ORIGINAL ARTICLE

USE OF WEARABLE CARDIOVERTER DEFIBRILLATOR SHORTENS THE ICU STAY AND ENABLES SAFE MANAGEMENT IN A GENERAL WARD

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Abstract   Wearable cardioverter-defibrillator（WCD）is an external device capable of automatic detection and treatment of ventricular tachycardia（VT）/ventricular fibrillation（VF）. We examined whether WCD use for patients at high risk for VT/VF is associated with shortening the length of stay in the intensive care unit（ICU）and safe management in the general ward until implantable cardioverter-defibrillator（ICD）implantation.

From June 2012 to May 2014, ICD was implanted in 44 patients for secondary prevention of VT/VF（control group）. From June 2014 to May 2016, WCD was prescribed in 50 patients for secondary prevention, of which 29 patients had ICD implantation（WCD group）. The median length（25th–75th percentiles）of the ICU stay was 3（1–7）days in the control and 0（0–1.5）days in the WCD group（p<0.05）. The period until ICD implantation in the general ward was 0（0–3）days in the control and 10（5–19）days in the WCD group（p<0.05）. No sudden cardiac death and no readmission to the ICU were reported in both groups before ICD implantation.

In patients with indication for ICD implantation for secondary prevention, WCD use can shorten the length of ICU stay and provide a safe management in a general ward.

Introduction

The benefit of implantable cardioverter-defibrillator（ICD）therapy for secondary prevention of ventricular tachycardia（VT）or ventricular fibrillation（VF）has been shown in large clinical trials[1,2]. However, ICD implantation may be inappropriate or delayed in some patients because of co-morbid conditions, including infection, and recovery from respirator or surgery. Many resuscitated patients need intensive care, and fever complicates up to 70 % of patients in the intensive care unit（ICU）because of infection or other conditions[3,4]. Given that infection and fever before ICD implantation are risk factors for device infections[5], it takes a long time until safe ICD implantation is achieved. During this period, the high-risk patients are generally managed in an ICU or cardiac care unit（CCU）. However, long stay there is costly and also causes mental instability and disuse atrophy in some patients. Furthermore, managing the high-risk patients in a general ward without ICD may be a high risk for a sudden cardiac death（SCD）even under

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electrocardiogram monitoring.

The wearable cardioverter defibrillator (WCD; ZOLL LifeVest 4000, Pittsburgh, PA, USA) is an external device capable of automatic detection and defibrillation of VT/VF. The safety and effectiveness of the WCD have been reported in retrospective and prospective studies[6-8]. The Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II Registry) is the first prospective and observational study of the WCD, but the majority of enrolled patients (91%) were prescribed the WCD for primary prevention[6]. The WCD has been available in Japan since April 2014, and we previously showed a single-center experience of the WCD use for patients at high risk for VT/VF[9, 10]. However, the safety and effectiveness of the WCD as secondary prevention is unclear. In the present study, we examined whether the WCD use as secondary prevention for high-risk patients is associated with shortening the length of ICU stay and the safe management in a general ward until ICD implantation.

Methods

Study population

From June 2014 to May 2016 (total 24 months), WCD was prescribed in 50 patients for secondary prevention. Of these patients, two died during WCD use and 15 were at only temporarily high risk for VT/VF, and their risks were reduced during WCD use, leading to no ICD implantation. Furthermore, four had infection at the implanted ICD site where the infected ICD was removed temporarily. Therefore, those 21 patients were excluded from the study. Finally, 29 patients with ICD implantation after WCD use were enrolled as the WCD group. On the other hand, from June 2012 to April 2014 (total 24 months), 44 patients for secondary prevention of VT/VF had an ICD implantation without WCD use and were defined as the control group. We retrospectively

compared patient characteristics, length of ICU stay after the arrhythmic events, and length of stay in a general ward until ICD implantation between the WCD and control groups.

The study was approved by the ethics committee of our institution.

