Clinician perception and patient compliance with the wearable cardioverter defibrillator

Donald Joseph Pohorence

The University of Toledo

Follow this and additional works at: http://utdr.utoledo.edu/graduate-projects
Clinician perception and patient compliance with the wearable cardioverter defibrillator

Donald Joseph Pohorence
The University of Toledo
2011
Acknowledgments

Advisor

AJ Farah MSBS, PA-C

Secondary Advisor

Dr. Patricia Hogue Ph.D, PA-C
Table of Contents

Introduction ......................................................................................................................................1
Pathophysiology of Arrhythmias .....................................................................................................3
Risk Stratification of sudden cardiac death .....................................................................................6
Treatment of Sudden Cardiac Death ..............................................................................................10
  Implantable cardioverter defibrillators ..................................................................................10
  Wearable cardioverter defibrillator ....................................................................................12
    Technical aspects of the wearable defibrillator ..........................................................13
    Indications for the wearable defibrillator ........................................................................14
    Clinical efficacy of the wearable defibrillator ...............................................................17
Methods..........................................................................................................................................19
Results ............................................................................................................................................21
Discussion ......................................................................................................................................24
Limitations of the study .................................................................................................................27
Conclusion .....................................................................................................................................28
References ......................................................................................................................................29
Appendix ........................................................................................................................................33
  Practitioner letter .....................................................................................................................33
  Practitioner survey ..................................................................................................................34
  Patient Letter .............................................................................................................................35
  Patient Survey ..........................................................................................................................36
Abstract ..........................................................................................................................................37
Introduction

Sudden cardiac arrest (SCA) is defined as the cessation of cardiac mechanical activity and is confirmed by the absence of signs of circulation (Jacobs, 2004). Sudden cardiac death (SCD) is a result of sudden cardiac arrest (SCA), the loss of consciousness within one hour after the onset of acute symptoms (Kayser, 1982). Based on the 2009 American Heart Association statistical update, 864,480 people died of cardiovascular related disease in 2005. Of those, 294,851 were due to SCA out of hospital while being treated by emergency medical staff; in addition, 21,748 were reported as in hospital SCA. Moreover, approximately 80% of out-of-hospital deaths occur in private residence (Loyde-Jones, 2009). Therefore one can assume the actual number of SCA patients is greater than reported because of lack of reporting and SCA that goes untreated by EMS staff. The number of sudden cardiac deaths in the community has been on the decline, as a direct result of resuscitation plans and the use of external defibrillators. However, on average only 8% of those receiving community-based resuscitation are discharged from the hospital alive (Estes, 2011).

The risk of SCD is high, and because most SCD occur in the home and a high percentage of them have ventricular tachycardia or ventricular fibrillation (VT/VF) as an initial rhythm, it is important to have preventative therapy options for patients at highest risk. The gold standard for prevention of SCA is an implantable cardiac defibrillator (ICD). However, Medicare guidelines prohibit the implantation of an ICD under certain circumstances. The use of a wearable cardiac defibrillator (WCD) has bridged that gap for these particular patients. The use of the WCD is under scrutiny because of distorted perceptions of patient compliance and practitioners’ satisfaction and views of this life saving device. Furthermore, this has led to an increase of inappropriate implantation of ICDs among patients who do not meet Medicare/Medicaid
guidelines. Thus the awareness and knowledge of patients’ satisfaction and the understanding the views of the practitioners with the wearable defibrillator will only enhance the understanding and usefulness of the device. The purpose of this study is to explore practitioners’ satisfaction and patient compliance with the wearable defibrillator. The information gathered from this study will help to educate practitioners and patients of the usefulness of the wearable defibrillator. In addition, understanding practitioners' views of the WCD will lead to a reduction of inappropriate implantation, increase use of WCD, and therefore ultimately reduce the incidence of SCD.
Pathophysiology of arrhythmia's

The pathology of arrhythmias is complex, but for the intentions of this article, I will only focus on the pathophysiology of ventricular arrhythmias. 20-38% of SCA patients have an initial rhythm of ventricular tachycardia or ventricular fibrillation (VT or VF) (Loyde-Jones, 2009). Understanding the mechanisms in which these events occur is very important in regards to prevention and treatment of ventricular arrhythmias. Abnormal impulse generation, abnormal impulse conduction and finally a combination of the two are three general ways in which a ventricular arrhythmia is born (Saffitz, 2005, Binah & Rosen, 1992). First, one must understand the normal automaticity of the heart to understand abnormal automaticity.

The sinoatrial (SA) node is the dominant pacemaker of the heart. All cardiac cells have an intrinsic pace; however, the SA node has the fastest intrinsic pace among the pacemaker cells. “Overdrive suppression” is the term used for the dominance of the SA node to establish a pace for the entire heart. This phenomenon refers to the reduction in the intrinsic rate of a potential pacemaker fiber when stimulated at a rate faster than its own (Binah & Rosen, 1992). The ionic mechanisms of impulse of the SA node are much more complex than that of the ventricular cells, therefore not emphasized in this article. Ventricular myocytes and the His-Purkinje system are the root for ventricular arrhythmia’s, more specifically injured myocytes near ischemic or infarcted areas of myocardium.

