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Review Article

Wearable cardioverter defibrillator: A life vest till the life boat (ICD) arrives

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ARTICLE INFO

Article history:
Received 16 February 2013
Accepted 20 December 2013
Available online 8 January 2014

Keywords:
Death
Sudden
Defibrillation
Tachyarrhythmias
Cardioversion

ABSTRACT

It is well established that implantable cardioverter defibrillator (ICD) is a life saving device ensuring protection against life threatening ventricular arrhythmias. But there are certain situations like a recent myocardial infarction where the standard guidelines do not recommend the implantation of an ICD while the patient can still be at a risk of demise due to a life threatening ventricular arrhythmia. There could also be a temporary indication for protection while explanting an infected ICD system. The wearable cardioverter defibrillator (WCD) is a device which comes to the rescue in such situations. In this brief review, we discuss the historical aspects of the development of a WCD, technical aspects as well as the clinical trial data and real world scenario of its use.

1. Introduction

It is well established that the implantable cardioverter defibrillator (ICD) is a life saving device, especially in patients with a previous myocardial infarction and reduced ejection fraction.[1] But the DINAMIT study[2] showed that prophylactic ICD implantation is not useful in patients with recent myocardial infarction. Still every clinician would have anecdotal experience of patients who have had sudden cardiac death (SCD) after a recent myocardial infarction and VALIANT (Valsartan in Acute Myocardial Infarction) study showed that the risk of SCD in post myocardial infarction patients with left ventricular dysfunction or heart failure is highest in the first 30 days after the event.[3] The wearable cardioverter defibrillator (WCD) (LifeVest, ZOLL, Pittsburgh, Pennsylvania) is a device which can be used to bridge the situation when a patient is waiting for an ICD. This could be either a patient with recent myocardial infarction and left ventricular dysfunction within the period of forty days when the definitive indication for ICD is not yet established or when ICD implantation needs to be deferred in patients with surgical contraindication (i.e. infection, vascular obstruction, treatable comorbidities). In this review we will examine the technical details of a WCD as well the current evidence for its clinical use since it is a relatively new introduction.

2. Historical aspects

In 1998, Angelo Auricchio and asssociates[4] published the preliminary data on the use of WCD in 15 persons who had

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0019-4832/$ – see front matter
http://dx.doi.org/10.1016/j.ihj.2013.12.050

survived a cardiac arrest due to ventricular tachycardia (VT)/ventricular fibrillation (VF). The WCD had four sensing electrodes and three defibrillation pads integrated into garment to be worn by the patient. The study was conducted in the electrophysiology laboratory under conscious sedation. The defibrillator device had a maximum capacity of 285 Joules (J) monophasic shock. Though the device was capable of automatic sensing and discharging, manual charging and discharging was used in this study to demonstrate the effectiveness of a 230 J shock to terminate an induced VT/VF episode. A single 230 J shock was successful in all the 10 cases in which a VF/fast VT was inducible during the study. The arrhythmia was correctly detected in nine of the ten cases while it was not detected in one case due to the erroneous disconnection of the sensing electrodes at the time of arrhythmia induction.

While the initial report was an acute evaluation of the efficacy of the WCD within the limits of an electrophysiology laboratory, the next one evaluated the efficacy in the field.[5] The WCD tested was a vest with ECG monitoring and defibrillator electrodes along with a monitor and an alarm system. The home based interrogation device was connected to the hospital through a modem. The WCD used had a weight of approximately 1500 g and a maximum energy output of 285 J. Of the 39 patients reported, six had ventricular fibrillation in the setting of acute myocardial infarction while 17 had left ventricular ejection fraction (LVEF) of less than 30% and 16 had non-sustained ventricular tachycardia (NSVT). Patients were provided two to three days in hospital training for the use of the device and adaptation. Three of four episodes of VT/VF were correctly identified and terminated. Two of these patients eventually received an ICD. Noteworthy, none of the patients had an inappropriate WCD discharge, though artifactual alarms occurred in 15%. All NSVTs were promptly recognized, but defibrillator discharge was withheld by the patients.

