



Wearable Cardioverter Defibrillator

— Initial Experience in the Outpatient Setting in Japan —

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Background: The wearable cardioverter defibrillator (WCD) has been available since 2014 in Japan, and its benefit in the in-hospital acute phase at high risk of ventricular tachyarrhythmia (VTA) has been established, but its clinical use in the outpatient setting remains unclear, especially in Japan.

Methods and Results: The subjects consisted of 43 consecutive patients with WCD use in the outpatient setting from April 2014 to October 2019 at the present institute. Event alerts and wearing compliance were checked via the remote monitoring system, and a dedicated WCD training team contacted the patients if necessary. The median observation period was 51 days (IQR, 37–68 days) and the median daily wearing time was 23.1 h/day (IQR, 22.0–23.6 h/day). WCD was prescribed for primary prevention of VTA in 7 patients (16%), and for secondary prevention in 36 (84%). The common reason for WCD use was preventive therapy and/or clinical observation. Two appropriate and one inappropriate shock were observed. Eleven patients were not indicated for ICD because of successful catheter ablation optimal medical therapy, VTA in early onset of heart disease and refusal. The remaining 32 patients, however, underwent ICD implantation.

Conclusions: In the present real-world study, the WCD wearing compliance was well-maintained in the outpatient setting. WCD is useful for patients at high risk of VTA.

Key Words: Sudden cardiac death; Ventricular tachyarrhythmia; Wearable cardioverter defibrillator

The importance of the implantable cardioverter defibrillator (ICD) is now widely accepted, due to the significant improvement in prognosis in ischemic and non-ischemic cardiovascular disease.^{1–3} Although various studies, such as MADIT I and II, SCD-HeFT and so on, demonstrated a clinical benefit of defibrillation devices, immediate ICD use in the acute recovery phase failed to exhibit a benefit of a decrease in total deaths.^{4,5} In contrast, the VALIANT study showed that the acute recovery phase, <3 months from disease onset, has the highest risk for sudden cardiac death (SCD).⁶ Therefore, a feasible bridge therapy is needed to prevent SCD in the acute recovery phase.

The wearable cardioverter defibrillator (WCD; LifeVest 4000, ZOLL, Pittsburgh, PA, USA) is designed to automatically detect and treat lethal arrhythmia by delivering a biphasic electrical shock through body-surface patches. WCD is considered suitable for temporary observation

of patients at high risk for lethal arrhythmia, that is, ventricular tachycardia (VT) and ventricular fibrillation (VF).⁷ Indications for WCD in Japan are as follows:^{8–10} (1) ≤ 40 days after the onset of acute myocardial infarction (AMI) with left ventricular ejection fraction (LVEF) $\leq 35\%$ and heart failure (HF) symptoms of New York Heart Association (NYHA) class II or III; (2) LVEF $\leq 35\%$ and ≤ 90 days after coronary artery bypass, or NYHA class II or III HF symptoms during or after percutaneous coronary intervention (PCI); (3) LVEF $\leq 35\%$ and ≤ 90 days after non-ischemic acute HF onset; (4) irreversible severe HF satisfying heart transplant standby condition; (5) indication for ICD but surgery unable to be performed immediately because of other physical conditions; (6) secondary prevention of SCD by ICD is considered but priority is given to clinical follow-up and preventive treatment; and (7) temporary removal of ICD for any reason, such as infection. WCD has been available since April 2014 in Japan