The spontaneous development of a lethal cardiac arrhythmia may be regarded as a stochastic event that arises from complex interactions between relatively fixed anatomic and functional substrates and transient triggering events (Saffitz, 2005). Most causes of sudden death are from lethal ventricular arrhythmias. Furthermore, most sudden deaths occur in patients with coronary artery disease. SCD can occur with congenital heart disease or non-ischemic
cardiomyopathies, or channelopathies, however, these cases are very rare. Therefore focusing on arrhythmogenesis from ischemic heart disease is more relevant to the discussion in this article.

Abnormal impulse generation is a result of aberrant or ectopic ventricular beats, most commonly a premature ventricular contraction (PVC) which is caused by either abnormal automaticity or triggered activity. Abnormal automaticity is defined as spontaneous initiation of an impulse that is independent of prior stimulation (Saffitz, 2005). This can be caused by numerous factors such as, hypoxia, ischemia, high levels of extracellular potassium, and increased sympathetic tone due to increased catecholamines and a decreased parasympathetic tone (such as in heart failure) (Binah & Rosen, 1992).

Triggered activity is an initiation of an impulse before repolarization can be complete. More specifically these are termed early-after-depolarizations (EADs), and delayed-after-depolarizations (DADs). This almost always happens in injured or infarcted myocardial cells, which is a result of hypoxia, acidosis, decreased intracellular potassium, and increased intracellular calcium. EADs are often seen in cardiac glycoside toxicity because of a rise in intracellular calcium (Binah & Rosen, 1992). Abnormal automaticity and triggered activity can lead to abnormal impulse conduction depending on multiple factors such as anatomical location of ectopic beat, refractoriness of adjacent tissue, and structural alterations of surrounding myocardium, which can lead to either a reentry arrhythmia or a non-reentry arrhythmia (Saffitz, 2005).

During a myocardial infarction or ischemia, myocardial tissue is devoid of oxygen. Many things happen on the molecular level that affects membrane potentials that have a huge impact on arrhythmia formation. First, there is a rise in extracellular potassium during the first few minutes of ischemia; this reason is still, for the most part unknown. However, we do know
that a meticulous balance between sodium and potassium is what maintains resting potential for most cells. Therefore a rise in extracellular potassium will depolarize the cell to a more positive value. This in turn inactivates the fast sodium channels responsible for quick depolarization of myocytes. Also because the sodium channels are inactivated by the increased membrane potential, slow calcium channels become the dominant mode of depolarization of the cell (Binah & Rosen, 1992, Ehlert & Goldberger, 1997). This results in reduced action potential amplitude and slowed conduction velocity and upstroke. This results in slower conduction which can cause heterogenous refractoriness of tissue, which is a substrate for re-entrant arrhythmia formation.

One speculation is that the Na-K ATP pump is inactivated while in a hypoxic state because of lack of ATP, therefore further resulting in depolarizing the cell (Binah & Rosen, 1992). Furthermore, a cascade of hypoxic substrates accumulates within the myocytes causing subsequent increases in permeability of the cell and efflux of potassium. Substrates such as lactic acid, lysophospholipids, and phosphates all contribute to a rise in resting membrane potential (Ehlert & Goldberger, 1997). Ultimately the rise in resting potential increases the susceptibility of a cell to depolarize at a faster rate, thus more prone to a ventricular tachycardia.
Risk Stratification for SCD

Several factors are involved with creating validated guidelines for identifying high risk patients for proper prevention of SCD. There is evidence from randomized controlled trials (RCT) that have set standard guidelines for proper prevention strategies. There have been over ten RCT that evaluate the effectiveness of preventions against SCD. Within these clinical trials heterogeneity among patient populations has made guideline recommendations very difficult and not very lucid. Economics and cost effectiveness of prevention of SCD is a major issue.

Structural heart disease can range from congenital cardiomyopathies to acquired ischemic disease. Left ventricular ejection fraction (LVEF) which is a predictor of structural heart disease, remains one of the most influential risk stratification criteria. Depressed left ventricular function is a result of either ischemic damage to the myocardium or compensation dysfunction from a non-ischemic cardiomyopathy. LVEF as a risk factor has been implemented in numerous clinical trials and has proven to be one of the strongest identifiers of risk.

Seven primary prevention implantable cardioverter defibrillator (ICD) trials show on average a 28% relative risk reduction (RRR) and 3% average risk reduction (ARR) in SCD in patients with depressed LVEF; with most of the affect seen in patients with the lowest LVEF. Primary prevention trials with ICDs show no significant difference in risk reduction in patients with a LVEF more than 30%. However, when compared to three secondary prevention trials with ICDs, an average LVEF was above 30% and still resulted in a RRR of 35% and a ARR of 7.5% in SCD. Therefore the prognostic value of LVEF is not yet concrete within the clinical literature (Lopera & Curtis, 2009). Buxton et al (2007) highlighted the fact that there are many other factors to consider when evaluating the risk of SCD. A risk stratification algorithm that accentuates the importance of other factors that may increase or decrease the validity of LVEF as
A determining factor in risk for SCD was created (Buxton et al., 2007).

