Wearable cardioverter defibrillator after cardiac surgery: Analysis of real-life data from patients at transient risk of sudden cardiac death

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Abstract

Background

Especially in the first 3 months after cardiac surgery, patients are at transient risk of sudden cardiac death (SCD). To close the gap between hospital discharge and the final implantable cardioverter-defibrillator (ICD) decision, guidelines recommend the temporary use of a wearable cardioverter-defibrillator (WCD) to protect these patients from SCD. We investigated real-life data on the safety, effectiveness, and compliance of the WCD in this population.

Methods

Data for analysis were collected via the Zoll Patient Management Network (ZPM) from patients who underwent cardiac surgery and who were discharged with a WCD between 2018 and 2021 at the Cardiac Surgery Center of the University of Erlangen in Germany.

Results

The majority of the 55 patients were male (90.9%) and underwent a coronary artery bypass graft (80.0%). The number of patients with left ventricular ejection fraction (LVEF) > 35% increased from 9.1% at the beginning of WCD use to 58.2% at the end of WCD use. 6 ventricular tachycardia (VT) episodes occurred in 4 patients. 2 patients with VT episodes were appropriately defibrillated by the WCD. There were no inadequate shocks and no fatalities during the observation time. WCD wearing compliance was high with a median wear time of 23.3 hours/day.

Conclusion

This retrospective analysis in a single cardiac surgery center confirms prior data on safety and effectiveness of the WCD in patients in post-surgery care in a real-life setting. The WCD successfully protected patients from SCD during life-threatening VT episodes. WCD wearing compliance was high.

Introduction

Sudden cardiac arrest (SCA) is the sudden cessation of cardiac activity. If there is no spontaneous resolution restoring blood circulation, or if no rapid measures are taken, such as defibrillation, cardioversion, or resuscitation, SCA can lead within minutes to sudden cardiac death (SCD), which is defined as death due to cardiac causes within an hour of symptom onset [1; 2]. In Germany, the SCD rate is approximately 81 cases/100,000 person/years, corresponding to 65,000 deaths per year (3). In 75–80% of the cases, life-threatening ventricular tachycardia/ ventricular fibrillation (VT/VF) are identified as a cause of SCD [4; 5; 2]. Severely reduced left ventricular ejection fraction (LVEF) is the most important risk factor for SCD (2) and highly correlates to life-threatening VT/VF (6). Cardiac surgery is recommended in patients with aortic valve stenosis and left ventricle (LV) dysfunction or significant ventricular arrhythmias (VA) even if they are asymptomatic (2) and can reduce the risk for SCD. Despite

vast advances in surgery techniques, post-surgery mortality risk is high, especially in the first 3 months after the intervention, and often due to reduced LVEF and life-threatening VT/VF [7; 8].

The European Society of Cardiology (ESC) guideline for the diagnosis and treatment of acute and chronic heart failure recommends an implantable cardioverter-defibrillator (ICD) to reduce the risk for SCD for patients with ongoing reduced LVEF for 3 months or longer after diagnosis of heart failure and despite surgery and/or guideline-directed medical treatment [9]. To close the gap between hospital discharge and the final decision on ICD implantation, the ESC guideline for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death recommends since 2015 the use of a wearable cardioverter-defibrillator (WCD) to reduce the risk of SCD in this particularly vulnerable time [10].

A WCD is a vest with non-adhesive electrocardiography electrodes, which continuously monitors the patient's heart rhythm, and defibrillation electrodes, which are designed to automatically deliver a therapeutic shock in case of potentially fatal ventricular tachyarrhythmia [6; 11]. The safety and effectiveness of the use of WCD were confirmed in the randomized controlled trial "VEST" and several large real-world studies. The VEST trial showed a significant reduction of overall mortality in the intention to treat analysis [12] and a significant reduction in mortality due to arrhythmia in the per-protocol and as-treated analysis [13].

Data on WCD use after cardiac surgery and after hospital discharge, until a final decision on implantation of an ICD has been made, are limited.