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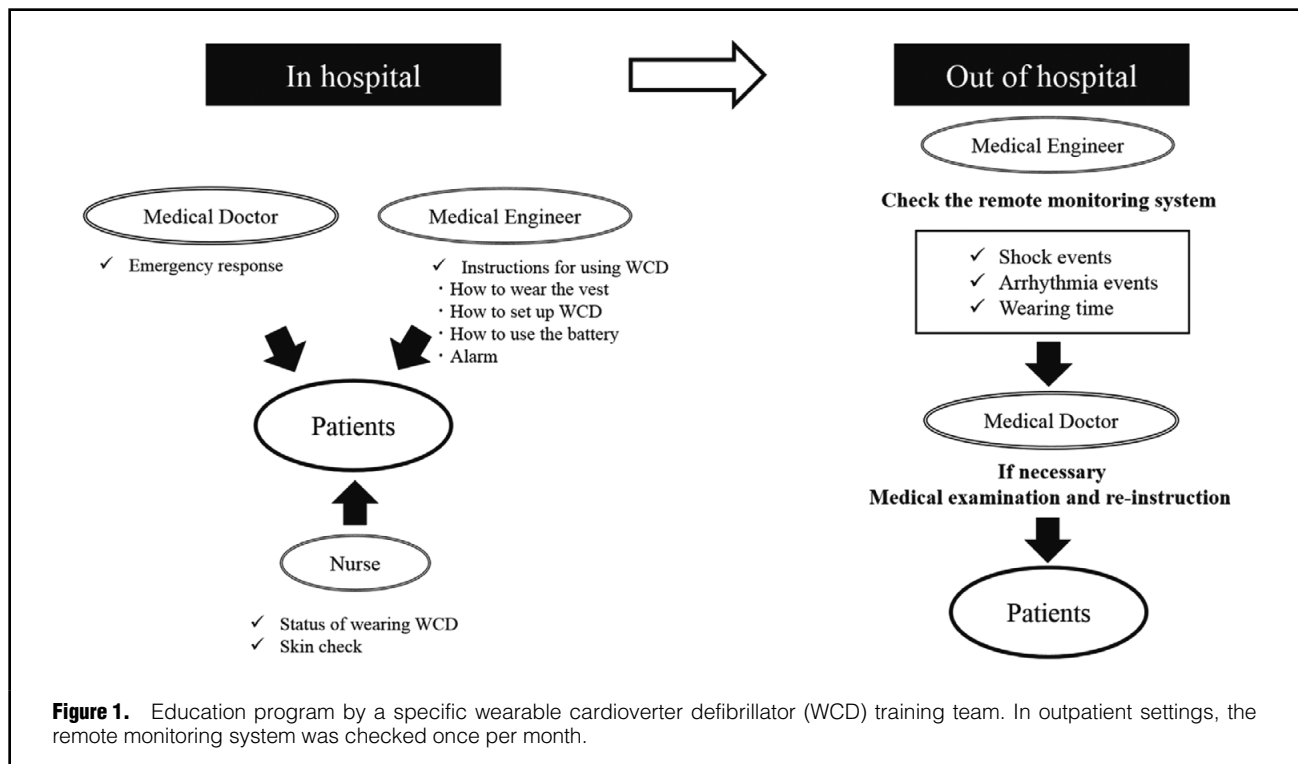


Table. Baseline Characteristics (n=43)	
Clinical backgrounds	
Age (years)	48 (41–66)
Male	36 (84)
LVEF (%)	54 (42–65)
Primary prevention of VTA	7 (16)
Secondary prevention of VTA	36 (84)
VT/VF RFCA	5 (12)
ICD implantation	32 (74)
TV-ICD	16 (37)
S-ICD	16 (37)
Underlying heart disease	
Ischemic heart disease	18 (42)
AMI	5 (12)
OMI	7 (16)
VSA	6 (14)
Non-ischemic cardiomyopathy	6 (14)
Adult congenital heart disease	1 (2)
Idiopathic VF	6 (13)
Idiopathic VT	4 (9)
Brugada syndrome	4 (9)
Long QT syndrome	3 (7)
Syncope of unknown cause	1 (2)

Data given as median (IQR) or n (%). AMI, acute myocardial infarction; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; OMI, old myocardial infarction; RFCA, radiofrequency catheter ablation; S-ICD, subcutaneous ICD; TV-ICD, transvenous ICD; VF, ventricular fibrillation; VSA, vasospastic angina; VT, ventricular tachycardia; VTA, ventricular tachyarrhythmia.

and its usefulness in the in-hospital acute phase at high risk of VT/VF has been confirmed,¹¹ but its clinical use in the outpatient setting in Japan remains unclear. In this report, we summarized our single-center experience of WCD use, with a focus on the outpatient setting.

