

# Analysis of Patients with LifeVest after Cardiac Surgery

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## Abstract

**Background:** Patients with left ventricular ejection fraction (LVEF)  $\leq 35\%$  are at a high risk of sudden cardiac death (SCD) and benefit from implantable cardioverter-defibrillator (ICD) therapy. ICD implantation is not indicated during the first 40 days after acute myocardial infarction and  $<3$  months after coronary artery bypass grafting, because of possible cardiac function recovery. The wearable cardioverter defibrillator (WCD) is a therapy option for preventing sudden cardiac death at the time of recovery. This study evaluated the effectiveness of the wearable cardioverter-defibrillator in preventing SCD after cardiac surgery. **Methods:** This is a retrospective study conducted in the Heart Center in Cottbus. From 02.2015 through 02.2018 26 WCD patients were retrospectively analyzed and followed-up. Patient demographics, defibrillation treatments, and daily wear times were retrospectively obtained from our clinical database and LifeVest network. The patients were questioned about actual NYHA grade and implanted ICD at the end of follow-up. **Results:** Twenty-five patients (mean age 65, 22 men, 3 women) were treated with a WCD in response to heart failure (mean EF = 24%) after cardiac surgery (21 CABG, 1 AVR, 1 AVR + CABG, 1 AVR + MVR, MVR + CABG). Average daily use of a WCD was 22.1 (SD  $\pm$  2.7) hours which were worn for 85 days (SD  $\pm$  35). At that time 11.96 (SD  $\pm$  15) events were detected but not treated, 1 defibrillation performed and no asystole seen. At the end of follow-up (12 months, SD  $\pm$  9) 20 patients were questioned. All of the patients were alive and 5 (25%) of them were with implanted ICD. 10 (50%) patients were in NYHA grade I, 3 (12%) in NYHA grade II, 3 (12%) between grade II-III, 2 (8%) in grade III and 2 (8%) patients in NYHA grade IV. **Conclusions:** A WCD is an effective therapy for prevention of sudden cardiac death during the recovery period of heart function after cardiac surgery. This is treatment with high patient compliance.

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## Keywords

Wearable Cardioverter-Defibrillator, LifeVest, Cardiac Insufficiency, Cardiac Surgery

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## 1. Introduction

Patients with left ventricular ejection fraction (LVEF)  $\leq 35\%$  are at high risk of sudden cardiac death (SCD) and benefit from implantable cardioverter-defibrillator (ICD) therapy [1] [2]. ICD implantation is not indicated during the first 40 days after acute myocardial infarction and <3 months after coronary artery bypass grafting, because of possible cardiac function recovery [3] [4]. The wearable cardioverter defibrillator (WCD) is a cost-effective therapy option for preventing sudden cardiac death at the time of recovery [5] [6] [7].

One recent literature review showed substantially higher rate of appropriately treated WCD patients over 3 months, compared with the VEST trial [8].

LVEF can increase up to 6 months after Bypass surgery [9]. A wearable cardioverter-defibrillator can be used to protect the patient during recovery time after cardiac surgery and reduce early mortality hazard [10] [11].

At our clinic, postoperative echocardiography is routinely performed before discharge into a rehabilitation program. Patients with LVEF lower than 35% are equipped with a WCD for 3 months to protect them from SCD after surgery. The objective of this study was to track the improvement in NYHA, ICD implantation, the incidence of ventricular tachyarrhythmias, the efficacy and safety of WCDs and patient compliance in patients who had cardiac surgery.

## 2. Patients and Methods

This is a retrospective study conducted in the Heart Center in Cottbus.

### 2.1. Study Population

We included all patients who were discharged between 2.2015 and 2.2018 with a WCD (LifeVest Wearable Defibrillator; Zoll, Pittsburg, Pennsylvania, United States) from the department after cardiac surgery. Patients with an LVEF of <35% were prescribed a WCD.

There were no exclusion criteria for this study.

### 2.2. Materials

The Life Vest is a device containing electrocardiogram and shock electrodes. Alarms are initiated in case of a detection of ventricular arrhythmia (VA). After which biphasic defibrillation shock is delivered if the WCD response button on the vest not pressed. This mechanism prevents inappropriate shocks. The WCD Life Vest records the wearing time, identified VA episodes and use of response button and shocks [12].