Indication of WCD use

The indication of WCD use in our hospital was based on the second revision of the statement for the clinical use of WCD published by the Japanese Heart Rhythm Society (JHRS)[11]. The flow chart of WCD use for patients at high risk for VT/VF in our hospital was shown previously[9]. Briefly, when a patient who was at high risk for SCD for a limited period but not a candidate for an ICD implantation was admitted, we assessed the circulatory dynamics of the patient. If circulatory dynamics was stable, we prescribed WCD as early as possible and managed the patient in a general ward. On the contrary, if circulatory dynamics was unstable, such as occurrence of incessant VT or severe condition with necessity of auxiliary devices, we managed the patient in the ICU. After the patient recovered, we prescribed WCD and managed him or her in a general ward.

The tachycardia detection rate for both VT and VF was programmed at 200 beats/minute (bpm) in the initial 14 patients, while its rate was done at 130 bpm for VT and 200 bpm for VF in the latter 15 patients in order to manage VT detection more intensively. Time from VT/VF detection to shock delivery was 60 s for VT and 25 s for VF. Electrical shock was applied biphasically, and its shock energy was set to 150 J for both VT and VF.

Indication of ICD implantation

The indication of ICD implantation was decided according to the guidelines of the Japanese Circulation Society[12]. When lethal arrhythmia occurred in the patients due to Wolff-Parkinson-White syndrome, electrolyte abnormality, acute phase (within 48 h) after onset of myocardial

Table 1. Clinical characteristics of the patients

	Control group n=44	WCD group n=29
Baseline characteristics		
Age (years)	63 (48.25-66.0)	52 (45.5-58.5) *
Male	33 (75%)	25 (86%)
LVEF (%)	51.6 (41.6-65.6)	56.0 (43.7-64.4)
VF event	22 (50%)	20 (69%)
Hypertension	20 (45%)	14 (48%)
Diabetes mellitus	7 (15%)	8 (28%)
Hemodialysis	1 (2%)	1 (4%)
Transferred from the other hospitals	27 (61%)	20 (69%)
Underlying heart diseases		
Atrial fibrillation	9 (20%)	6 (21%)
CAD	12 (27%)	10 (35%)
HCM	13 (30%)	4 (14%)
DCM	2 (5%)	1 (4%)
ARVC	1 (2%)	0 (0%)
Brugada syndrome	1 (2%)	3 (10%)
Idiopathic VF	7 (16%)	7 (24%)
Others	8 (19%)	4 (14%)
Events and care in our hospital before implantation of ICD		
Ventilator	5 (11%)	5 (17%)
PCPS	0 (0%)	2 (7%)
Cerebral hypothermia	4 (9%)	4 (14%)
Ablation or EPS	8 (18%)	6 (21%)
PCI or CABG	2 (5%)	1 (4%)
Hospital infections	5 (11%)	6 (21%)

Data are shown as median (25th-75th percentiles) or n (%). LVEF indicates left ventricular ejection fraction, VF; ventricular fibrillation, CAD; coronary artery disease, HCM; hypertrophic cardiomyopathy, DCM; dilated cardiomyopathy, ARVC; arrhythmogenic right ventricular cardiomyopathy, PCPS; percutaneous cardiopulmonary support, EPS; electrophysiological study, PCI; percutaneous coronary intervention, CABG; coronary artery bypass grafting. * $p<0.05$.

infarction, and coronary spastic angina, treatment for the causative diseases is given priority, and such cases are out of the indication of ICD.

Statistical analysis

Data were expressed as mean ± SD, median (25th–75th percentiles), or n (%). Mann-Whitney U test or chi-square test was used to compare differences between two groups, as appropriate. All statistical analyses were performed using JMP Pro 11 software (SAS, Cary, NC). A p-value <0.05 was considered statistically significant.

