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Retrospective Study

Outcomes after asystole events occurring during wearable defibrillator-cardioverter use

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Abstract

AIM

To examine whether wearable cardioverter defibrillator (WCD) alarms for asystole improve patient outcomes and survival.

METHODS

All asystole episodes recorded by the WCD in 2013 were retrospectively analyzed from a database of device and medical record documentation and customer call reports. Events were classified as asystole episodes if initial presenting arrhythmia was asystole (< 10 beats/minor \geq 5 s pause). Survival was defined as recovery at the scene or arrival to a medical facility alive, or not requiring immediate medical attention. Episodes occurring in hospitals, nursing homes, or ambulances were considered to be under medical care. Serious asystole episodes were defined as resulting in unconsciousness, hospital transfer, or death.

RESULTS

Of the total 51933 patients having worn the WCD in

2013, there were 257 patients (0.5%) who had asystole episodes and comprised the study cohort. Among the 257 patients (74% male, median age 69 years), there were 264 asystole episodes. Overall patient survival was 42%. Most asystoles were considered "serious" ($n = 201$ in 201 patients, 76%), with a 26% survival rate. All 56 patients with "non-serious" asystole episodes survived. Being under medical care was associated with worse survival of serious asystoles. Among acute survivors, 20% later died during WCD use (a median 4 days post asystole episode). Of the 86 living patients at the end of WCD use period, 48 (56%) received ICD/pacemaker and 17 (20%) improved their condition.

CONCLUSION

Survival rates after asystole in patients with WCD are higher than historically reported survival rates. Those under medical care at time of asystole exhibited lower survival.

Key words: Asystole; Bradycardia; Cardiac arrest; Defibrillator; LifeVest

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Core tip: Survival rates after asystole, including serious episodes, in patients being treated with wearable cardioverter-defibrillators is higher than historically reported survival rates in the emergency medicine literature. Wearable cardioverter-defibrillators may improve outcomes by alarming and alerting bystanders to assist patients with asystole events.

Liang JJ, Bianco NR, Muser D, Enriquez A, Santangeli P, D'Souza BA. Outcomes after asystole events occurring during wearable defibrillator-cardioverter use. *World J Cardiol* 2018; 10(4): 21-25 Available from: URL: <http://www.wjgnet.com/1949-8462/full/v10/i4/21.htm> DOI: <http://dx.doi.org/10.4330/wjc.v10.i4.21>

INTRODUCTION

Survival to hospital discharge for out-of-hospital cardiac arrest (OHCA) victims found to be in bradycardia or asystole is low (2%). The wearable cardioverter-defibrillator (WCD) has been increasingly utilized to detect and treat potentially fatal ventricular arrhythmias in high-risk patients with cardiomyopathy and low left ventricular ejection fraction (LVEF). Most life-threatening arrhythmias recorded by the WCD are ventricular arrhythmias (VA) such as ventricular tachycardia (VT) and ventricular fibrillation (VF). The WCD can deliver treatment shocks to terminate these tachyarrhythmias. However, a significant percentage of recorded episodes with WCD have been asystole or severe bradycardia episodes; 24.5% of SCAs in the study by Chung *et al*^[1]. The WCD does not have

antibradycardia pacing capabilities, but does alarm and instruct bystanders to call for help and perform CPR.

Patients with OHCA due to bradycardia or asystole are less likely than those with VT or VF to arrive to the hospital alive and survive to discharge^[2,3]. Shorter time intervals between collapse to initiation of bystander cardiopulmonary resuscitation (CPR) and notification of emergency medical services (EMS) are associated with improved overall survival as well as neurologically favorable survival^[4-9]. Since the WCD alerts for asystole, it may contribute to improved outcomes in patients who suffer from severe bradycardia or asystolic cardiac arrest by alerting bystanders to perform CPR and contact EMS. We examined the incidence of WCD alerts related to outcomes in patients with asystole and/or severe bradycardia.

MATERIALS AND METHODS

Patient population and definitions

All patients prescribed a WCD between January 1, 2013 and December 31, 2013 were analyzed using a corporate database (ZOLL LifeVest). This database includes indications for WCD prescription, baseline demographics (age and gender), complaints, and all device-recorded events. All patients signed consent to use their data and all data were de-identified.

An "asystole episode" was defined as bradycardia with heart rate < 10 beats/min, or having a pause lasting ≥ 5 s. To identify patients with asystole episodes, the database was retrospectively screened to identify all episodes of primary asystole ECG recordings. Episodes of post-shock asystole or asystole following untreated VT episodes were excluded from the study. All episodes were manually adjudicated to ensure that a true asystole event had occurred. For the purposes of this study, a "serious asystole episode" was defined as any life-threatening asystole episode which either required hospitalization or led to unconsciousness or death. "Acute survival" was defined as recovery at the scene or arrival to a medical facility alive, or not requiring immediate medical attention. For the purposes of this study, asystole episodes occurring in a "health care setting" were defined as any events in a hospital, nursing home, or ambulance. Survival was determined by customer call reports at the end of WCD use, or by a mortality search of the Social Security death index if the customer call report at the end of WCD use did not indicate death (data available to 2/28/2014).

