Available online at www.sciencedirect.com
ScienceDirect
Journal of Electrocardiology 43 (2010) 63–67
JOURNAL OF Electrocardiology
www.jecgonline.com

Evaluation of the effectiveness of a wearable cardioverter defibrillator detection algorithm

Katie A. Dillon, MPH,* Steven J. Szymkiewicz, MD, Thomas E. Kaib, MS

ZOLL Lifecor Corporation, Pittsburgh, PA, USA

Received 21 November 2008

Abstract

Background: Wearable cardioverter defibrillators (WCDs) provide protection from sudden cardiac death. The efficacy of a WCD detection algorithm has not been reported outside of clinical trial.
Methods: The efficacy of the algorithm was reviewed through a retrospective analysis of appropriate shocks, inappropriate shocks, and arrhythmia detections during a 1-year period.
Results: WCD patients had an appropriate shock rate of 1.58 per 100 patient-months and an inappropriate shock rate of 0.99 per 100 patient-months. Most of the arrhythmia detections in a 3-month period were short in length, with only 2.7% of the detections lasting over 25 seconds, the time at which a shock becomes possible.
Conclusions: By incorporating a patient responsiveness test, as well as features that eliminate or reduce signal interference common to external electrocardiogram electrodes, the WCD detection algorithm has a low risk of inappropriate shocks.

Keywords: Wearable cardioverter defibrillator; Ventricular tachycardia; Ventricular fibrillation

Introduction

Outpatient sudden cardiac arrest (SCA) is a major public health problem, affecting an estimated 166 000 people[1] every year. Ventricular tachyarrhythmias, including ventricular tachycardia (VT) and ventricular fibrillation (VF), are commonly responsible for SCA and may be reversed by a shock from a defibrillator. Some patients who are at high risk of SCA receive implantable cardioverter defibrillators (ICDs) that automatically detect and treat arrhythmias with defibrillation. Most, however, must rely on bystanders to both witness the event and act upon it. Many public places are now equipped with automatic external defibrillators (AEDs) that witnesses can use to treat the arrhythmia before emergency medical service arrives. Nevertheless, few without ICDs survive VT/VF SCA despite the increased availability of public access AEDs, as witnessed events are uncommon.[2]

Another option that does not require a witness to be present has become commercially available in recent years. Wearable cardioverter defibrillators (WCDs) are intended for use by adult patients who have an increased risk of SCA. WCDs provide constant electrocardiogram (ECG) monitoring and automatic defibrillation without bystander intervention. Because WCDs do not require surgery, they are primarily used when SCA risk is temporary or changing, and the need for surgery to implant an ICD is uncertain, such as immediately after myocardial infarction or coronary revascularization, recently diagnosed nonischemic cardiomyopathy or optimizing therapy for congestive heart failure, or in patients listed for cardiac transplant. A WCD may also be used to provide protection when an ICD requires explantation or when implantation surgery must be postponed.

When sensing electrodes are worn on the skin, the cardiac signal is prone to signal interference from skin deformation, electrode movement on the skin, electromagnetic interference (EMI), and noncardiac electrical potentials from the body. Signal interference may dramatically reduce the sensitivity and specificity of arrhythmia detection algorithms. Signal interference, as well as nonsustained ventricular tachyarrhythmias and supraventricular tachycardias, may also lead to inappropriate shocks. The WCD was found to have a high rate of successful defibrillations as well as a low inappropriate shock rate in the WEARIT/BIROAD studies.[3] However, the efficacy of the WCD algorithm has

* Corresponding author. ZOLL Lifecor Corporation, 121 Freeport Road, Pittsburgh, PA 15238, USA.
E-mail address: dillon.katie@gmail.com

0022-0736/$ – see front matter © 2010 Elsevier Inc. All rights reserved.
doi:10.1016/j.jelectrocard.2009.05.010

not been reported outside a clinical trial. To determine the efficacy of the algorithm outside a clinical trial, the machine records from all WCD (LifeVest, ZOLL Lifecor Corporation, Pittsburgh, PA) patients during 2006 were reviewed.

Methods

Wearable cardioverter defibrillator description

The WCD consists of 3 nonadhesive defibrillation electrodes, 4 nonadhesive-sensing ECG electrodes, and a vibrator incorporated into a garment worn by the patient along with a monitor defibrillator worn at the waist containing the monitoring and defibrillation electronics. The 4 ECG electrodes provide 2 channels of ECG monitoring as front-to-back and right-to-left leads.