Results

Clinical characteristics of the study patients

Clinical characteristics of the study patients are shown in Table 1. The patients in the WCD group was significantly younger than those in the control group [52 (45.5–58.5) versus 63 (48–66) years old, Mann-Whitney U test, p<0.05]. Other characteristics including gender, left ventricular ejection fraction, VF event, hypertension, diabetes mellitus, and hemodialysis did not differ significantly between the two groups. Both groups also included patients who
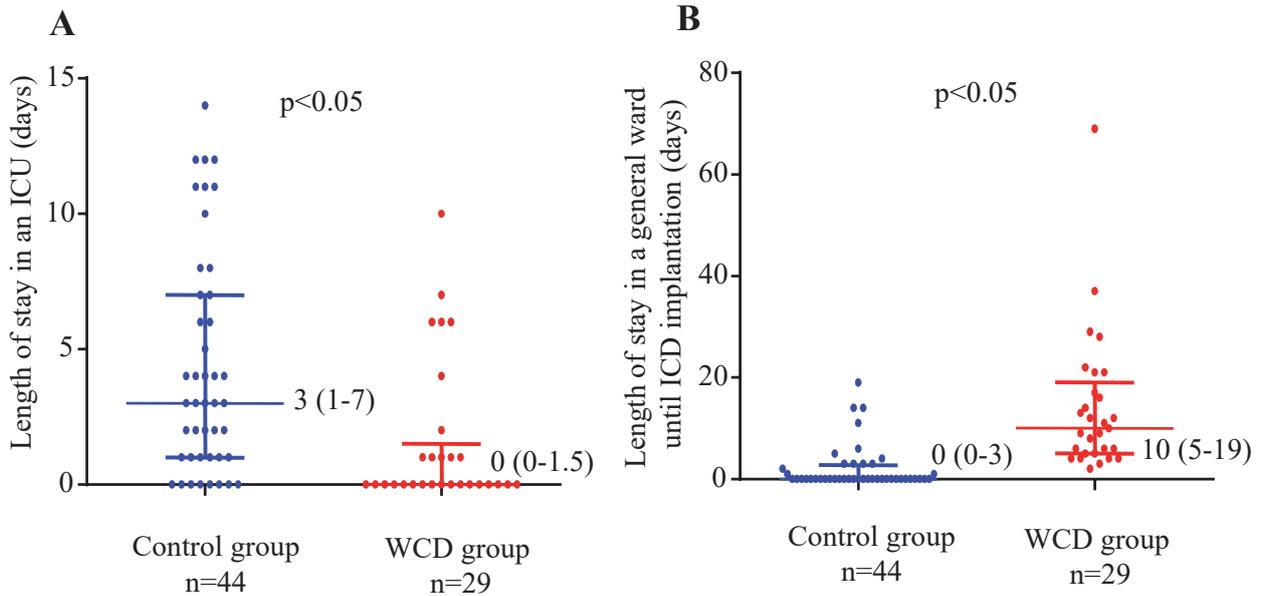
Figure 1 Comparison of length of stay（day）in an ICU（A）and in a general ward（B）between the control and the WCD groups. Data are shown as median（25th–75th percentiles）.

were referred from other hospitals, but there was no statistically significant difference in their proportions. Underlying heart diseases also did not differ significantly between the two groups.

The proportion of patients with ventilator, percutaneous cardiopulmonary support（PCPS）, and cerebral hypothermia was not significantly different between the two groups（chi-square test, p>0.05）. Furthermore, the proportion of patients who underwent ablation or revascularization and those with hospital infections before ICD implantation did not differ between the two groups.

In the WCD group, the mean usage time of WCD was 23.1 ± 1.6 h per day, which shows an excellent compliance（23.1/24 hours = 96 %）.

Length of stay in an ICU after VT/VF events

Figure 1A shows the length of ICU stay after VT/VF events. The median length of ICU stay was 3（1–7）days in the control and 0（0–1.5）days in the WCD group（Mann-Whitney U test, p<0.05）. In the control group, 8/44（18 %）patients were admitted to the general ward directly without being admitted to the ICU. On the contrary, 17/29（59 %）patients in the

WCD group were admitted to the general ward directly without being admitted to the ICU（chi-square test, p<0.05）.

Length of stay and VT/VF events in a general ward until ICD implantation

Figure 1B shows the length of stay in a general ward until ICD implantation. It was 0（0–3）days in the control group and 10（5–19）days in the WCD group（Mann-Whitney U test, p<0.05）. There was no event of SCD and no patient was readmitted to the ICU in both groups before ICD implantation. While 30/44（68 %）patients in the control group were implanted ICD during their stay in the ICU/CCU, no patient in the WCD group was implanted ICD in the ICU. Sustained VT（HR, 176 bpm）without losing consciousness occurred in one patient of the WCD group in the general ward, but shock was avoided by pressing response buttons of the device. ICD was implanted, and catheter ablation was performed for VT therapy afterwards.