Another tool in the risk stratification arsenal is evaluating a patient for ectopic ventricular beats or non-sustained ventricular tachycardia (NSVT). NSVT and ectopic ventricular beats are found upon electrophysiological studies (EPS), where the heart can be induced to produce a ventricular tachycardia. These studies can also find an anatomic location of an ectopic beat within the ventricles. However, NSVT can also be found incidentally on telemetry or a holter monitor of a patient. NSVT can be a sign of something that needs to be done to protect this patient from a deadly rhythm. NSVT or ectopic beats are a sign of structural heart disease, most commonly a result of scar tissue within the myocardium. Furthermore, LVEF is inversely proportional to the frequency and complexity of NSVT and/or ectopic ventricular contraction (Lopera & Curtis, 2009). However, a paradoxical relationship arises when looking at patients with heart failure. More patients with NYHA class I-II die suddenly as do patient with more severe heart failure. The rational is that patients with more severe heart failure will die of pump failure rather than sudden death due to arrhythmia, therefore NSVT or ectopic beats are a marker of structural heart disease rather than a marker for arrhythmia.

A study was done to evaluate the predictive power of arrhythmia markers for SCD after an acute myocardial infarction. This study found that the predictive power of LVEF, NSVT, and signal averaged electrocardiogram (SAECG) was no different than the predictive power for non-sudden cardiac death (Huikuri et al., 2003). Therefore LVEF and NSVT are good markers for predicting cardiac mortality, but just not specific enough to predict sudden cardiac death due to arrhythmia. However, three major primary prevention ICD trials used NSVT along with LVEF as criteria for patients who benefit from ICD prophylactic implantation. A review of all three trials found a RRR of 55% among those who received and ICD for primary prevention of SCD
Electrocardiogram (ECG) findings suggestive of repolarization abnormalities or electrical instability are used as risk stratification tools for preventative treatment options for SCD. T-wave alternans (TWA) is used in such a way. TWA has been evaluated in numerous clinical studies; Lopera & Curtis (2009) conduct a meta-analysis of 19 different trials evaluating the predictive value of TWA. Based on the meta-analysis of 19 studies between the years 1990-2004 found an overall 19.3% positive predictive value (PPV) and a 97.2% negative predictive value (NPV) of TWA for arrhythmic events. A study done by Chow et al (2007) found that the number of patients needed to treat with an ICD for two years to save one life, was nine among patients who had a positive TWA and 76 among those who tested negative (Chow et al., 2007).

Autonomic instability and its correlation to arrhythmogenesis have been studied extensively. Heart rate variability (HRV) and baroreflex sensitivity (BRS) are important entities for evaluating someone at risk for SCD. Lopera & Curtis (2009) provide a meta-analysis of 11 clinical studies of post MI patients with abnormal HRV and BRS (n = 5719). This analysis showed a PPV ranging from 9 to 54% in predicting arrhythmic events (Lopera & Curtis, 2009). Most specifically the ATRAMI study (1998) evaluated the prognostic value of HRV and BRS in post MI patients and found that patients with a low HRV and BRS and ejection fraction lower than 35% had a significantly higher mortality rate than those who had a higher or near normal HRV and BRS with ejection fractions higher than 35% (La Rovere, 1998).

As you can see the risk stratification for patients at high risk for SCD is validated in the literature, however there is inconclusive evidence for patients who are not "high-risk" for SCD. High risk patients only represent a small portion of patients who die of sudden cardiac arrest. There are numerous risk factors for SCA, however, LVEF is the most influential and important
factor while looking at high risk patients. The risk factors that are less lucid in the literature can be utilized in borderline cases where physicians are unsure of the risk.
Treatment of SCD

Treatment options to prevent SCD are limited. More than 30 years have passed since Mirowski first introduced the implantable cardioverter defibrillator in 1980 (Mirowski, Mower, & Reid, 1980). The ICD is now the cornerstone of cardiology for reducing the risk of sudden cardiac death related to ventricular fibrillation (VF) and ventricular tachycardia (VT) (Auricchio, 1998). Optimal medical management with antiarrhythmic medications and a cocktail of cardiac drugs is the mainstay used for patients at risk for SCD and for patients with CAD or have had an arrhythmic event along with ICD implantation. Also on the forefront of cardiology is the wearable external cardiac defibrillator for the treatment of SCD in patients who do not meet the criteria for ICD implantation.

Implantable Cardioverter Defibrillator

Decades of research has been done on prevention of SCD. Protection with an ICD is broken down into two categories, primary prevention and secondary prevention. ICD therapy for primary prevention is prophylactic protection against SCD because of a patients' presumed high risk. Primary prevention of SCD by means of an ICD has been grounded with numerous studies. These studies compared patients treated with an ICD to patients either treated with traditional medical therapy, anti-arrhythmic therapy, cardiac resynchronization therapy, or a combination of these treatments.

A meta-analysis was performed on all ten clinical trials involved with the primary prevention of SCD with an ICD. With these pooled results, a relative risk reduction (RRR) of 25% in all cause mortality among groups who receive an ICD was calculated, with a death rate of 26.4% among the control groups and 18.5% among the ICD groups. This also corresponds to an absolute risk reduction (ARR) of 7.9%. The meta-analysis excluded three trials that found no
benefit with ICD implantation and excluded them from the analysis and reported results based off the seven trials with beneficial results. Similar results were found with all cause mortality among control groups to be 24.1% and 17.5% among ICD groups. This corresponds to a RRR of 26% and ARR of 6.6% (Nanthakumar, Epstein, Kay, Plumb, & Lee, 2004).