Methods

Subjects

The subjects consisted of 43 consecutive patients with WCD use in the outpatient setting from April 2014 to October 2019 at the present institute. We extracted the patient data from the database of Kitasato University Hospital. Indications for WCD were based on the second revision of the statement for the clinical use of WCD published by the Japanese Heart Rhythm Society (JHRS).^{8,9} The default WCD settings were as follows: VT zone, 150–200 beats/min; VF zone, >200 beats/min; time from VT detection to shock delivery, 60 s for VT and 25 s for VF. The shock energy was set to 150 J biphasic for both VT and VF. A dedicated WCD training team consisting of nurses and medical engineers looks after the introduction of the WCD. After the doctor's decision for WCD use, the nurses measure the patient's body size for the vest and educate the patient on how to deal with skin irritation. Medical engineers then explain the WCD to each patient: how to assemble the vest, handle the battery, respond to the siren alarm and so on. In the outpatient setting, daily WCD wearing time and electrocardiogram recordings were transmitted via remote monitoring system (LifeVest Network) and were analyzed in detail by the WCD training team. When VT/VF events were detected, doctors urged the patients to visit the hospital. If the wearing compliance was insufficient, we explained the necessity of WCD use to these patients repeatedly (Figure 1).

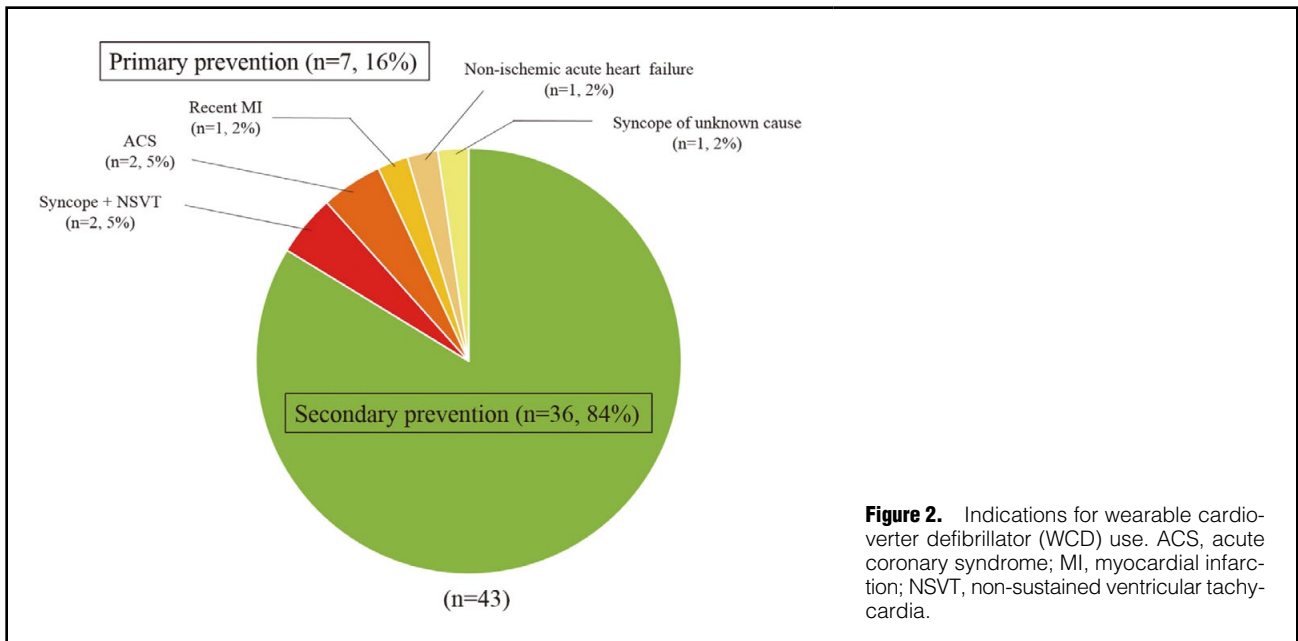


Figure 2. Indications for wearable cardioverter defibrillator (WCD) use. ACS, acute coronary syndrome; MI, myocardial infarction; NSVT, non-sustained ventricular tachycardia.