### 2.3. Data Collection

Clinical data such as age, sex, type of surgery, atrial fibrillation events and post-operative LVEF were collected retrospectively from our records. ECGs of VAs, WCD shocks and WCD-wearing time were analyzed in the automatically recorded WCD data provided by Zoll. We divided the patients into two groups according to detected arrhythmias and compared all variables. The patients were questioned per telephone about actual NYHA grade and implanted ICD at the end of follow-up.

All procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments.

### 2.4. Statistical Analyses

Clinical data were analyzed using descriptive statistics with median, interquartile range (IQR) and mean standard deviation as appropriate. 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).

## 3. Results

We identified twenty-five patients who were treated with a WCD in response to heart failure after cardiac surgery between 2015 and 2018 (**Table 1**). The mean age in patient cohort was  $65 \pm 9$  years. 22 patients were male and 3 female. Twenty-four patients had CABG surgery from them 21 were isolated CABG (21 CABG, 1 AVR, 1 AVR + CABG, 1 AVR + MVR, MVR + CABG). Nineteen patients experienced VA's of which 1 was defibrillated by the WCD. None of the patients received inappropriate shock and no asystole seen. Eleven patients-initiated recordings and from those 2 were negative, without arrhythmia.

In comparison of patients with detected VA's and those without total worn days showed significance (median [IQR] 54 [41] [56], 92 [78] [105]  $p = 0.004$ ) and patient-initiated recordings showed significant trends (median [IQR] 0 [0, 0], 1 [0, 3]  $p = 0.054$ ). Five (33%) out of 19 patients with detected VA's and 1 (16.7%); patient out of 7 without detected VA received ICD implantation (**Table 2**).

At the end of follow-up (12 months,  $SD \pm 9$ ) 20 patients were questioned. All of the patients were alive and 6 (28.6%) of them were with implanted ICD. Ten (50%) patients were in NYHA grade I, 3 (12%) in NYHA grade II, 3 (12%) between grade II-III, 2 (8%) in grade III and 2 (8%) patients in NYHA grade IV. Average daily use of WCD was 23.3 hours which were worn 85 days ( $SD \pm 35$ ).

## 4. Discussion

A WCD is indicated for patients with an elevated risk for arrhythmias. This includes patients with LVEF lower than 35% with potential cardiac function improvement.

**Table 1.** Characteristics of study population.

	<b>Overall</b>
<b>n</b>	26
<b>Sex = w (%)</b>	3 (11.5)
<b>Age (mean (SD))</b>	64.61 (8.99)
<b>Type of surgery (%)</b>	
<b>AKR</b>	1 (3.8)
<b>AKR + CABG</b>	2 (7.7)
<b>AKR + MKR</b>	1 (3.8)
<b>CABG</b>	21 (80.8)
<b>MKRe + CABG</b>	1 (3.8)
<b>EF post-operative (median [IQR])</b>	25.00 [20.00, 27.75]
<b>Rhythm = SR (%)</b>	20 (76.9)
<b>Diuretics therapy (%)</b>	25 (96.2)
<b>B-Blockers therapy (%)</b>	25 (96.2)
<b>ACE-i/Sartans therapy (%)</b>	23 (88.5)
<b>Alive at the end of follow Up = 1 (%)</b>	21 (100.0)
<b>ICD = 1 (%)</b>	6 (28.6)
<b>NYHA (median [IQR])</b>	1.50 [1.00, 2.50]
<b>Total days worn (median [IQR])</b>	80.50 [55.00, 100.25]
<b>Treatments = 1 (%)</b>	1 (3.8)
<b>Asystoles = 0 (%)</b>	26 (100.0)
<b>Detected not treated (median [IQR])</b>	6.50 [0.50, 10.75]
<b>Patient initiated recordings (median [IQR])</b>	0.00 [0.00, 2.00]
<b>Total patient use percent (median [IQR])</b>	97.50 [93.25, 99.00]
<b>Average daily patient use (median [IQR])</b>	23.34 [22.30, 23.70]

**Table 2.** Characteristics of study population by detected/not detected arrhythmia.

	<b>No</b>	<b>Yes</b>
<b>n</b>	7	19
<b>Sex = w (%)</b>	1 (14.3)	2 (10.5)
<b>Age (mean (SD))</b>	64.92 (7.28)	64.49 (9.72)
<b>Type of surgery (%)</b>		
<b>AKR</b>	0 (0.0)	1 (5.3)
<b>AKR + CABG</b>	1 (14.3)	1 (5.3)
<b>AKR + MKR</b>	0 (0.0)	1 (5.3)
<b>CABG</b>	5 (71.4)	16 (84.2)
<b>MKRe + CABG</b>	1 (14.3)	0 (0.0)

