable cardioverter defibrillator. This figure is available in color online (www.jcrpjournal.com).

feasibility and safety of a WCD during inpatient CR. Another limitation of the study was the small sample size that shows the underutilization of CR measures in Austria, especially in the cohort of WCD patients with elevated risk of arrhythmias.

CONCLUSIONS

Cardiac rehabilitation is important to improve outcomes and QoL and is still underutilized in patients with cardiac diseases. The data suggest that CR is safe for patients with a WCD and feasible while close monitoring to potentially readjust garment and/or programming is necessary. The wearing compliance of patients in CR is consistently good, despite the numerable accounts of automatically triggered alarms due to artifacts.

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