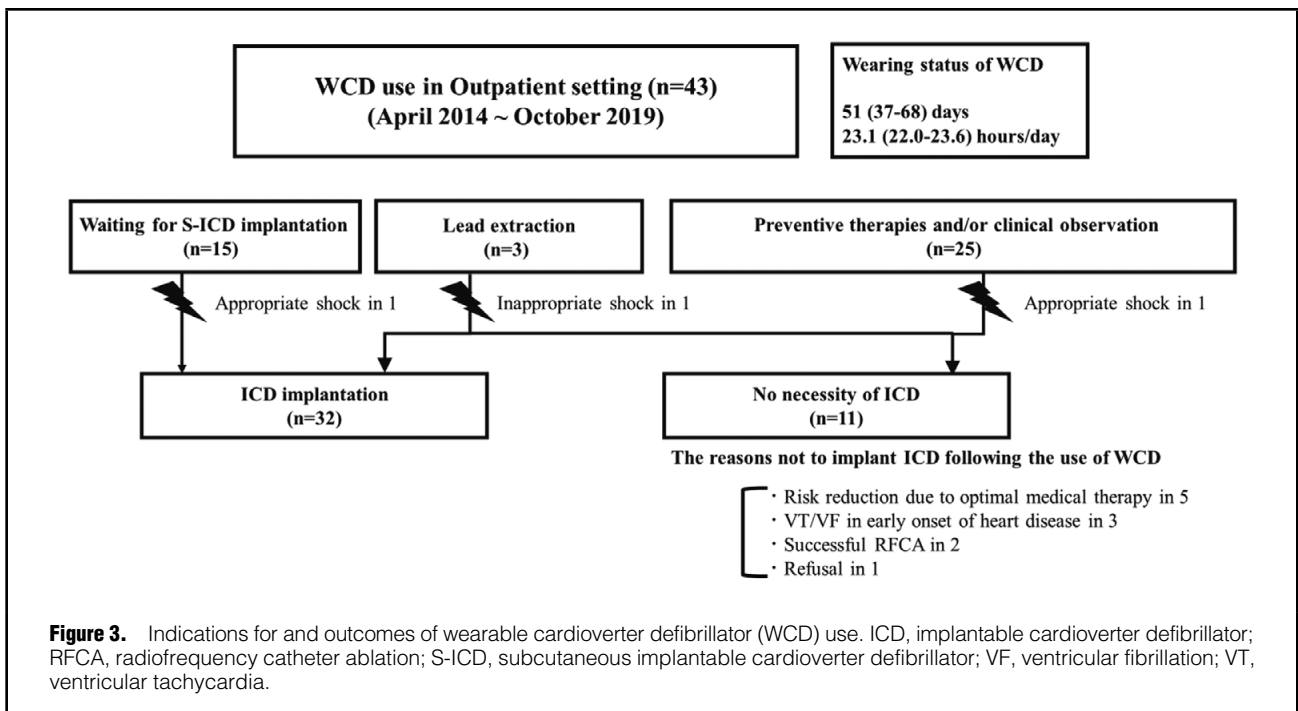


Figure 3. Indications for and outcomes of wearable cardioverter defibrillator (WCD) use. ICD, implantable cardioverter defibrillator; RFCA, radiofrequency catheter ablation; S-ICD, subcutaneous implantable cardioverter defibrillator; VF, ventricular fibrillation; VT, ventricular tachycardia.

This study was conducted in accordance with the Declaration of Helsinki and this protocol was approved by the ethics committees of Kitasato University Hospital.

Analysis

Continuous variables are described as median (IQR). Categorical variables are described as absolute numbers and percentages. All analyses were performed using JMP 11.2.0 (SAS, Cary, NS, USA).