Results from the ten primary prevention trials of ICDs show significant clinical results that should be used in guidance for patient care. However, the risk reduction of ICD should and must be compared to risk reduction of ACE-I, B-Blockers, aldosterone antagonists respectively. Nanthakumar et al (2004) found that 90% of the patients within the ten primary prevention trials where on ACE-I, B-blockers, aldosterone antagonists while under the protection of ICD. Moreover, the ability to study the impact that ICDs have on mortality alone is impossible. The benefits and protection of an ICD are additive to the state-of-the art medical treatment (Nanthakumar et al., 2004).

Secondary prevention of SCD using an ICD is for patients who have had a previous SCA or VT/VF events. There have been three main trials evaluating the effectiveness of ICD therapy for secondary prevention of SCD compared to conventional antiarrhythmic therapy (amiodarone). Based on a meta-analysis of all three trials it was found that all trials were similar in patient population and results. Within these trials, 47.6% of the sudden death reported was due to arrhythmia (VF/VT). The mean LVEF reported for all three trials was just under 35%, and CAD was the most common underlying comorbid condition. All three trials are consistent and show a 28% RRR in death with an ICD. The annual death rate was reduced by 3.5% per year with the use of an ICD for secondary prevention of SCD as compared to antiarrhythmic therapy alone. This correlates 29, the number needed to treat (NNT) to save one life per year of follow up of ICD protection. Furthermore, and interesting paradox was found, the amount of
protection from an ICD will decrease over time as a result of non-arrhythmic death (heart failure or pump failure) increasing over time (Connolly et al., 2000).

**Wearable Cardioverter Defibrillator**

The wearable cardioverter defibrillator (WCD) is an alternative approach to protect patients with a temporary high risk of sudden cardiac arrest (SCA) or arrhythmic death until either ICD implantation is indicated or the arrhythmic risk is considered significantly lower or absent (Klein, 2009). This allows a patient’s physician time to assess the patient’s long-term arrhythmic risk and make appropriate plans. Unlike an implantable cardioverter defibrillator (ICD), a wearable cardioverter defibrillator (WCD) is worn outside the body rather than implanted in the chest. The WCD was first introduced into clinical practice about eight years ago by the Zoll-LifeCor Corporation® Pittsburgh, PA (Klein, 2009).

The Zoll-LifeCor LifeVest® was approved by the FDA in 2002. The WCD continuously monitors the patient’s heart rhythm. If a life threatening abnormal rhythm is detected, an electric shock is delivered to defibrillate the patient back to a normal rhythm. Since the eve of its arrival on the market, three generations of the device have been introduced as smaller more comfortable user friendly devices. Over 30,000 patients worldwide have worn the Zoll-LifeCor LifeVest®. The LifeVest® is marketed in the United States and in parts of Europe. The LifeVest® was FDA approved after being tested on 289 patients worldwide in three separate clinical trials. The evidence of those trials proved the safety and efficacy of the device, and marketing of the device was begun.
**Technical aspects of the wearable defibrillator.** The LifeVest® consists of a chest garment that holds two posterior and one anterior self-gelling (each lead is self gelling prior to shock delivery to minimize electrode-skin impedance and to prevent irritation upon shock delivery) defibrillator electrodes and three non-adhesive electrodes for long-term electrocardiogram (ECG) monitoring. ECG monitoring and event history are sent to Zoll LifeCor Web server (Klein, 2009). The series of events that occur prior to a shock delivery are very straightforward. First, the defibrillator electrodes vibrate, then two low and high volume alarm tones and a voice warning to warn that a shock will be delivered. If the patient remains conscious they may delay the shock or terminate it by holding a button on the capacitor. Next, if the shock button is not used the capacitor will release an impedance-adapted biphasic truncated exponential impulse. This impulse is utilized to measure the transthoracic impedance (TTI). From the onset of VF or VT, detection of abnormal rhythm lasts 5-10 seconds, confirmation of tachycardia lasts 10 seconds, and the series of alarms to warn the patient of shock delivery lasts 25 seconds. Time for detection, capacitor charging, and synchronization of the shock, 45-50 seconds will elapse before shock is delivered if response buttons are not pressed (Klein, 2009).

The LifeVest® is programmable for VF between 120-250 bpm. The total capacitor charge is between 75 and 150 J. The LifeVest® has a flash memory system programmed to store and retrieve ECG readings up to 30 seconds before arrhythmia occurs and 15 seconds after arrhythmia alarms stop. This allows the patients physician to analyze ECG changes through the Zoll-LifeCor Web server for further evaluation and treatment. The physician can also monitor patient's wearing compliance, ECG signal quality, alarm history, and noise occurrence. After the patient is prescribed the LifeVest®, the patient is educated and trained on how to use the device properly. The patient is advised to have monthly visits with the physician. The LifeVest®
electrodes must be replaced after an event and shock delivery because the electrodes need new self-gelling pads (Klein, 2009).

