

Wearable Cardioverter–Defibrillators following Cardiac Surgery—A Single-Center Experience

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Abstract

Background A wearable cardioverter–defibrillator (WCD) can terminate ventricular fibrillation and ventricular tachycardias via electrical shock and thus give transient protection from sudden cardiac death. We investigated its role after cardiac surgery. **Methods** We retrospectively analyzed all patients who were discharged with a WCD from cardiac surgery department. The WCD was prescribed for patients with a left ventricular ejection fraction (LVEF) of $\leq 35\%$ or an explanted implantable cardioverter–defibrillator (ICD).

Results A total of 100 patients were included in this study, the majority ($n = 59$) had received coronary artery bypass graft surgery. The median wearing time of a WCD patient was 23.5 hours per day. LVEF was $28.9 \pm 8\%$ after surgery and improved in the follow-up to $36.7 \pm 11\%$ ($p < 0.001$). Three patients were successfully defibrillated. Ten patients experienced ventricular tachycardias. No inappropriate shocks were given. An ICD was implanted in 25 patients after the WCD wearing period.

Conclusion Ventricular arrhythmias occurred in 13% of the investigated patients. LVEF improved significantly after 3 months, and thus a permanent ICD implantation was avoided in several cases. Sternotomy did not impair wearing time of the WCD. A WCD can effectively protect patients against ventricular tachyarrhythmias after cardiac surgery.

Keywords

- Arrhythmia Therapy
- surgical
- heart failure
- postoperative mortality

Introduction

Cardiac surgery in patients with severely reduced left ventricular ejection fraction (LVEF) has become a routine procedure. Advancements in surgical therapy reduced the operative risk and reached good outcomes.¹ Yet, impaired LVEF is associated with high perioperative and postoperative mortalities, with arrhythmias being among the relevant causes of death. The risk of sudden cardiac death (SCD) is especially high in the first 3 months after cardiac surgery.^{1–3}

Nonsurgical patients with severely reduced LVEF showed an elevated risk of ventricular tachycardias and ventricular fibrillation (VF).^{4,5} An implantable cardioverter–defibrillator

(ICD) can terminate potentially lethal ventricular arrhythmias (VAs) and thus prevent SCD. The prophylactic implantation of an ICD led up to 30% less mortality in nonsurgical patients with ischemic and nonischemic cardiomyopathies.^{4,6} Consequently, the European Society of Cardiology and the American Heart Association recommend an ICD implantation for patients with LVEF $\leq 35\%$. The decision is made after 3 months of optimal medical therapy for congestive heart failure because an improvement in pump function is expected.^{7,8} A severely reduced LVEF is seen as the most important risk factor and thus a patient may be at risk for SCD when first diagnosed with low LVEF but may cease to be at risk after a period of cardiac regeneration via

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medical or surgical therapy. LVEF was seen to increase up to 6 months after surgical revascularization.^{9,10} In those cases, the permanent implantation of an ICD can be avoided along with potential complications such as device infection or bleeding. Furthermore, regular, life-long ICD device interrogations are avoided which may be beneficial for the patients' comfort and potentially reduces health care expenditure.

To protect patients at risk before the definite decision about an ICD implantation, a wearable cardioverter–defibrillator (WCD) can be used to terminate hemodynamically relevant ventricular tachycardia and VF.^{11,12} The use of a WCD is currently recommended in patients who need transient protection from SCD.^{13–15}

At our department, patients are routinely screened after cardiac surgery and before discharge into rehabilitation program. Patients with LVEF $\leq 35\%$ are equipped with a WCD for 3 months to protect them from SCD after surgery. Patients with ICD infections undergo aggregate explantation and are then discharged with a WCD until proper freedom from infection is achieved and a reimplantation of the ICD can safely be made. The objective of this study was to track the improvement in LVEF, the incidence of ventricular tachyarrhythmias, and the efficacy and safety of WCDs in patients who had undergone recent cardiac surgery.

Patients and Methods

Study Population

We included all patients who were discharged with a WCD (LifeVest Wearable Defibrillator; Zoll, Pittsburgh, Pennsylvania, United States) from the department of cardiothoracic, transplantation, and vascular surgery. Patients with LVEF of $\leq 35\%$ or those who underwent an explantation of an existing ICD due to infection were prescribed a WCD.