Results

Baseline Characteristics

Baseline characteristics are summarized in **Table**. Median age was 48 years (IQR, 41–66 years), 36 were male, and median LVEF was 54% (IQR, 38–63%). The underlying diseases consisted of ischemic heart disease (IHD) in 18, non-ischemic cardiomyopathy in 6, adult congenital heart disease in 1, idiopathic VF in 6, idiopathic VT in 4, Brugada syndrome in 4, long QT syndrome in 3, and syncope of unknown cause in 1. In total, WCD was prescribed for primary prevention of ventricular tachyarrhythmia (VTA)

only in 7 patients (16%), and for secondary prevention in 36 (84%). Indications for primary prevention were acute coronary syndrome in 2, syncope with non-sustained VT in 2, recent MI in 1, non-ischemic acute HF in 1 and syncope of unknown cause in 1 (Figure 2).

Wearing Status of WCD

The WCD wearing status is summarized in Figure 3. The most common indications for WCD use were preventive therapy and/or clinical observation. The reasons not to implant ICD following WCD use were as follows: risk reduction due to optimal medical therapy in 5, successful catheter ablation in 2, VT/VF due to early onset of heart disease in 3, and refusal by patient in 1.

Following WCD use, 32 patients underwent ICD implantation. As shown in Table, 16 of these patients underwent subcutaneous ICD (S-ICD) implantation. Although 15 of 16 patients had indications for secondary prevention, including IVF, these patients on the waiting list for S-ICD implantation required temporary hospital discharge.

WCD Alarms and Shock Delivery Status

The siren alarms were activated in 36 patients (84%). Noise was detected in 32 patients, supraventricular tachycardia was detected in 2 patients, and VTA was detected in 2 patients. In other words, 34 patients (79%) had alarms other than for VTA. Two appropriate and one inappropriate WCD shock were observed during this period. A 22-year-old woman received the first case of successful appropriate WCD shock therapy in an outpatient setting in Japan, as we previously reported.¹² One case of inappropriate shock occurred in a 75-year-old man in whom WCD was prescribed after ICD lead extraction due to infective endocarditis. The shock was delivered due to noise detection but he could not cancel that shock because his hand was fixed because of hemodialysis. Thirty-three patients avoided the inappropriate shock by pressing the response button.

WCD Compliance

All patients were provided with WCD instructions before use by a dedicated WCD training team and were able to manage the WCD system by themselves. The median duration of WCD use was 51 days (IQR, 37–68 days) and median daily wearing time was 23.1 h/day (IQR, 22.0–23.6 h/day). Two patients had skin irritation, but it was improved with ointment. Only one pregnant woman with twins wore the WCD for <20 h/day, because she was >30 weeks pregnant and had difficulty in wearing the WCD vest. Patient compliance was therefore well-maintained.

Discussion

The present study describes a single-center experience of WCD use, focusing on the outpatient setting, in patients who all had potential indications for ICD. The main findings are as follows: (1) the number of patients with primary prevention indication was relatively small; and (2) patient compliance was well-maintained and important for maximizing the effectiveness of WCD.

Low Proportion of Primary Preventive Indications

The WEARIT-II Registry recorded a high rate of sustained VTA at 3 months in at-risk patients, most of whom had WCD for primary prevention of SCD, suggesting that the WCD can be safely used to protect patients during this

period of risk assessment.¹³ Klein et al reported on the indications for WCD use in Germany between 2000 and 2008 in 354 patients, 82% of whom had WCD for primary prevention of SCD.¹⁴ From the manufacturer's database of >100,000 patients from USA, Chung reported that 83% of the patients had WCD for primary prevention of SCD.¹⁵ WCD may protect against SCD during the immediate period after MI, before ICD implantation is indicated under current guidelines.^{8,16,17} Several registries and case reports involving high-risk SCD patients have demonstrated that WCD were effective in terminating VTA.^{7,13,18–20} The WCD guidelines in Japan also noted that the indication of WCD for primary prevention would be an important issue.¹⁰

In the present study, however, primary preventive indication comprised only 16%. There are several reasons for this discrepancy.

Although the WCD cost is partly reimbursable, the hospital contribution was 91,700 yen/month until March 2018. This might be an obstacle to wearing WCD, especially for primary prevention patients. From April 2018, although the hospital contribution decreased to approximately 27,000 yen/month (i.e., from 91,700 down to 27,000), there still exists some imbalance in the cost. For the expansion of appropriate WCD use, such imbalanced insurance reimbursement in Japan should be resolved as soon as possible. Accumulating evidence regarding cost-effectiveness of WCD use will help to resolve this problem.