**Indications for the wearable cardiac defibrillator.**

**Early Phase after Myocardial Infarction (MI).** It has been found that ICDs significantly reduce sudden arrhythmic death in the remote phase of a myocardial infarction. Overall mortality, however, is not reduced according to the Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) (2004) and the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) (2002) trials, when the ICD was implanted within the first 40 days of infarction (Hohnloser et al., 2004; Moss et al., 2002). In addition the Immediate Risk Stratification Improved Survival (IRIS) trial (2009) found that there was no difference in mortality between patients treated with ICD and patients treated with medical therapy alone (Steinbeck et al., 2009). Current guidelines do not recommend ICD implantation early after infarction in patients with left ventricular ejection fractions less than or equal to 35% (Zipes et al., 2006). The WCD will bridge the gap for the few months after an MI until ICD implantation will be appropriate, or until LVEF improves and ICD implantation is deemed unnecessary. Roughly 30% of patients with an acute MI will continue to have a LVEF below 35% and will need ICD implantation (Solomon et al., 2005). The Vest Prevention of Early Sudden Death Trial/ Prediction of ICD Therapies Study (VEST/PREDICTS) (2013) which is an ongoing randomized study evaluating whether the WCD reduces overall mortality in the first 60 days after acute myocardial infarction, will be the first study to evaluate the use of WCD early after MI (Clinicaltrials.gov identifier NCT00628966).

**After heart surgery with poor ventricular function.** Patients that have had revascularization surgery that have a low LVEF are at risk for SCA. In fact, about 50% of those patients will die in the hospital of sudden arrhythmic death (Toda et al., 2002). ICD implantation
one to three months after major open heart surgery in patients with reduced LVEF is not indicated and can be very risky. Implantation of an ICD is deferred until LVEF improves, or waiting to see if LVEF will improve. These recommendations are based on results of the CABG-PATCH trial (1997). The CABG-PATCH trial (1997) compared patients treated with an ICD after open heart surgery to patients without an ICD; the survival was no different between the groups. The WCD can be used to bridge the gap between ICD implantation and allow the patient to be cared for as an outpatient (Bigger, 1997).

**Acute heart failure and bridging until heart transplant.** In an article by Schmidinger (1999), the overall mortality in patients awaiting heart transplant is 27%, in which, 32% of those patients died of sudden cardiac death (Schmidinger, 1999). Many factors are taken into consideration when prescribing an ICD for patients awaiting a heart transplant. Besides the issues of cost, there is a higher incidence of infection among this patient population. Also ICD testing upon implantation can subject the patients' failing heart to an extreme amount of stress. With immunosuppression therapy after transplant, an ICD may become a culprit for demise (Klein, 2009). Heart transplant patients only consist of about 1% of the population who receive an WCD. However, it is still an important reminder of the usefulness of the the wearable defibrillator.

**Syncope of unknown origin.** The underlying mechanism of syncope with or without cardiac arrest is often times very difficult. Current guidelines recommend a delay in ICD implantation if a condition is reversible or can be corrected (Zipes et al., 2006). Congenital abnormalities and genetic defects can cause syncope especially in younger patients. Rare disorders such as Takotsubo cardiomyopathy and other cardiomyopathies can be hard to detect and not high on a differential diagnosis. Therefore detection of such congenital and rare
disorders can be long standing. The WCD can bridge the gap safely during the period of risk assessment until persistent arrhythmic risk can be confirmed or denied (Klein, 2009).

*Patients with inherited arrhythmogenic disorders.* The prevalence of such disorders like, congenital long QT syndrome, short QT syndrome, arrhythmogenic right ventricular cardiomyopathy, catecholaminergic polymorphic VT, right ventricular outflow tract VT, left ventricular outflow tract VT, and Brugada syndrome is rare, however the risk of SCD among these patients is high. Electrophysiological testing and risk stratification can be difficult and inconclusive, let alone invasive. ICD implantation can be delayed for a considerable amount of time, therefore a WCD can secure the patients' safety until ICD risk stratification becomes more evident (Klein, 2009).

* Interrupted ICD therapy. * Among the indication for a WCD, interrupted ICD therapy is one of the largest indications for a WCD. Device implantation runs the risk of pocket infections, pneumothorax, air embolism, cardiac perforation, dislodgement of leads, venous thrombosis and superior venacava syndrome. If an infection is evident, then the device must be removed and the patient is at risk for a life threatening arrhythmia. ICD complications can range from 10-16% of procedures, while ICD infection and explantation is as high as 2-8% (Pavia & Wilkoff, 2001). If the ICD is for secondary prevention then the patient is at even higher risk of SCD. Also if implantation is delayed due to infection or another disease process making the patient unsuitable for surgery, the WCD is the bridge to allow continuous monitoring of the patient while confounding problems are resolved (Klein, 2009).
Clinical efficacy of wearable cardioverter defibrillator. The clinical efficacy of WCD has been proven in several studies. One of the first studies to test the efficacy of WCD was done by Auricchio and colleagues (1998) in Magdeburg, Germany. This study was designed to measure the efficacy of the WCD at terminating VF or VT. Ten patients underwent inducible VF or VT by programmed electrical stimulation. Of the ten patients in the study, all ten were given a monophasic 230J shock to defibrillate their rhythm. All ten patients had successful termination of VF/VT on the first shock. Therefore a 100% first shock success rate was determined for the WCD (Auricchio et al., 1998). Adverse effects from a high energy shock were not identified in this study, however, it is an important consideration when dealing with a monophasic defibrillation device.