The aim of this retrospective data analysis of a single cardiac surgery center in Germany was to collect clinical and demographic data on cardiac surgery patients, as well as to analyze the safety, effectiveness, and compliance of WCD use in a real-life setting.

Patients And Methods

Study design and patient population

For this retrospective analysis, data of 55 patients who underwent cardiac surgery between 2018 and 2021 at the Cardiac Surgery Center of the University of Erlangen, Germany, were included. These patients were at risk for sudden cardiac death (SCD) and were discharged with a wearable cardioverter-defibrillator (WCD, LifeVest® Wearable Cardioverter Defibrillator; ZOLL Pittsburgh, Pennsylvania, United States). According to the ethics committee of the Faculty of Medicine University of Erlangen, Erlangen, Germany, this retrospective analysis with fully anonymized patient data did not require a specific assessment by the ethics committee.

Zoll Patient Management Network (ZPM)

The WCD integrated monitoring system documents, and transfers all detected arrhythmias, as well as several other parameters, such as heart rate and rhythm, electrocardiography (ECG), and wear-time, to the Zoll Patient Management Network (ZPM). Based on this information, the treating physician can adjust

therapy and medication as needed. The ZPM automatically processes and stores data. For this retrospective data analysis, data from the ZPM as well as data collected during clinical routine were used. Components and detailed functionality of the WCD are described elsewhere (15).

Data collection

Demographic characteristics, data on diagnosis, cardiac surgery, and hospital stay, as well as data on medication and cardiac arrhythmia pre- and post-surgery, were collected in routine clinical care. Moreover, LVEF was determined before surgery, at the beginning and end of WCD use. During WCD use, average wear time per day, occurrence of arrhythmia and their treatment, post-shock rhythm as well as reason for the end of WCD use were collected.

Statistical analysis

The proportion of days when the WCD was worn (i.e., number of days actually wearing the WCD in relation to the number of days having the WCD), the time until the first episode with VT/VF after surgery as well as the first episode of VT/VF after the start of WCD use were calculated.

All data were analyzed descriptively. LVEF was analyzed as numeric and categorical variables (≤ 35% vs > 35%) at various time points (before hospital stay, at the beginning of WCD use, at the end of WCD use). LVEF was also analyzed stratified by age (≤ 60 years vs. > 60 years), sex, original diagnosis, and surgical procedure. Variables related to adherence (average wearing time per day, wear time in days, proportion of days wearing the WCD) were analyzed stratified by age, sex, diagnosis, surgical procedure, LVEF before hospital stay (≤ 35% vs. > 35%), and reason for the end of WCD use.

All analyses were performed using statistical software (SAS, version 9.4).

Results

Patient and clinical characteristics

In total, 55 patients, who received a WCD after cardiac surgery at discharge from the hospital, were included in this retrospective data analysis. Most of the patients were male (90.9%) with a median age of 60 years (IQR: 55–70 years) (Table 1). A total of 44 patients (80%) underwent coronary artery bypass graft (4 [7.3%] in combination with heart valve intervention), and 6 patients (10.9%) had an ICD explantation mainly due to device infection. The median time in hospital was 17 days (IQR: 13–24). 14.5% of the patients had a history of atrial fibrillation.

The occurrence of arrhythmia before and after surgery is described in Table 2. The majority of patients (> 65%) were treated with beta-blockers, diuretics, angiotensin-converting enzyme (ACE) inhibitors, and/or statins before surgery. After surgery, even more patients received medical treatment (beta-blockers: 96.5%, diuretics: 90.9% ACE inhibitors: 85.5%, statins: 83.6%).

No deaths occurred during the use of a WCD.