Materials

The LifeVest WCD is a vest containing electrocardiogram (ECG) and shock electrodes. A sequence of alarms is initiated in case of a detection of VA. A biphasic defibrillation shock is delivered if the alarm is not stopped by pressing the WCD response button on the vest. The patient will do so as long as the VA episode has no hemodynamic relevance and does not lead to unconsciousness. The mechanism also prevents inappropriate shocks in case of ECG misinterpretation. The device can deliver up to (...) five shocks per VA episode. A pacing function is not included. The LifeVest records the wearing time (based on the ECG) as well as automatically identified VA episodes, use of response button and shocks. A detailed description of the technical features is given by Klein et al.¹⁶

Data Collection

Clinical data were collected retrospectively from our institutions' electronic records. Included in the data analyses were age, sex, type of surgery, atrial fibrillation events, mitral valve insufficiency, extent of coronary vessel disease, and LVEF at the time of WCD prescription and at a 3-month follow-up. ECGs of VAs, WCD shocks, and WCD-wearing time

were analyzed in the automatically recorded WCD data provided by Zoll. The institution's ethics board approved the study.

Statistical Analyses

Clinical data were analyzed using descriptive statistics with median and interquartile range (IQR) or mean \pm standard deviation, as appropriate. Possible predictors of VAs and WCD shocks were analyzed using chi-square and Student's *t*-tests in independent samples. The change in LVEF was compared by Student's *t*-test in paired samples. Differences in median wearing time were compared between genders using the nonparametric Mann–Whitney's *U*-test. A two-sided level of significance of $p < 0.05$ was assumed. Statistical analyses were performed with SPSS 24.0 (IBM, Chicago, Illinois, United States).

Results

We identified 100 patients who were discharged with a WCD after cardiac surgery between 2012 and 2017. The mean age in the patient cohort was 67 ± 10 years. Seventy-nine patients were male and 21 were female. Fifty-eight patients had coronary artery bypass graft (CABG) surgery of which 41 procedures were isolated coronary revascularizations. The types of cardiac surgeries performed on the patient cohort are presented in ►Table 1.

Thirteen patients experienced VAs of which three were defibrillated by the WCD. All shocks were successful and no patient received inappropriate shocks by the WCD. Asystole did not occur in any of the patients. Out of 16, 3 (18.75%) patients with ICD explantation experienced VAs. Out of the 16, 1 (6.25%) patient received a WCD shock while having VA. Out of 84, 10 (11.9%) patients with heart–lung–machine surgery had VA of which 2 patients (2.38%) received a WCD shock. These two patients had a severe ischemic cardiomyopathy with a significant left main coronary artery stenosis. The patient with WCD shock after ICD explantation was a 50-year-old woman who had received an ICD because of a long-QT syndrome. An ECG of a WCD shock due to VF is

Table 1 Types of surgery

Type of surgery	Number of patients
Isolated CABG	41
CABG and valve	16
CABG and aortic	1
Isolated valve surgery	22
ICD explant	16
LVAD explant	1
Aortic surgery (isolated)	2
Vascular surgery	1
Total	100

Abbreviations: CABG, coronary artery bypass graft; ICD, implantable cardioverter–defibrillator; LVAD, left ventricular assist device.

