Journal of Cardiology xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Original article

Potential roles of the wearable cardioverter-defibrillator in acute phase care of patients at high risk of sudden cardiac death: A single-center Japanese experience

Shingo Sasaki (MD, PhD, FJCC)[a], Yoshihiro Shoji (MD)[b], Yuji Ishida (MD, PhD)[b], Takahiko Kinjo (MD, PhD)[b], Yuichi Tsushima (MD)[b], Maiko Seno (MD)[b], Fumie Nishizaki (MD, PhD)[b], Taihei Itoh (MD, PhD)[b], Kei Izumiyama (MD, PhD)[b], Takashi Yokota (MD, PhD)[b], Hiroaki Yokoyama (MD, PhD)[b], Masahiro Yamada (MD, PhD)[b], Daisuke Horiuchi (MD, PhD)[a], Masaomi Kimura (MD, PhD)[b], Takumi Higuma (MD, PhD, FJCC)[b], Hirofumi Tomita (MD, PhD)[b], Ken Okumura (MD, PhD, FJCC)[c,*]

[a] Department of Advanced Management of Cardiac Arrhythmias, Hirosaki University Graduate School of Medicine, Hirosaki, Japan
[b] Department of Cardiology, Hirosaki University Graduate School of Medicine, Hirosaki, Japan
[c] Advanced Arrhythmia Therapeutic Branch, Division of Cardiology, Saiseikai Kumamoto Hospital Cardiovascular Center, Japan

ARTICLE INFO

Article history:
Received 26 May 2016
Received in revised form 21 July 2016
Accepted 1 August 2016
Available online xxx

Keywords:
Wearable cardioverter-defibrillator
Sudden cardiac death
Ventricular tachyarrhythmias

ABSTRACT

Background: The wearable cardioverter-defibrillator (WCD) has been expected to play a role as an effective bridge therapy to implantable cardioverter-defibrillator (ICD) implantation in patients at high risk of ventricular tachyarrhythmias (VA). Although WCD has been available since April 2014 in Japan, its usefulness remains unclear.

Methods and results: During the early period after hospitalization, patients at high risk of VA after excluding some elderly patients were prescribed WCD. The consecutive 50 patients with WCD use (median age 56 years, 38 for secondary prevention) were studied. We analyzed clinical efficacy and safety of WCD, and examined its potential roles. Of the 50 patients, 38 used WCD only during hospitalization. During WCD use [median 16 (IQR 8–33) days], all patients wore WCD for 98% of a day regardless of in or out-of-hospital use. Sustained VA was detected in 4 patients (8%; for primary prevention in 1) with 7 episodes, and 6 of 7 episodes required shock therapy. Of the 6 shock therapies, 4 were for sustained ventricular tachycardia with the median rate of 236 beats/min (IQR 203–250), and the other 2 for ventricular fibrillation. Subsequently, only 27 patients (54%) of all underwent ICD implantation following the WCD use, because of reduced risk of VA after optimal pharmacological therapy or improvement in the left ventricular function.

Conclusions: The WCD use for the acute phase care of patients at high risk of VA can be safe and effective, and may be useful for evaluating indication of ICD implantation.

Introduction

The wearable cardioverter-defibrillator (WCD; Life Vest 4000, Zoll, Pittsburgh, PA, USA) is a vest-type device capable of automatic detection of and shock therapy for ventricular tachyarrhythmias (VA), such as ventricular tachycardia (VT) and ventricular fibrillation (VF). It has been expected to play a role as an effective bridge therapy to implantable cardioverter-defibrillator (ICD) implantation, recovery of left ventricular (LV) function, and heart transplantation in patients at high risk of VA, mainly in the outpatient setting in Europe and the USA [1–4].

In May 2015, the second revision of the statement for the clinical use of WCD was published by the Japanese Heart Rhythm Society (JHRS) [5]. The statement mentioned WCD use for patients

* Corresponding author at: Advanced Arrhythmia Therapeutic Branch, Division of Cardiology, Saiseikai Kumamoto Hospital Cardiovascular Center, 5-3-1 Chikami, Minami-ku, Kumamoto 861-4193, Japan. Fax: +81 96 326 3045.
E-mail address: okumura@hirosaki-u.ac.jp (K. Okumura).

http://dx.doi.org/10.1016/j.jjcc.2016.08.004
0914-5087/

within 40 days of acute myocardial infarction (MI) with low left ventricular ejection fraction (LVEF) (≤35%) and New York Heart Association (NYHA) class II or III heart failure (HF) symptoms, patients within 90 days of coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) with low LVEF (≤35%) and NYHA class II or III HF symptoms, patients within 90 days of onset of non-ischemic acute HF with low LVEF (≤35%), patients with irreversible severe HF who satisfied requirements for heart transplantation, patients with accepted indications for ICD implantation who also have temporary contraindications for implantation, patients who preferred clinical follow-up and prophylactic treatment rather than secondary preventive implantation of ICD, and patients waiting for re-implantation of ICD after extraction because of infection or other reasons.

Although WCD has been available in Japan since April 2014, its clinical use is still limited (only about 300 cases in December 2015) [6,7], largely because of limited reimbursement, and therefore its usefulness and potential roles are still unclear, especially in-hospital use. Here, we report our single center experience of WCD use describing its utilization for in-hospital acute phase care of patients at high risk of VA and its potential roles.