No episode of appropriate or inappropriate shock by WCD was detected. Although there was no case of appropriate shock of ICD in a general ward in the WCD group, two patients in

the control group were given proper shock after ICD implantation.

Discussion

Major findings

The present study showed that length of ICU stay is significantly shorter in the WCD group than in the control group. Furthermore, the length of stay in a general ward until ICD implantation is longer in the WCD group than in the control group. These findings indicate that WCD use for management of patients at high risk for SCD shortens the length of ICU stay and is capable of safe management in a general ward.

Beneficial effect of WCD use for secondary prevention in a general ward

No report has examined the beneficial effect of WCD use for secondary prevention in a general ward. Tanawuttiwat et al. reported the potential utility of WCD in a general ward[13]. WCD was used in 97 patients after ICD removal because of ICD-related infections. There were eight deaths (five at the hospital and three at home) during the observation period. Of the five deaths in the hospital, one patient died of VF that occurred in the general ward when WCD was not worn. The remaining four patients died of infection and intracranial bleeding. This report indicates that WCD use in a general ward may be useful for preventing SCD due to VT/VF.

Patients after resuscitation from VT/VF events are generally managed in an ICU and have a high incidence of catheter-related infections, ventilator-related pneumonia, and complex urinary tract infections. Therefore, ICD implantation at the early stage is often difficult. Since management of such patients in a general ward without ICD is at very high risk for SCD, the patients tend to stay in an ICU for a long time until ICD implantation. In such a case, WCD use may be useful for preventing SCD in a general ward. Indeed, most patients in the control group

who stayed in an ICU for more than 10 days in the present study had some infections. Although most patients in the WCD group who were managed in a general ward for more than 20 days had also some infections, their stay in an ICU was not as long as that in the control group. Taken together, WCD use in patients with infection can shorten their stay in an ICU and enable safe management in a general ward. The fact that the number of patients with direct admission to the general ward in the WCD group was higher than that in the control group also supports beneficial effect of WCD use.

Beneficial effect of WCD use for determining indication of ICD implantation

Although 15 patients with WCD use followed by no ICD implantation were excluded from the current study, it is important to discuss the beneficial effects of WCD use for determining indication of ICD implantation. Some patients require a certain period in order to judge the indication of ICD implantation. For example, it remains controversial whether patients with first VF occurrence caused by coronary spasm should have ICD implantation. Many patients can be able to avoid lethal arrhythmias by optimal drug treatment with calcium channel blockers, but some patients are resistant to the drugs[14, 15]. To avoid over-indication of ICD implantation, the efficacy of drug treatment should be carefully managed under WCD use in a general ward or in an outpatient clinic. VT/VF sometimes occurs in the acute phase of acute myocarditis. However, the risk of lethal arrhythmias may be reduced if cardiac function recovers. Temporal WCD use may be useful for such patients until recovery of cardiac function and achievement of risk reduction of VT/VF occurrence.

Cost reduction by early WCD use

There is a significant difference in the cost for daily stay in an ICU and a general ward between countries; therefore, discussing the medical economic effect of WCD use may be

difficult. However, ICU stay is generally very expensive. Our data showed that WCD use leads to shorten ICU stay. This finding suggests that WCD use at the early phase can reduce the total cost of admission of each patient.

Study limitations

Several limitations in the analyses of the present study should be noted. First, our study was a single-center retrospective study; therefore, generalization of our results may be limited. Second, it is relatively clear how indication for ICU admission was determined (namely, VT/VF occurrence in the current study), but the criteria for leaving the ICU was dependent on doctor's decision, which may affect the length of ICU stay. Third, a majority of patients (60%–70%) in both groups were transferred from other hospitals. These patients were generally under stable circulatory respiratory dynamics. Fourth, the medical economic effect by early WCD use was not analyzed in details.

Conclusion

In patients with indication of ICD implantation for secondary prevention, WCD use can shorten the length of an ICU stay and can provide a safe management in a general ward.

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