Temporary hospital discharge was required for 15 patients on the waiting list for S-ICD implantation because it was necessary to adjust the schedule with anesthesiologists and the staff of the operating room.

Several reports have noted the low incidence of SCD with prior MI and reduced EF in Japanese patients. Tanno et al reported that only 2 of 90 MADIT II-like patients died suddenly in the Japanese population. They concluded that it may be inappropriate to apply MADIT II criteria to ICD implantation in Japanese patients.²¹ Shiga et al reported that there is a low incidence of SCD in survivors of MI in the Japanese population in the primary PCI era.²² These results could be another explanation for the low proportion of primary prevention indications, especially in IHD. In contrast, Satake et al showed that patients with HF with reduced LVEF had a high incidence of SCD.²³ These results require more data on primary prevention of SCD in Japan and reconsideration of the indications for primary prevention of SCD.

WCD Use: Importance of Education

The VEST trial is a landmark clinical trial of WCD that enrolled 2,302 patients with AMI and EF ≤35% to receive WCD plus guideline-directed therapy or to receive only guideline-directed therapy.²⁴ WCD, however, did not lead to a significantly lower rate of the primary outcome of arrhythmic death. In that study, the wearing compliance had not been maintained sufficiently. During follow-up the device was worn a median of 18.0 h (IQR, 3.8–22.7 h) per day and the wear time was bimodal, with patients who were consistently wearing the device having it in place >20 h per day and those with low wear time mostly not wearing it at all.²⁴ Frequent device alarms (72% of the patients in the device group had any arrhythmia alarm), skin irritation, inappropriate shock, and emotional distress can deter some patients from continuing to wear the device.²⁵

In the present study, frequent device alarms occurred (in 84% of patients), but 33 patients (92% of the patients who

had alarm) avoided inappropriate shock by pressing the response button. Daily wearing time was maintained (median, 23.1 h/day; IQR, 22.0–23.6 h/day) and all of the patients wore the WCD >20 h/day except for 1 pregnant woman. This good wearing compliance is partly because of our education program, which is handled by a dedicated WCD training team to maintain compliance and safety (Figure 1). This education program also improves patient understanding and the level of comfort with the device and increases the wearing time per day, which is essential for increased WCD efficacy.²⁶ The choice of an optimally sized vest and electrode and patch settings is important, because fitting these materials to the skin surface is essential for arrhythmia detection and therapeutic shock delivery.¹⁴ In clinical practice, a doctor does not have enough time to explain these practical but important points, but a dedicated WCD training team can promote good understanding, as noted by the JHRS.⁸ Furthermore, we have maintained good compliance by establishing a follow-up system in the outpatient setting. Through the remote monitoring system (LifeVest Network), the arrhythmia events and the wearing compliance were checked daily and any patients with insufficient wearing time were provided with further advice accordingly (Figure 1). The continuous education and patient approach are important.

Study Limitations

The present study had several limitations. First, this study was a retrospective observational study, therefore there was a possible selection bias and unmeasured confounders. In particular, the median age was relatively young (48 years; IQR, 41–66 years) and the WCD is required to be operated by the patients themselves. Therefore, elderly patients may have difficulty with WCD use. In addition, the data of patients who declined to wear the WCD were not collected. The actual number of people who declined the WCD was difficult to determine, because the present study was a retrospective observational study. This selection bias may affected the results. Second, because the duration of WCD use was limited to ≤3 months because of Japanese insurance, the follow-up period was limited. Finally, because this study was performed in a single Japanese center, the number of patients was relatively small. A multi-center study with a larger number of patients is required.

Conclusions

We have described the initial experience of WCD in an outpatient setting. Although the number of indications for WCD for primary prevention was relatively small, the WCD wearing compliance was well-maintained via the education program, which was handled by a dedicated WCD training team. WCD is useful for patients at considerable risk for VTA in the outpatient setting.

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Disclosures

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IRB Information

This study was approved by the ethics committee of Kitasato University Hospital, reference number: B18-195.

Data Availability

The de-identified participant data will not be shared.

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