Statistical analysis

Descriptive statistics were utilized to describe this population based on data collected at the time of referral for WCD prescription or during use. All continuous values were reported as mean \pm SD, or median and range for skewed distributions. Categorical values were expressed as absolute numbers and percentages. To test for differences in the proportions

Table 1 Patient demographics at the start of wearable cardioverter defibrillator use

Parameter	All (<i>n</i> = 257)	Not serious (<i>n</i> = 56)	Serious (<i>n</i> = 201)
Age, yr (median, range)	69 (25-90)	69 (25-82)	69 (39-90)
Sex			
Male (%)	191 (74.3)	41 (73.2)	150 (74.6)
Female	65 (25.3)	15 (26.8)	50 (24.9)
NA	1 (0.4)	0 (0)	1 (0.5)
LVEF % (median, range) (<i>n</i> = 241 reported)	25 (10-65)	25 (10-65)	27.5 (10-60)
Primary indication, <i>n</i> (%)			
MI/NICM	198 (77.0)	43 (76.8)	155 (77.1)
ICD Explant	22 (8.6)	6 (10.7)	16 (8.0)
VT/SCA	35 (13.6)	7 (12.5)	28 (13.9)
Genetic risk	1 (0.4)	0 (0)	1 (0.5)
NA	1 (0.4)	0 (0)	1 (0.5)
History of diabetes mellitus			
Yes	128 (49.8)	18 (32.1)	110 (54.7) ^c
No	111 (43.2)	38 (67.9)	73 (36.3)
NA	18 (7.0)	0 (0)	18 (9.0)
History of ESRD/HD			
Yes	34 (13.2)	5 (8.9)	29 (14.4)
No	204 (79.4)	51 (9.1)	153 (76.1)
NA	19 (7.4)	0 (0)	19 (9.5)
History of arrhythmias ¹	237	54	183
Patients reported			
Any arrhythmia listed below	169 (71.3)	41 (75.9)	128 (69.9)
Sustained VT/VF	68 (28.7)	19 (35.2)	49 (26.8)
Bundle branch block	49 (20.7)	18 (33.3) ^b	31 (16.9)
AFib/Aflutter/SVT/AT	98 (41.4)	23 (42.6)	75 (41.0)
Bradycardia/Heart Block/PEA	31 (13.1)	6 (11.1)	25 (13.7)

¹Percentages were calculated based on patients with information. ^b $P < 0.05$ as no serious group compared to serious group using Fisher's exact test, P -value are calculated based on patients with information; ^c $P < 0.001$ as no serious group compared to non-serious group using Fisher's exact test. AFib: Atrial fibrillation; Aflutter: Atrial flutter; SVT: Supraventricular tachycardia; AT: Atrial tachycardia; PEA: Pulseless electrical activity; NA: Not reported.

of clinical variables between serious and non-serious asystole episodes, Fisher's exact test was used. Univariate logistical regression analysis was used to identify potential variables associated with survival of serious asystole episodes, where a P value of 0.05 was considered statistically significant.

RESULTS

Of the total 51933 patients having worn the WCD in 2013, there were 257 patients (0.5%) who had isolated asystole episodes and comprised the study cohort (Supplemental Figure). The cohort wore the WCD for 40.8 total patient-years during which a total of 264 asystole episodes occurred (one asystole episode in 251 patients, 2 asystole episodes in 5 patients, 3 asystole episodes in 1 patient). The cohort was 74% male and had a median age of 69 years. Over three-fourths of WCD prescriptions were for recent myocardial infarction (MI) or non-ischemic cardiomyopathy (NICM). Table 1 summarizes the baseline characteristics. A greater proportion of patients having a serious event had a history of diabetes mellitus ($P < 0.001$), while more patients with non-serious asystole episodes had a history of a bundle branch block ($P < 0.05$).

Overall survival for patients with asystole episodes was 42%. The majority of patients had asystole episodes that were considered serious (201; 78%).

The rate of acute survival in patients with serious asystole episodes was 26%, while all 56 patients with non-serious asystole episodes survived. Further analysis for patients with serious asystole episodes suggested that survival was worse when the location was in a healthcare setting (Supplemental Table).

For the 108 patients that survived the acute event, twenty-two (20%) of them later died (median 4 d post-asystole episode), while 86 (80%) survived post-WCD use. Information regarding reason for WCD discontinuation is shown in Table 2. Overall, 44% of patients were implanted with an ICD or pacemaker a median of four days after the asystole episode.

DISCUSSION

This study examines the outcomes of asystole and severe bradycardia during WCD use among patients who were prescribed the device to prevent sudden death due to ventricular arrhythmias. In this population, asystole episodes were infrequent, occurring in 0.5% of patients treated with WCD during the time period. Over three quarters of these asystole episodes were serious enough to result in unconsciousness, hospitalization, or death. Survival rates after asystole episodes and serious asystole episodes were 44% and 26% respectively. These rates are significantly higher than those reported in the literature for non-shockable cardiac arrest.