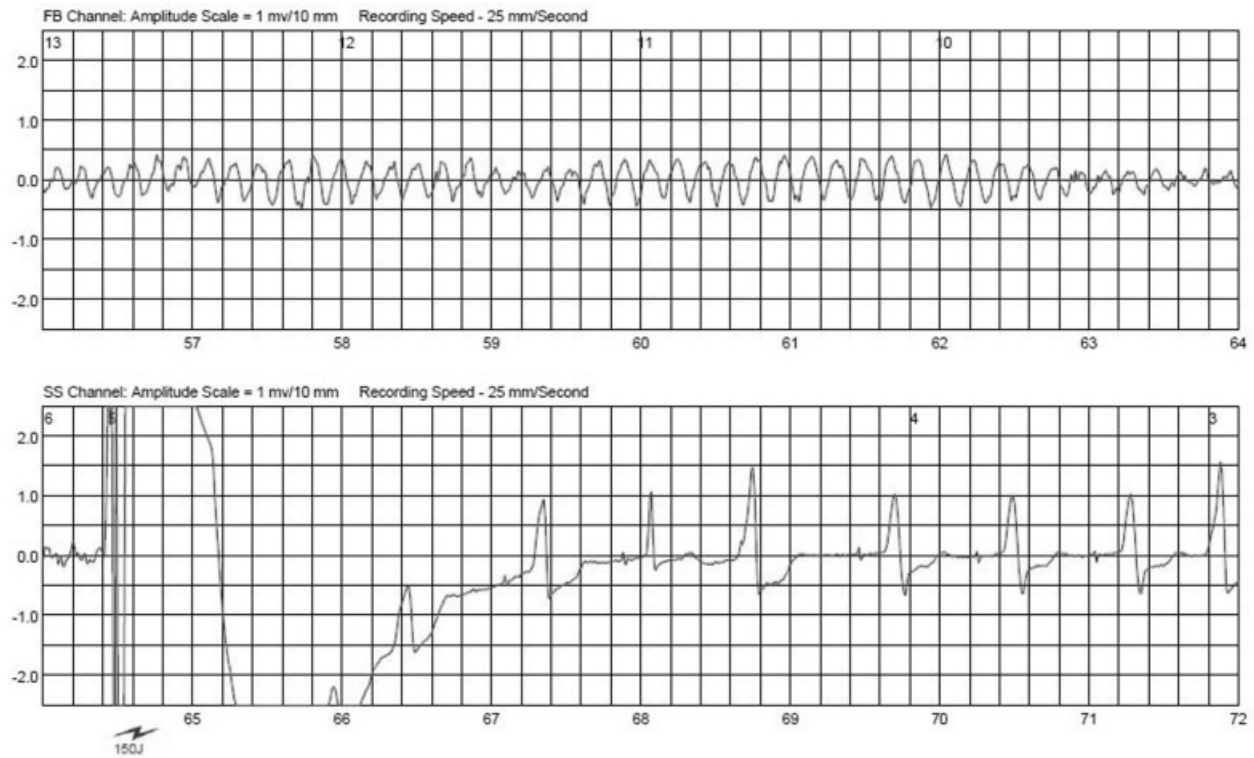


Fig. 1 Treatment of ventricular fibrillation.

shown in ►**Fig. 1**. There were 10 patients with ventricular tachycardias which were not hemodynamically relevant and the WCD button was pressed by the patient to prevent a device shock (►**Table 2**). Mean tachycardic cycle length of self-terminating VTs was 370 ± 50 milliseconds (range: 294–420 milliseconds). Mean duration was 47.25 ± 75.35 seconds (range: 3.12–199.52 seconds). An ECG of a self-terminating VT as recorded by the WCD is shown in ►**Fig. 2**. The majority of patients had ischemic cardiomyo-

pathy, most of them had coronary artery disease and some of them combined with valvular diseases. One patient had only valvular heart disease and two patients were treated with ICD explantation due to device infection. An ICD was implanted in 25 patients after the wearing period of the WCD. The majority received a reimplantation of the ICD after infection-related explantation: out of 16 patients with ICD explantation as primary surgery, 12 received a reimplantation after being prescribed with a WCD (75%). Of the four

Table 2 Patients with ventricular tachycardias

Patient	Sex	Age	Surgery	CM	LVEF (%)	CAD	Time to VT (d)
1	Male	63	MVR + CABG	ICM	15	CAD-3	105
2	Male	76	CABG	ICM	25	CAD-3	32
3	Male	78	CABG	ICM	30	CAD-3	78
4	Male	48	CABG	ICM	30	CAD-3	16
5	Male	77	AVR + CABG + Maze	ICM	25	CAD-3	11
6	Male	63	CABG	ICM	20	CAD-3	34
7	Male	57	MVR + CABG	ICM	20	CAD-2	15
8	Male	50	AVR + TVR + ASD	DCM	30	No	11
9	Male	77	ICD explant (infection)	DCM	25	No	5
10	Male	68	ICD explant (infection)	ICM	35–40	CAD-1	20

Abbreviations: ASD, atrial septal defect closure; AVR, aortic valve replacement; CABG, coronary artery bypass graft; CAD, coronary artery disease; CAD-3, three-vessel coronary artery disease; CM, cardiomyopathy; DCM, dilated cardiomyopathy; ICD, implantable cardioverter–defibrillator; ICM, ischemic cardiomyopathy; LMCA, left main coronary artery stenosis; MVR, mitral valve replacement; TVR, tricuspid valve reconstruction; VT, ventricular tachycardia.

Note: Time to VT, days from date of surgery.