Newer defibrillation devices incorporate a biphasic shock. A biphasic shock is different than a monophasic shock. A biphasic shock is both positive and negative in polarity. This means that less energy is needed to defibrillate a heart rhythm. This in turn will reduce the amount of adverse neurological effects that a high energy shock may have on the human body. In order to test this mode of electrical charge, Reek and company (2003) studied the clinical efficacy of the WCD that incorporated a biphasic shock. 285 patients with increased risk of SCD were given a WCD for three months. Shocks given to these patients were between 70J-150J almost half that of a monophasic shock. 22 out of 22 successful defibrillation attempts were recorded (Reek et al., 2003). The results of this study are comparable to the efficacy of monophasic shocks; however, it has been shown that patients who have been resuscitated by a biphasic shock have a better cerebral performance upon discharge from the hospital (Schneider et al., 2000).

The Wearable Defibrillator Investigative Trial (WEARIT) and Bridge to ICD in Patients at Risk of Arrhythmic Death (BIROAD) studies (2004) were combined to focus on the clinical
The efficacy of WCD in patients who are at high risk for SCD that did not meet ICD indications or ICD implantation was delayed. The WEARIT arm (177 patients) enrolled patients with NYHA class III and IV heart failure. The BIROAD arm (112 patients) enrolled patients in which ICD implantation was delayed (ventricular arrhythmia within 48 hours of CABG surgery, LVEF < 30% after CABG, SCA 48 hours after CABG, any patients who refused ICD implantation). There were six successful defibrillations out of eight total attempts, with two successful attempts in the WEARIT arm and four successful attempts in the BIROAD arm. The two unsuccessful attempts were due to inappropriate placement of the electrodes (Feldman et al., 2004). If you take away the two unsuccessful attempts due to human error, there was a 100% success rate. This trial again emphasizes the clinical efficacy of the WCD at terminating ventricular arrhythmias.

The largest study to evaluate the clinical efficacy and survival rates of WCD as compared to patients with ICD was done on 3569 patients over the course of one year (Chung et al., 2010). There were 80 sustained VT/VF events that occurred in 59 different patients throughout the study. First shock success rate was recorded at 99% (79/80 patients successfully defibrillated). This study also looked at the overall survival while wearing WCD. There was a 90% survival rate for arrhythmic events and 73.6% survival rate for non-arrhythmia events. There was no significant difference in survival rates between patients with a WCD or patients with an ICD (Chung et al., 2010).
Methods

The research design of this study is a survey. A survey to patients (protocol 1) will be used to evaluate patient compliance, defined as wearing the device for greater than or equal to 20 hours per day. Other aspects like comfort level, level of protection and satisfaction with the device will also be addressed. A survey to practitioners (protocol 2) will be used to assess practitioner satisfaction with the WCD along with concerns they have with the device. There is no research or statistical hypothesis within this study, basic descriptive statistics will be calculated and general observation and conclusion of the results will be addressed.

Protocol 1

Survey one (patient survey) consists of 10 questions regarding the use and comfort of the WCD among patients who are currently wearing a WCD or those that have worn a WCD from January 2010 to December 2010 in the state of Ohio. Approval of survey one was obtained by the ProMedica IRB, and was sent out via USPS. Once the survey was received by the subjects, they were requested to fill out the survey either electronically or by mail. Subjects had the option to go to the direct link provided for them in the information letter or by going to the Association of Physician Assistants in Cardiology (APAC) website (link also provided in the informed letter) where a link on the homepage directs them to the survey. The survey consists of 10 question regarding the use, views, and satisfaction with the WCD. Completed surveys were returned via USPS with the pre-addressed, pre-paid return envelope. Completed surveys returned electronically were viewed by an authorized user with the correct user-name and password. The electronic version of the survey was disabled four months after the initial mailing of the survey. Subjects' names and mailing addresses were only used for mailing of the survey. Once mailing was complete the names and addresses were destroyed. The answers to the
questions of the surveys were pooled and basic descriptive statistics calculated. A sample of the
survey and letter sent to the patients is represented in the appendix.

**Protocol 2**

Survey 2 (practitioner survey) consists of eight questions regarding the prescription, satisfaction, and concerns of the WCD by prescribing practitioners in the state of Ohio from January 2010 to December 2010. A formal letter along with the survey was sent describing the purpose of the study. Approval of survey two was obtained from the ProMedica IRB, and was sent out via USPS. Once received by the subjects, they were requested to fill out the survey electronically. Subjects had the option to go to the direct link provided for them in the information letter or they had the option to go to the Association of Physician Assistants in Cardiology (APAC) website (link also provided in the informed letter) where a link on the homepage directs them to the survey. Completed surveys returned electronically were viewed by an authorized user with the correct user-name and password. The electronic version of the survey was disabled four months after the initial mailing of the survey. Subjects' names and mailing addresses were only used for mailing of the survey. Once mailing was complete the names and addresses were destroyed. The answers to the questions of the surveys were pooled and basic descriptive statistics calculated. A sample of the survey and letter sent to the patients is represented in the appendix.
Results

A total of 78 patients were randomly selected from the Zoll database based on criteria evident in protocol 1. Of the 78 patients selected, 14 patients responded via mail, and zero patients responded via internet. Three surveys were sent back with return to sender. Therefore 75 patient surveys were received from subjects. This correlates to a 18.6% response rate.