Table 1
Patient and clinical characteristics

Characteristic		
Male, n (%)		50 (90.9%)
Age (years), median [IQR]		60 [55–70]
History of atrial fibrillation, n (%)		8 (14.5%)
Diagnosis*, n (%)	ICM	42 (76.4%)
	Myocardial infarction	5 (9.1%)
	Myocarditis	1 (1.8%)
	Peripartum cardiomyopathy	0 (0.0%)
	Other NICM	5 (9.1%)
	Miscellaneous	3 (5.5%)
Procedure, n (%)	CABG	40 (72.7%)
	Combined CABG/valve intervention	4 (7.3%)
	Isolated valve surgery	3 (5.5%)
	ICD explantation	6 (10.9%)
	Miscellaneous	2 (3.6%)
Days in hospital, median [IQR]	Total time	17 [13–24]
	General ward	12 [9–18]
	Intermediate care	1 [0–4]
	Intensive care unit	2 [1–4]

CABG: coronary artery bypass graft; ICD: implantable cardioverter/defibrillator; ICM: ischemic cardiomyopathy; IQR: interquartile range, 1st – 3rd quartile; NICM: non-ischemic cardiomyopathy

*One patient with two diagnoses

Table 2
Arrhythmia and medication before and after surgery

		Before surgery	After surgery
Arrhythmia, n (%)	nsVT, n (%)	5 (9.1%)	4 (7.3%)
	VT	7 (12.7%)	4 (7.3%)
	VF	4 (7.3%)	2 (3.6%)
	Bradycardia	2 (3.6%)	5 (9.1%)
Medication, n (%)	Beta-blockers	43 (78.2%)	53 (96.4%)
	Diuretics	41 (74.5%)	50 (90.9%,)
	ACE inhibitors	39 (70.9%)	47 (85.5%)
	Statins	36 (65.5%)	46 (83.6%)
	Entresto	8 (14.5%)	10 (18.2%)
	Dapagliflozin	10 (18.2%)	16 (29.1%)
	Amiodaron	2 (3.6%)	5 (9.1%)
	Other	42 (76.4%)	51 (92.7%)

ACE: angiotensin converting enzyme; nsVT: non-sustained ventricular tachycardia, VF: ventricular fibrillation; VT: ventricular tachycardia

Left ventricular ejection fraction (LVEF)

Median LVEF before hospital stay and at start of WCD use was 25.0% (IQR before hospital stay: 20.0–35.0%; IQR at start of WCD use: 20.0–30.0%) and improved at the end of WCD use (median: 40.0%, IQR: 25.0–45.0%) (Fig. 1A). The proportion of patients with LVEF > 35% dropped from 21.8% before hospital stay to 9.1% after surgery/beginning of WCD use and increased to 58.2% at the end of WCD use (Fig. 1B).

The percentage of patients with LVEF > 35% for each time point by subgroups is given in Table 3. At each time point, the percentages of men and women with LVEF > 35% were similar. While the percentage of patients with LVEF > 35% before hospital stay and at the beginning of WCD use did not differ essentially between age groups, a higher percentage of patients ≤ 60 years of age (67.9%) showed LVEF > 35% at the end of WCD therapy compared to older patients (48.1%). Because of the low number of patients in some of the subgroups, the results should be interpreted with caution.

Table 3
Patients with LVEF > 35% in subgroups.

		N	Before hospital stay	Beginning of WCD use	End of WCD use
			n (%)	n (%)	n (%)
Total		55	12 (21.8%)	5 (9.1%)	32 (58.2%)
Sex	Female	5	1 (20.0%)	1 (20.0%)	3 (60.0%)
	Male	50	11 (22.0%)	4 (8.0%)	29 (58.0%)
Age	≤ 60 years	28	6 (21.4%)	3 (10.7%)	19 (67.9%)
	> 60 years	27	6 (22.2%)	2 (7.4%)	13 (48.1%)
Diagnosis	ICM	42	7 (16.7%)	1 (2.4%)	24 (57.1%)
	Myocardial infarction	5	1 (20.0%)	0 (0.0%)	2 (40.0%)
	Myocarditis	1	1 (100.0%)	1 (100.0%)	1 (100.0%)
	Other NICM	5	1 (20.0%)	1 (20.0%)	4 (80.0%)
	Miscellaneous	3	2 (66.7%)	2 (66.7%)	2 (66.7%)
Procedure	CABG	40	7 (17.5%)	0 (0.0%)	22 (55.0%)
	Combined CABG/ valve intervention	4	0 (0.0%)	0 (0.0%)	3 (75.0%)
	Isolated valve surgery	3	0 (0.0%)	0 (0.0%)	2 (66.7%)
	ICD explantation	6	4 (66.7%)	4 (66.7%)	4 (66.7%)
	Miscellaneous	2	1 (50.0%)	1 (50.0%)	1 (50.0%)