Wearable cardioverter defibrillator detection algorithm

The WCD detection algorithm considers 3 inputs when monitoring for arrhythmias as follows: heart rate, template matching, and persistence of the event. To eliminate, reduce, or identify disturbances in the ECG signal, the algorithm uses several features including a driven ground, analog and digital filters, a 2-lead detection system, a falloff detection signal for each electrode, and a review of each lead for obvious interference. The algorithm also incorporates a patient responsiveness test that allows a conscious patient to respond to alarms to prevent an inappropriate shock.

Heart rate is assessed independently from each of the 2 leads. The algorithm considers rate matching between the leads, signal quality, and historical rate values to determine the best rate value. The default VT and VF detection rate thresholds are 150 and 200 beats per minute (bpm), respectively. However, the prescribing physician may change the rate thresholds for an individual patient when prescribing the device. In addition to basic rate detection, the cardiac signal is compared to a template recorded during device setup to determine if the QRS morphology has changed. If the input from one of the leads is unusable due to falloff or interference, template matching is not used, and the algorithm relies only on rate, stability, and persistence. The algorithm uses time windows rather than x of y beats in determining the presence of an arrhythmia. In the absence of any significant signal interference, an arrhythmia exceeding the rate threshold exists for 3 to 5 seconds before the presence of an arrhythmia is flagged internally. The arrhythmia must persist for an additional 10 seconds before the presence of an arrhythmia is confirmed, and the device declares that an arrhythmia has been detected. When the arrhythmia detection has started, the patient responsiveness test begins, and the ECG is recorded.

Each lead is reviewed for loss of skin contact, obvious interference, the presence of clipping, and the overwhelming presence of higher frequencies in the signal. If a disturbance is identified on one lead, the algorithm will ignore the input from that lead and use single-lead monitoring. In addition, the patient is notified and instructed to correct the improper electrode contact when persistent ECG disruption or loss of skin contact is identified. Although using the input from both leads results in the highest sensitivity and specificity, having 2 independent leads reduces the time during which the patient is not monitored. A driven ground eliminates or reduces interference common to all electrodes by summing the signal from all electrodes and returning a filtered result onto the skin. The WCD also uses analog and digital filters to eliminate or reduce signal components that are not part of the ECG signal.

If a persistent arrhythmia is detected, the WCD notifies the patient via a responsiveness test, allowing a conscious patient to prevent treatment. A conscious patient can hold the response buttons during the responsiveness test to prevent an unnecessary treatment. The patient responsiveness test begins with a tactile vibration alarm, which persists throughout the duration of the test. If the patient does not use the response buttons, the responsiveness test continues with a low-volume dual tone alarm that increases to a high-volume (approximately 100 dB) dual tone alarm. Before shock delivery, gel is released from the therapy electrodes to provide a low-impedance electrical pathway, and voice alarms begin, warning bystanders not to touch the patient. In the absence of a patient response and the continuing detection of an arrhythmia through the responsiveness test, up to 5 shocks are delivered. The device uses a biphasic waveform with programmable energy levels of up to 150 J. The duration of the patient responsiveness test is at least 25 seconds but may last longer if the response buttons are activated or if ECG signal interference is detected.

Data collection

The WCD monitor automatically stores data flags with information on the operation of the device, including patient use, periods of ECG disturbances, and arrhythmia detections. The time when the data flag was stored is recorded along with information that can be decoded to evaluate the device performance. The monitor also stores ECG recordings obtained during arrhythmia detections, manual recordings initiated by the patient, and the ECG used to create the template during device setup. The ECG recordings from arrhythmia detections contain the signal from 30 seconds before the onset of the arrhythmia alarms, during the arrhythmia alarm sequence, and 15 seconds after the arrhythmia alarms have ended. Patients are instructed to download the information recorded by the monitor to a secure server for later access.

Data analysis

The effectiveness of the algorithm was reviewed through a retrospective analysis of appropriate shocks, inappropriate shocks, and arrhythmia detections. Patient age, sex, and clinical indications for WCD use were obtained from the medical order that physicians use to prescribe the WCD. Patient use and compliance were calculated using the data flags stored by the WCD monitor. Patient data used in the analysis were located on the secure server to which patients download the information recorded by the monitor. All patients who wore the WCD for at least 3 days during 2006 were included in the analysis. Patients with less than 3 days