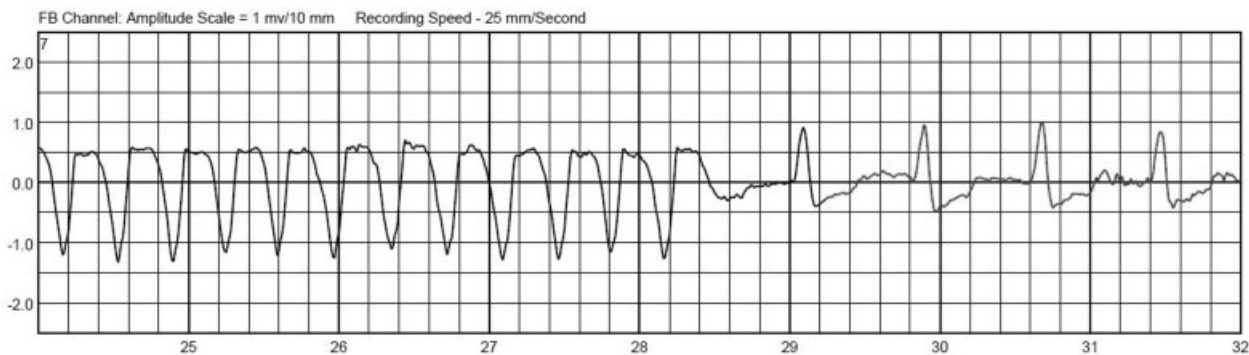


Fig. 2 Self-terminating ventricular tachycardia.

remaining patients, two had no preventive indication anymore and thus were not reimplanted. Two patients decided against reimplantation after the follow-up period.

The median time to WCD shock was 21 days (IQR: 10–50). The patients who received a WCD shock are presented in **Table 3**. The median time to the first episode of ventricular tachycardia was 19 days (IQR: 12–52).

The median wearing period was 60 days (IQR: 28–95), median time to echocardiographic follow-up of LVEF was 98 days (IQR: 55–106). Wearing time per day in our patient cohort was almost all day with a median of 23.5 hours per day (IQR: 21.4–23.8). There was no difference in the wearing time per day between male and female patients ($p = 0.587$).

At the follow-up echocardiography, LVEF significantly improved compared with the postsurgery measurement. LVEF was $28.9 \pm 8\%$ after surgery, and at the follow-up, showed a mean LVEF of $36.7 \pm 11\%$ ($p < 0.001$). The mean change in LVEF was 7.8% (95% confidence interval [CI]: 4.3–11.4, $p < 0.001$). Subgroup analysis showed a significantly higher improvement in LVEF in isolated valve surgeries compared with other types of surgeries, with a mean improvement of $+11.98\%$ (95% CI: 3.99–19.96, $p = 0.004$). Patients with ICD explantation had a nonsignificant decrease in LVEF.

There was no significant difference in the occurrence of VT or VF in the type of surgical procedure. Three-vessel disease, left main coronary artery stenosis, mitral regurgitation, and atrial fibrillation were not significant factors for the occurrence of VAs or WCD shocks. After the wearing period of the WCD, an ICD was implanted in 25 patients. Eight revascularized patients out of the 58 revascularization surgeries needed a permanent ICD (13.8% of the revascularization

subgroup) and 5 patients with valve surgery out of 22 were provided permanently with an ICD (22.7% of the valve-only subgroup).

Discussion

AWCD is prescribed for patients with elevated risk for tachyarrhythmias. This includes patients with LVEF $\leq 35\%$ with the potential to improve cardiac function and patients with other temporary risks for tachyarrhythmias without an ICD.

We present the findings of our single-center experience from WCD patients after cardiac surgery. The daily wearing time was 23.5 hours which shows a high level of acceptance despite recent sternotomy and partial wound healing still in progress. Anatomic differences in male and female patients might have disturbed wearing comfort but a gender-specific difference in wearing time could not be seen ($p = 0.587$). Our results show that the cardiac pump function after surgery was severely impaired (LVEF 28.9%), and at the follow-up, improved above the threshold for an ICD indication (LVEF 36.7%, $p < 0.001$). The subgroup analysis showed significant improvements in LVEF for patients with CABG as well as for valvular surgeries. Patients with ICD explantation declined in their LVEF during the 3-month period of WCD (**Fig. 3**). This may be attributed to a longer history of cardiac disease. In comparison to surgical revascularization or valve replacement, a functional improvement is not the aim of the operation. A permanent ICD implantation after WCD was performed in 25 patients. In 12 patients, ICD explantation due to infection was the primary surgery before WCD. Eight revascularized patients out of the 58 revascularization surgeries needed a permanent ICD (13.8% of

Table 3 WCD defibrillated patients

Patient	Sex	Age	Surgery	CM	LVEF (%)	CAD	Time to shock (d)
1	Male	79	CABG	ICM	25–30	LMCA, CAD-3	21
2	Male	80	CABG	ICM	20	LMCA	70
3	Female	50	ICD explant (infection)	Long-QT	55	No	21

Abbreviations: AVR, aortic valve replacement; CABG, coronary artery bypass graft; CAD, coronary artery disease; CAD-3, three-vessel coronary artery disease; CM, cardiomyopathy; ICD, implantable cardioverter–defibrillator; ICM, ischemic cardiomyopathy; LMCA, left main coronary artery stenosis; WCD, wearable cardioverter–defibrillator.