United States Food and Drug Administration (FDA) approval for the first WCD from Lifecor Inc. of Pittsburgh was obtained in 2002.[6] As per the FDA Consumer Magazine, March–April 2002, the device was to be worn 24 h a day, except during bathing or showering. User had to transfer the data to the monitoring hospital usually once a week using the modem. FDA had on its file, data from 289 patients across the United States and Europe. The average usage was 20 h a day for about three months, in patients either awaiting cardiac transplants or with a recent myocardial infarction or coronary artery bypass surgery, and an increased risk of sudden cardiac death. Temporary skin rash was the only major side effect noted.

While the original WCD was a monophasic device, a biphasic device was tested for acute termination of VF by Reek et al.[7] The biphasic device had a maximum output of 150 J and it could terminate induced VF at the first attempt with 70 J in 12 and with 100 J in 10 episodes tested. Thus it would provide an adequate safety margin for defibrillation, though the authors recommended programming maximum energy output for ambulatory WCD patients.

As per the manufacturer's website, over 100,000 patients have been using the WCD by July 2013, with a first shock success rate of 98%. Inappropriate shocks were less than one per month of use and the shock event survival was 92% (conscious on arrival at the emergency department or remained at home). Median daily use has been 22.5 h per day.[8]

3. Technical aspects

3.1. *Components of a WCD system*

The WCD system has three defibrillation and 4 ECG sensing electrodes, fitted within a garment to be worn by the patient. The defibrillation electrodes are self gelling type and the ECG electrodes are non-adhesive dry tantalum oxide capacitive electrodes. The defibrillator unit is carried on a waist belt (Figs. 1 and 2). Two ECG channels can be monitored with the two pairs of ECG electrodes from front to back and right to left lead sets.[9] Microampere alternating current is used to check electrode contacts as in conventional monitoring systems.

3.2. *Functioning of WCD system*

The system uses heart rate, template matching and the event persistence before deciding on defibrillation. There is a sensing function to detect electrode fall off as it is used in externally worn electrode systems. If the signal from one lead is found to be suboptimal, the device will revert to single channel mode, ignoring the inputs from the faulty channel. A patient responsiveness system allows aborting of defibrillation attempt in a conscious patient. Patient responsiveness system gives out a vibratory alarm once the arrhythmia is detected. This is followed by a cascade of audible alarms of increasing intensity so that the patient has the option to press the patient response button to avert a shock. Just before delivering the shock, the defibrillation electrodes release a gel to reduce the electrical impedance and the device gives an announcement for bystanders to keep off the patient. If the patient does not respond to the alarms or the response button is released by an unconscious patient the system delivers 5 shocks. ECG records from 30 s prior to the alarm until 15 s after the alarm can be stored and sent to a secure server by modem later. Patients can also initiate manual ECG recordings.[9] If the WCD detects an asystole, it gives an announcement to call the ambulance so that bystanders can respond.

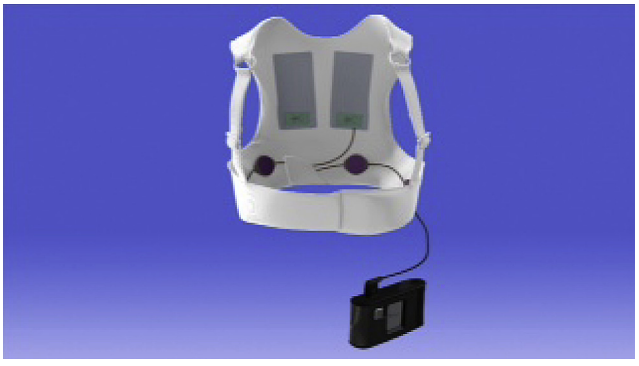

Fig. 1 – Components of a WCD system (Courtesy, ZOLL).