CABG: coronary artery bypass graft; ICD: implantable cardioverter/defibrillator; ICM: ischemic cardiomyopathy; NICM: non-ischemic cardiomyopathy; WCD: wearable cardioverter/defibrillator

VT/VF episodes and treatment shocks during WCD use

During WCD use, only appropriate shocks (i.e., no superfluous or inappropriate shocks) were delivered. 10 patients (18.2%) experienced atrial fibrillation, and 4 patients (7.3%) experienced VT episodes (in total, 6 VT episodes). All initial VT episodes occurred within 3 months after surgery (range: 14–58 days). No treatment shocks were required for 4 VT episodes because of the following reasons: For 2 VT episodes, patients were conscious and pressed the response button to prevent the shock; 1 episode was a non-sustainable VT (nsVT) (15 sec), and 1 episode showed only two short ventricular salves. Two VT episodes warranted shocks and were adequately treated by the WCD. These two patients are described in detail in Table 4.

Both patients were male and underwent cardiac surgery without complications. Patient 1 underwent cardiac surgery because of Ebstein malformation, and patient 2 had an ICD explantation because of infection. Initially, ICD was implanted as secondary prophylaxis. While patient 1 had LVEF > 35% before surgery, at the beginning and at the end of WCD use, patient 2 had LVEF ≤ 35% at all time points. After WCD use, patient 1 underwent an ICD implantation for the first time, and patient 2 underwent ICD re-implantation. Patient 1 experienced VT episodes 21 and 30 days after surgery, respectively. Patient 2 experienced VT episodes 29 and 110 days after surgery, respectively. In both patients, WCD defibrillation was successful in re-establishing a sinus rhythm.

Table 4
Description of two patients with shocks

	Patient 1	**Patient 2**
Sex	Male	Male
Age (years)	64	59
Diagnosis	Aneurysm of sinus valve; Ebstein malformation	ICM
Procedure	Repair of congenital cardiac malformation	ICD explantation due to infection
LVEF (%)		
Before hospital stay	60	25
At beginning of WCD use	50	35
At end of WCD use	55	20
Mean daily wearing time (hours)	20.0	23.3
Wear time (days)	21	92
Reason for end of WCD use	ICD implantation	ICD re-implantation
Time between surgery and VT episode (days)	21	29
1st episode	30	110
2nd episode		
VT: ventricular tachycardia; WCD: wearable cardioverter/defibrillator		

WCD compliance

The general WCD wearing compliance was very satisfactory. However, one patient refused to wear the WCD at all. For about half of the patients (50.9%), WCD use could be discontinued upon doctor's advice

because of improvement of their LVEF (Table 5). For more than one-third of the patients (36.4%), WCD use was discontinued because an ICD implantation was performed. WCD use was terminated for 5 patients (9.1%) because of non-compliance.

Median wearing time was 23.3 hours per day (IQR: 21.9–23.8 hours) on 66 days (IQR: 37–87 days). The median proportion of days with WCD use was 96.2% (IQR: 88.9–97.6%). There was no difference in sex, age, original diagnosis, LVEF, and surgical procedure concerning median wearing time per day. Patients with LVEF > 35% showed a shorter median wear time in days (30.0 days [IQR: 16.0–77.5]) than patients with LVEF ≤ 35% (66.0 days [IQR: 45.0–88.0]). Median wear time in days was somewhat longer in patients ≤ 60 years (67.0 days [41.5–86.0]) compared to elderly patients (57.0 days [31.0–88.0]). No essential differences in compliance between other subgroups were observed (data not shown).