## Continued

<b>EF post-operative (median [IQR])</b>	25.00 [22.50, 28.50]	25.00 [20.00, 27.00]
<b>Rhythm = SR (%)</b>	6 (85.7)	14 (73.7)
<b>Diuretics therapy (%)</b>	7 (100.0)	18 (94.7)
<b>B-Blockers therapy (%)</b>	7 (100.0)	18 (94.7)
<b>ACE-i/Sartans therapy (%)</b>	7 (100.0)	16 (84.2)
<b>Alive at the end of follow Up (%)</b>	6 (100.0)	15 (100.0)
<b>ICD (%)</b>	1 (16.7)	5 (33.3)
<b>NYHA (median [IQR])</b>	1.00 [1.00, 3.00]	2.00 [1.00, 2.50]
<b>Total days worn (median [IQR])</b>	54.00 [41.00, 56.00]	92.00 [78.00, 105.50]
<b>Treatments (%)</b>	0 (0.0)	1 (5.3)
<b>Asystoles (%)</b>	7 (100.0)	19 (100.0)
<b>Detected not treated (median [IQR])</b>	0.00 [0.00, 0.00]	9.00 [5.00, 26.50]
<b>Patient initiated recordings (median [IQR])</b>	0.00 [0.00, 0.00]	1.00 [0.00, 3.00]
<b>Total patient use percent (median [IQR])</b>	95.00 [94.00, 98.00]	98.00 [91.00, 99.00]
<b>Average daily patient use (median [IQR])</b>	22.90 [22.51, 23.45]	23.57 [21.82, 23.71]

We presented a single-center study of WCD patients after cardiac surgery. The daily wearing time was 23.3 hours which shows a high level of compliance despite recent sternotomy. A permanent ICD after a WCD was implanted in 6 (28.6%) patients although directly after surgery 25 patients were identified as at risk for VAs and SCD. 76% (19) experienced ventricular tachyarrhythmias and 5.3% (1) of all patients received appropriate WCD shock in 3 months postoperatively. 198 ventricular tachyarrhythmias occurred after surgery, most of them during the second month (101; 51%) postoperatively.

In analysis of the subgroup with detected and non-detected arrhythmias, total worn days showed significance and patient indicated recordings showed a significant trend. ICD implantation rate was higher in the group with detected arrhythmias. As we see from our analysis, it is not necessary to wear a WCD for all three months. In our study patient group where no arrhythmia was detected a WCD was only worn for 54 days.

At the end of follow-up 20 patients who were reachable by phone were questioned. All of those patients were alive and 6 (28.6%) of them were with implanted ICD. 10 (50%) patients were in NYHA grade I, 3 (12%) in NYHA grade II, 3 (12%) between grade II-III, 2 (8%) in grade III and 2 (8%) patients in NYHA grade IV. Only 1 Patient with implanted ICD had NYHA > 3 grade at the end of follow-up.

The average daily use of a WCD was 23.3 hours which were worn 85 days (SD  $\pm$  35). It shows high patient compliance which was found in several studies [13] [14].

Significant reduction in early mortality was found in the setting of left ventricular dysfunction < 0.35 after CABG or PCI in patients treated with a WCD

[13]. This finding is consistent with our study group after cardiac surgery in which 24 out of 25 operations were CABG.

Avoiding implantation of an ICD has many advantages such as preventing surgical complications, low battery-related replacement, as well as life-long ICD interrogations. This may positively affect the health care system [15]. This can save patients from SCD and allow a quicker discharge [16].

## 5. Conclusion

A WCD is an effective therapy for prevention of sudden cardiac death during the recovery period of heart function after cardiac surgery. It is a treatment with high patient compliance. In some cases, therapy may be prolonged up to 6 months if further improvement is possible.

## Note

The study was presented at the annual meeting of the ESCVS 68th in Groningen (Holland, 2019).

## Limitations

The study is limited due to its retrospective design and heterogeneous cohort.

## Disclosure

All the authors have nothing to disclose.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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