A total of 100 practitioners were randomly selected from the Zoll database based on criteria evident in protocol 2. Of the 100 practitioners sampled, six responded via online survey. Three letters were sent back as return to sender; therefore the total number of physicians who received the survey was 97. However, one survey response was thrown out because the practitioner stated they have never prescribed the device, resulting in 5 total responses. This correlates to a 5.15% response rate.

Total response rate of combined patient and practitioner surveys correlates to a 10.85% response rate with a total of 19 responses out of 175 surveys.

Patient Analysis

Based on the results 29% (n=4) received the WCD for interrupted ICD therapy. 14% (n=2) received the device early after MI, while 14% (n=2) received the device after cardiac surgery. Only 7% (n=1) received the device for an inherited arrhythmia. However, 29% (n=4) selected other for why they received the device. Current status of protection is as follows, 14% (n=2) are currently wearing the device, 57% (n=8) received an ICD, and 29% (n=4) are not currently wearing the device or received ICD.

When asked if the subjects could carry out all desired activities while wearing the defibrillator, 86% (n=12) said "yes," while 14% (n=2) stated they could not. However, one of those subjects stated they could not wear the device while bathing. As stated, bathing was an
exception to the question, therefore that response was disregarded. Subjects were asked if the
WCD provided adequate protection and 64% (n=9) said "yes" and 7% (n=1) said "no," while
21% (n=3) did not respond to the question. Subjects' protection level was assessed and results
are as follows, 29% (n=4) "very protected," 43% (n=6) "somewhat protected," 29% (n=4)
"neutral." Comfort level with the device was assessed and results are as follows, 21% (n=3)
"comfortable," 43% (n=6) "somewhat uncomfortable," 21% (n=3) "uncomfortable," 14% (n=2)
"neutral." 93% (n=13) wore the device for 20-24 hours a day, while 7% (n=1) subject wore the
device for 10-15 hours a day. One subject (7%) had an event while wearing the device. The
duration of use with the device was assessed and results are as follows, 21% (n=3)
1-4 weeks, 7% (n=1) 4-6 weeks, 7% (n=1) 6-8 weeks, 21% (n=3) 8-10 weeks, and 43% (n=6)
more than 10 weeks. Eleven subjects (79%) knew that their prescriber can monitor their use of
the device and three subjects (21%) did not know their prescriber could monitor their use.

Practitioner Analysis

Three practitioners (60%) said that patient compliance was their biggest concern when
prescribing the WCD. One practitioner (20%) specified that cost of the device was their biggest
concern. Factors that were most important to prescribing practitioners are as follows, patient
compliance 20% (n=1), left ventricular ejection fraction 40% (n=2), ventricular ectopy 20%
(n=1). Multiple indications for prescribing the device could have been given by each respondant
and the results are as follows, early after MI (n=3), early after cardiac surgery (n=2), newly
diagnosed non-ischemic cardiomyopathy (n=2), interrupted ICD therapy (n=3). 75% of
practitioners (n=3) thought the indications for the WCD should be expanded, while 25% (n=1)
said that they should not. When asked if the indications for the ICD should be expanded 40%
(n=2) said "no," and 60% (n=3) said they should. The level of satisfaction with the WCD of
prescribing practitioners are as follows, 80% (n=4) were "satisfied," 20% (n=1) were "somewhat unsatisfied. According to the practitioners, patients benefit from the WCD, in such a way as in that it gives the patients "peace of mind" (n=3), life saving properties of the device (n=4), increases follow-up for ICD implantation (n=1). Three practitioners knew about online monitoring, while three practitioners did not know about online monitoring.
Discussion

This study is reporting the use and compliance of a small population of patients who have worn the WCD. Popularity and prescription of the device has been limited due to lack of practitioner knowledge and perceptions of patient compliance. Based on the results of this study, practitioners' biggest concern when prescribing the WCD is patient compliance. However, patient compliance is 93% among subjects in this study. Although the sample size and response was small, the results of a study performed by Chung et al (2010) found a compliance rate of about 90% among a sample size of 3000 patients. When analyzing patient comfort of the WCD, 64% (n=9) responded with some discomfort, while only 36% (n=5) responded that the device was "comfortable" or "neutral."

Interestingly, Chung et al (2004) found that 14.2% of patients stopped wearing the device based on comfort issues (Chung et al., 2010). In this study, 64% (n=9) of subjects stated some discomfort with the device. However, all subjects wore the device for more than 20 hours a day. In a recent study, patients discharged from the hospital on aspirin, an ACE inhibitor and a beta blocker after an myocardial infarction, 15% of them stopped taking all three medications within 30 days of discharge (Ho et al., 2006). Similar discontinuation and comfort rates exist for the WCD.