Table 5
WCD compliance and reason for the end of WCD use

	Reason for end of WCD therapy			
	ICD implant	LVEF improvement	Non-Compliance	Others
Reason for end of WCD use, n (%)	20 (36.4)	28 (50.9%)	5 (9.1%)	2 (3.6%)
Mean daily wearing time (hours), median [IQR]	23.6 [22.7–23.8]	23.1 [13.0–23.6]	21.2 [19.9–24.0]	23.5 [23.3–23.6]
Wear time (days), median [IQR]	68.5 [60.5–93.0]	56.0 [37.5 – 81.5]	16.0 [3.0–18.0]	94.5 [87.0–102.0]

ICD: implantable cardioverter/defibrillator; IQR: Interquartile range; LVEF: left ventricular ejection fraction; WCD: wearable cardioverter/defibrillator

Discussion

In this retrospective analysis from a single cardiac surgery center in Germany, safety, effectiveness, and compliance of WCD use were investigated in patients after cardiac surgery in a real-life setting. The presented data complement the study results of a recent, large German multi-center study reported by Kuehn et al. [14]

In post-surgical patients, the temporary use of WCD is particularly warranted in patients at high risk for SCD. In our study population, 50 (90.9%) patients had an LVEF ≤ 35% after surgery and were, therefore, by broad consensus, at high risk for SCD. A substantial number (n = 4, 7.3%) of the study patients experienced VT episodes while wearing the WCD. In these patients, as expected, the first VT episode occurred within 3 months (14–58 days) after surgery. In 2 patients (3.6%) the WCD registered a life-threatening VT warranting an intervention and successfully delivered a defibrillation shock in both cases. During the observational time, none of the WCD devices delivered inappropriate shocks. In four instances, shock delivery was not necessary, and VT episodes were, correctly not treated. These findings on the

effective delivery of shocks are in line with the recently published German multi-center study, which included 1168 patients using WCD after cardiac surgery [14]. In the multi-center study, 9.1% of the patients experienced VT/VF episodes. Almost all episodes (93.2%) occurred within the first three months after surgery. 1.5% of the patients required a shock delivery. 0.7% received an inappropriate shock.

In approximately half of the patients in our study, a prophylactic ICD implantation was eventually not necessary due to a clinically relevant improvement of LVEF. This observation is in line with prior data and strengthens the role of a WCD as a crucial bridging therapy during the waiting time until a final decision on the need for an ICD can be made and particularly during the high-risk postoperative period. The ESC has clearly pointed out the need for temporary protection from SCD by a WCD, especially in patients after cardiac surgery [10; 9]. Notably, ICD implantation remains a necessity for many patients due to ongoing symptomatic heart failure and LVEF $\leq$ 35% despite $\geq$ 3 months of medical treatment [9]. In our study, one-third of the patients had to undergo ICD implantation.

There were differences shown in the further clinical course between patients < 60 and > 60 years. The data show that the proportion of patients with an EF > 35% at < 60 years increases from 21.4–67.9%, while at > 60 years, it only increases from 22.2–48.1%. We couldn't have a clear clue why that happened regarding this data. That is why we designed a prospective observational study that should be completed in the next five years to address whether the patient's physical activity after the operation might influence the recovery of the myocardium.

To ensure high effectiveness, the continuous wearing of the WCD is one of the main requirements for effective protection from SCD [13]. In this real-life setting, WCD-wearing compliance of patients in post-surgery care with transient risk for SCD was very high, as the device was worn on almost all days (96%), with an average daily wearing time of more than 23 hours. These findings are in accordance with previous studies on patients using a WCD [14; 16].

Strengths and limitations

A limitation of this study is the rather low number of patients from a single cardiac surgery center, making comparisons between subgroups difficult. However, our study still gives valuable insight in the efficacy of the WCD in a real-life setting. Moreover, our study supports the reported findings of a large German multi-center study [14].