Methods

The consecutive 50 patients prescribed WCD between April 2014 and December 2015, at the Hirosaki University Hospital were studied. Details of WCD and the algorithm of arrhythmia detection were described elsewhere previously [8,9]. Daily WCD wearing time and electrocardiogram (ECG) recordings were transmitted via remote monitoring system (LifeVest Network) and were analyzed in detail. The indication of WCD use in our hospital was based on the indication suggested by Klein et al. [9] and the second revision of the statement for the clinical use of WCD published by the JHRS [5]. All patients were considered to be potentially indicative of ICD [10]. As WCD needs self-management for its appropriate use, some elderly patients at high risk of VA were excluded in the present study.

We used WCD from the early period of admission according to the flowchart shown in Fig. 1. Briefly, when a patient who was at high risk of sudden arrhythmic death for a limited period but not candidates for an ICD was admitted, we first assessed circulatory dynamics of the patient. If circulatory dynamics was stable, we prescribed WCD as early as possible and managed the patient in the general ward. On the other hand, if circulatory dynamics was unstable, such as occurrence of incessant VT or severe condition with auxiliary devices, we managed the patient in intensive care unit (ICU) or coronary care unit (CCU). After the patient recovered, we prescribed WCD and managed him or her in the general ward. The tachycardia detection rate was programmed at 200 beats/min (bpm) in the former 20 patients, while dual tachycardia detection zone (VT/VF, 130/200 bpm) was programmed in the latter 30. Time from VT detection to shock delivery (shock delay) was 60 s for VT and 25 s for VF. Shock energy was set to biphasic 150 J for both VT and VF. The study was approved by the Ethics Committee of our institution.

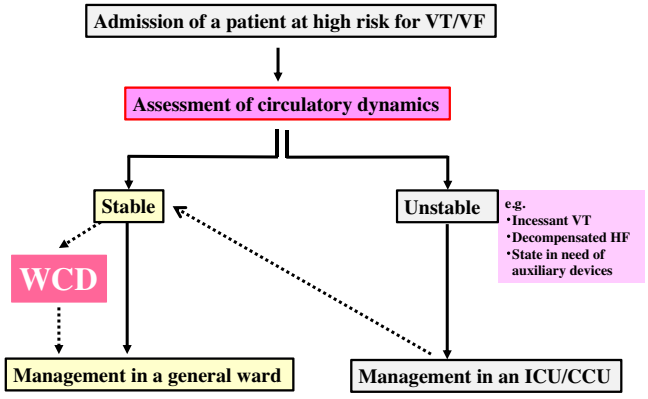

Fig. 1. Flowchart of WCD use for patients at high risk of VT/VF in the Hirosaki University Hospital.
CCU, coronary care unit; HF, heart failure; ICC, intensive care unit; VT, ventricular tachycardia; VF, ventricular fibrillation; WCD, wearable cardioverter-defibrillator.

Continuous variables are expressed as the median (interquartile range [IQR]) or mean ± SD. Variables between in-hospital WCD use and out-of hospital WCD use were compared by the Student *t* test or Fisher's exact test. A *p*-value <0.05 was considered statistically significant. Statistical analyses were performed using JMP 11 software (SAS, Cary, NC, USA).

Results

Patient profiles

Clinical characteristics of the patients are summarized in Table 1. The median age was 56 (49–66) years, and 46 (92%) were male. The median LVEF, evaluated by echocardiography, was 52.2% (34.7–63.7%). The underlying heart diseases included prior MI in 23 patients (11 recent MI defined as that within one month and more than 72 h from the onset, and 12 previous MI as that after one month from the onset), variant angina in 3, hypertrophic cardiomyopathy (HCM) in 5, idiopathic VF in 5, Brugada syndrome in 3, post aortic valve replacement in 2, post-surgical repair of tetralogy of Fallot in 2, unexplained syncope in 2, and fulminant myocarditis, cardiac amyloidosis, residual ventricular septal defect, sustained VT after ICD removal, and congenital muscular dystrophy (one in each). Of all patients, 38 (76%) were prescribed

Table 1
Clinical characteristics of the patients with the WCD use.

	All patients (*n* = 50)
Age (years)	56 (49–66)
Male gender	46 (92%)
Body mass index (kg/m^2)	24.3 (21.5–27.4)
Baseline heart diseases	
Myocardial infarction	23 (46%)
Recent	11 (22%)
Previous	12 (24%)
Variant angina	3 (6%)
Hypertrophic cardiomyopathy	5 (10%)
Idiopathic VF	5 (10%)
Brugada syndrome	3 (6%)
post aortic valve replacement	2 (4%)
post-surgical repair of TOF	2 (4%)
Unexplained syncope	2 (4%)
Residual VSD	1 (2%)
Fulminant myocarditis	1 (2%)
Cardiac amyloidosis	1 (2%)
Sustained VT after ICD removal	1 (2%)
Muscular dystrophy	1 (2%)
LVEF (%)	52.2 (34.7–63.7)
History of VT/VF	38 (76%)
Daily WCD wearing time (hours/day)	23.7 (23.6–23.9)
Duration of WCD use (days)	16 (8–33)
Out-of-hospital use	81 (42–85)*
In-hospital use	12 (6–21)
Shock delivery during WCD use	3 (7.5%)

Data are shown as median (25th–75th percentiles) or *n* (%).
TOF, tetralogy of Fallot; VSD, ventricular septal defect; VT, ventricular tachycardia; VF, ventricular fibrillation; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; WCD, wearable cardioverter-defibrillator.
* $p < 0.0001$ versus in-hospital use.

Please cite this article in press as: Sasaki S, et al. Potential roles of the wearable cardioverter-defibrillator in acute phase care of patients at high risk of sudden cardiac death: A single-center Japanese experience. J Cardiol (2016), http://dx.doi.org/10.1016/j.jjcc.2016.08.004