Table 2 Wearable cardioverter defibrillator discontinuation among acute survivors

Reason	Patients [<i>n</i> = 108, <i>n</i> (%)]	Days post-asystole (median, range)
Received ICD or pacemaker	48 (44.4)	4 (0-175)
Condition improved	17 (15.7)	39 (3-525)
Condition deteriorated	10 (9.3)	4 (0-44)
Patient decision	5 (4.6)	73 (12-80)
Unknown/other	5 (4.6)	33 (0-96)
Died	22 (20.4)	4 (0-44)
Still wearing	1 (0.9)	NA

Due to the increased incidence of life-threatening ventricular arrhythmias in patients with cardiomyopathy and low ejection fraction, a WCD is often recommended for patients who are not immediate candidates for ICD therapy^[10]. These patients may possess a history of palpitations or syncope which may cause concern for sustained VAs. However, it is important to recognize that in such patients with structural heart disease there is also a high incidence of conduction disease; furthermore, conduction disease may be exacerbated by the concomitant use of medications such as beta-blockers, digoxin, or antiarrhythmic drugs (*i.e.*, amiodarone, sotalol, dofetilide, *etc.*).

The WCD appears to serve as an effective monitoring device for severe bradycardic events. While the WCD has been shown to prevent sudden cardiac death due to VAs in certain patients^[1,11-16], our study suggests that it may also provide an additional benefit in improving outcomes in patients who suffer from bradycardic conditions both in the acute setting as well as long-term by helping to determine which patients qualify for permanent pacemaker devices. Of the 86 patients surviving to WCD discontinuation, 48 (56%) of them were implanted with an ICD or pacemaker, a median of four days after the asystole episode. Although the device does not provide antibradycardia treatment, it does aid patients by alerting bystanders with an audible tone, thus potentially decreasing time to CPR and EMS notification. Shorter time to CPR and EMS arrival have been repeatedly shown to correlate with improved survival and neurologic outcome after cardiac arrests^[8]. Just as pacemakers or rhythm monitors may detect sustained ventricular arrhythmias which would meet indications for ICD implantation or upgrade, the WCD may detect symptomatic bradycardic rhythms which would lead to permanent pacemaker or ICD implantation.

Limitations

This was an observational retrospective study and data was derived from the manufacturer's database. While rhythm strips for each recorded event was adjudicated to assure that a bradycardic/asystolic event meeting criteria for device detection had occurred, the clinical details surrounding the asystole episodes for each patient were limited. The WCD database included a

limited amount of patient information, and information regarding patient comorbidities, medical therapy, and outcomes. For example, the fact that the overall survival rates among patients with serious episodes was lower in patients whose event occurred in a location under medical care (*i.e.*, hospital, emergency room, dialysis center, rehabilitation center, or long-term care nursing facility) could be due to the fact that patients already under medical care may have had more comorbidities than those whose serious asystole episode occurred outside of a medical facility. Thus our findings, while interesting, should be considered hypothesis-generating.

In conclusion, while the current indication for WCDs in high-risk patients is to detect and treat VAs, patients with reduced LVEF are also at increased risk of having severe bradycardic events. The WCD may improve survival in patients with severe bradycardic/asystolic episodes by alerting bystanders to notify EMS and to perform early CPR, as well as to detect episodes leading to appropriate permanent device implantation.

ARTICLE HIGHLIGHTS

Research background

Outcomes in patients with asystole and severe bradycardic events is poor. The wearable cardioverter defibrillator (WCD) can deliver shocks to terminate ventricular tachycardia and fibrillation, and also alarms for asystole and severe bradycardia events which can alert bystanders to help.

Research motivation

Minimal data exists on whether WCD improves outcomes and survival in patients with asystole and severe bradycardia events.

Research objectives

This study aimed to examine whether WCD alarms for asystole improve patient outcomes and survival.

Research methods

Retrospective analysis all asystole episodes documented in the WCD registry during the year of 2013 and examination of outcomes and survival.

Research results

There were 264 asystole episodes in 257 patients and 76% of these events were considered "serious". Overall patient survival after asystole or severe bradycardia events was 42%, and survival after "serious" asystole events was 26%. Among acute survivors, 20% later died during WCD use. Of the 86 living patients at the end of WCD use period, 48 (56%) received ICD/pacemaker and 17 (20%) improved their condition.

Research conclusions

While the current indication for WCDs in high-risk patients is to detect and treat ventricular arrhythmias, patients with reduced LVEF are also at increased risk of having severe bradycardic events. The WCD may improve survival in patients with severe bradycardic/asystolic episodes by alerting bystanders to notify emergency medical services and to perform early cardiopulmonary resuscitation, as well as to detect episodes leading to appropriate permanent device implantation.

Research perspectives

Future large prospective studies examining outcomes of WCD for asystole and severe bradycardia events are necessary to confirm a survival benefit with the device.

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