Conclusions

In conclusion, our retrospective analysis confirms the effectiveness and safety of the WCD in a real-life setting. It supports prior data on good patient compliance, in spite of the specific situation of heart surgery patients, especially those after thoracotomy. We showed that the WCD successfully protected patients from SCD during life-threatening VT episodes after cardiac surgery. The collected data support the high benefit of WCD use to increase patient safety after cardiac surgery.

Declarations

Conflicts of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics approval and consent to participate:

According to the ethics committee of the Faculty of Medicine University of Erlangen, Erlangen, Germany, this retrospective analysis with fully anonymized patient data did not require a specific assessment by the ethics committee.

Consent for publication:

Not applicable

Availability of data and materials:

The raw data supporting the conclusions of this article will be made available by the authors without undue reservation to any qualified researcher.

Competing interests:

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Authors' contributions:

The concept/design was done by M.B. and T.S., and critical revision of the article was done by M.W.; Data interpretation and drafting of the article were made by M.B., F.H. . All authors reviewed the manuscript.

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Figures

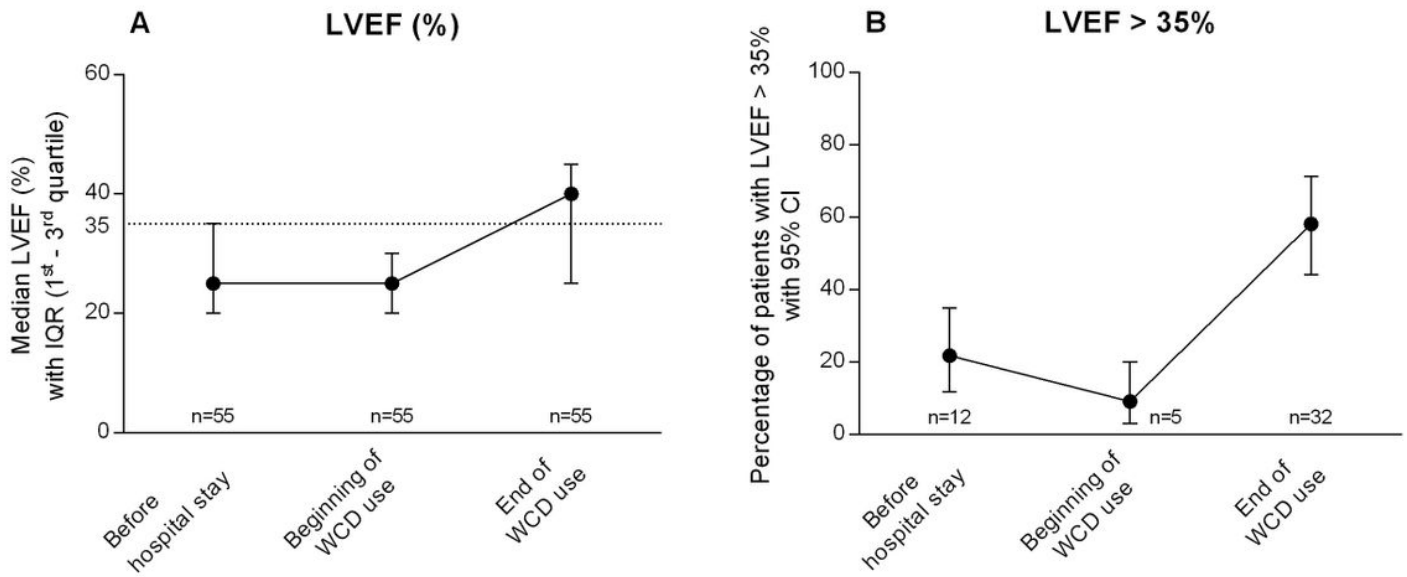

Figure 1

1. Progress of LVEF

CI: confidence interval; LVEF: left ventricular ejection fraction; WCD: wearable cardioverter/ defibrillator