Note: Time to shock, days from date of surgery.

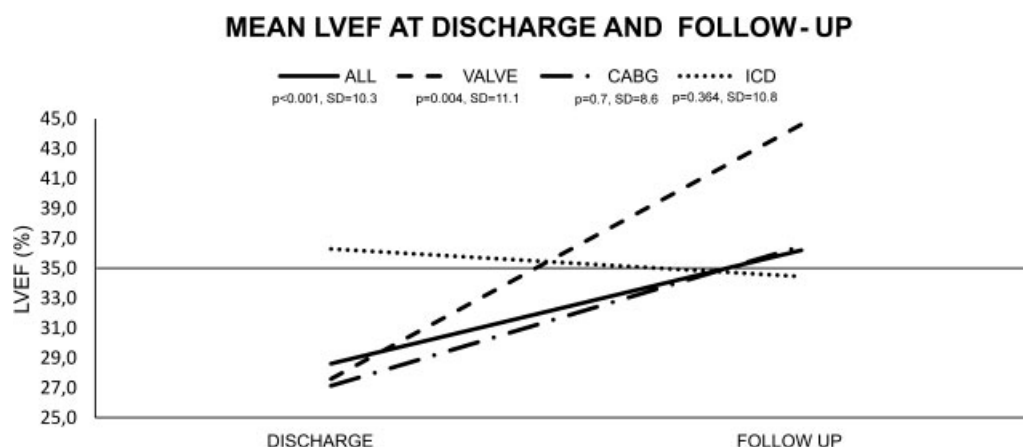


Fig. 3 LVEF in % at discharge and follow-up. CABG, coronary artery bypass graft; ICD, implantable cardioverter–defibrillator; LVEF, left ventricular ejection fraction; SD, standard deviation.

the revascularization subgroup) and 5 patients with valve surgery out of 22 were provided permanently with an ICD (22.7% of the valve-only subgroup). This shows a rather low rate of permanent device implantation although directly after surgery 100 patients were identified as “at risk” for VAs and thus SCD. A substantial proportion of our patients (13%) experienced ventricular tachyarrhythmias and 3% of all patients received appropriate WCD shocks in 3 months postoperatively. Ventricular tachyarrhythmias occurred within 5 to 105 days after surgery, most of them during the first 40 days postoperatively. In the light of 3% VF and therefore potentially fatal arrhythmic events, should it be considered to implant an ICD directly before discharge? In patients with ICD explantation due to infection, we try to avoid a timely insertion of implants to prevent reinfections. A protection through WCD has been successful in other institutions.^{17,18} Patients with CABG or valve surgery significantly improved in their LVEF and therefore ceased to be at risk after a 3-month period of protection through the WCD. An immediate implantation of an ICD would be unnecessary for a relevant part. This finding is consistent with studies for nonsurgical patients with WCD who were treated medically.¹⁹ Avoiding the permanent implantation of an ICD will also prevent possible surgical complications, such as device infections, low battery-related replacement or bleedings, as well as life-long ICD interrogations. This may place less strain on the health care system. We consider the WCD an effective tool in patients with ICD explantation or in those patients with transient risk of experiencing VA. This may save patients from SCD and allow a quicker discharge into a rehabilitation program as proposed by several authors.^{20,21} An alternative might be a prolonged hospital stay for telemetry and intensive care monitoring due to possible VAs. This may not only slow the patient's progression of physical activity after surgery but also cost valuable resources of the medical care system.

In conclusion, the main findings of this study are that (1) WCDs were a safe and effective therapy after cardiac surgery, (2) 13% of patients discharged with WCD had tachyarrhythmias and 3% of all patients received a successful WCD shock, and (3) LVEF improved significantly in our cohort, and thus, an ICD implantation could often be avoided.

Note

The study was presented at the annual meeting of [blinded]. Annual meeting of the German Society for Thoracic and Cardiovascular Surgery (DGTHG) on February 19th, 2018 at Leipzig, Germany.

Limitations

The study provides new data on the use of wearable defibrillators in patients following cardiac surgery, but it is limited due to its retrospective design. The results may be skewed because only 100 patients over the course of 5 years were included which led to a heterogeneous cohort.

Disclosure

All the authors have nothing to disclose.

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