Discomfort with the WCD seems to be irrelevant to patient compliance and the ability to carry out daily activities. 86% of subjects stated they could carry out all daily activities while wearing the defibrillator. Two patients stated they could not carry out all desired activities, one subject explained activities that increased his heart rate would trigger an alarm on his device. There are setting on the device that are set by the prescribing practitioner, it seems in this subjects case that the device was not set properly. Another subject explained that bathing was an
issue with the device; this is an inherent disadvantage with the device.

Patient compliance is irrelevant to ICD therapy, however, what if a patient has a complication with their ICD and there is a need for explantation. The WCD can replace or bridge the gap to re-implantation. The largest population to receive a WCD was the patients that experience interrupted ICD therapy. According to this study that is true, 29% (n=4) subjects received the WCD because of interrupted ICD therapy. Furthermore, the only person to respond with having an event while wearing the WCD was a subject that had interrupted ICD protection. This emphasizes the importance of the utilization of the WCD.

Chung et al (2010) found an interesting correlation between the duration of time the patient wears the WCD and compliance. The longer a patient has to wear the device the more compliant they were. Patients wearing the device for more than 60 days averaged around 20 hours of use a day, while patients wearing the device for less than 15 days, and wore the device for about 17 hours a day (Chung et al., 2010). In this study, the majority of patients (64%) wore the device for more than eight weeks (60 days) and all patients except for one were compliant and wore the device for more than or equal to 20 hours a day.

When observing practitioners concerns with the WCD, it seems that patient compliance in the biggest concern. This study along with several others has demonstrated that patient compliance with the WCD is more than 90% respectively. Practitioner satisfaction with the WCD is high among individuals in this study. If this device is truly not being used because of misconception of patient compliance, than this study will further solidify the myth behind patient compliance. It can be speculated that practitioners are limiting their prescription of the WCD to patients who they think will be most compliant with the device, which could be one reason why compliance rates are so high and prescription of the device is low.
Another interesting observation was found when looking at practitioners' thoughts on the expansion of the indications for either the ICD or WCD. 75% of respondents said that they do not think the indications for the WCD should be expanded, while 60% stated that the indications for the ICD should be expanded. Al-Khatib et al (2011) found that 22.5% of patients in the NCDR-ICD registry from the year 2006-2009 were inappropriately implanted (patients who did not meet Medicare/Medicaid guidelines for implantation) (Al-Khatib et al, 2011). It is speculated that practitioners are inappropriately implanting ICDs for patients who qualify or who have indications for WCD.
Limitations of the study

The biggest limitation in this study was the small sample size. Only 78 patients were sampled. The small sample size remained small because of financial concerns regarding mailing costs. Physician sample size was limited to financial reasons regarding mailing costs. Limitation and biases that are inherent with survey research are evident within this study. Closed ended questions and answers were used in the surveys. No statistical analysis was performed with this study because of the nature of this study and small samples sizes. Interpretations of the results of this study can only be speculated and were meant to spark interest and understanding of the WCD. Further research is needed to expand the indications and use of the WCD.
Conclusions

The compliance rate within this study was 93%. About half of the practitioners stated that patient compliance with the WCD was their biggest concern while prescribing the device. This study proves on a very small scale that patient compliance is very good with the WCD. This study can be used as a teaching tool to ease the worries of practitioners and to increase the prescription of the device. This study can also help educate future patients that this device is safe and effective. This study raises the concerns and questions regarding the importance of prevention of sudden cardiac death. In order to prevent SCD, risk stratification for SCA needs to be more lucid and evident in the literature. The VEST/PREDICT trial (Clinicaltrials.gov identifier NCT00628966) which will be completed in 2013 will further increase our knowledge and usefulness of the WCD. Until then, the WCD is a perfect bridge clinically, for patients at risk for SCD as well as academically until risk stratification becomes more lucid in the literature.
References


Hi, my name is Don Pohorence, I am a physician assistant student at the University of Toledo. I am conducting a research study with a physician assistant in cardiology from ProMedica on patient and practitioner satisfaction with a wearable cardiac defibrillator (LifeVest®). The title of the research is Clinician perception and patient compliance with the wearable cardioverter defibrillator. You are being asked to complete a survey online. The survey will take no longer than 7-10 minutes of your time. There are eight brief questions regarding your views of the Zoll LifeVest® and risk stratification of sudden cardiac death. Your response is greatly appreciated. Your participation in completing this survey is voluntary. The information obtained from completed surveys will be greatly valuable to the verification of my study and to the future use of wearable cardiac defibrillators.

You have received this survey because you are currently have a patient who is wearing a defibrillator or you have prescribed the LifeVest® in the past. Your name and mailing address were taken from the Zoll-LifeCor Corporation® database. I approached the Zoll-LifeCor Corporation® after hearing about the LifeVest®, I wanted to learn more about patient compliance and also about the views of physicians who prescribe the LifeVest®. Understanding patients’ views of the device and comparing that to the physicians' views, we will be better equipped to educate patients and health care providers of the utility of the LifeVest® and help to reduce the incidence of sudden cardiac death.

In order to achieve this goal, I ask for your effort in completing the enclosed survey. A link is provided below to complete the survey online. There is an additional link available at www.cardiologypa.org. If you are uncomfortable answering a question you may leave it blank or simply skip that question. Again, your response is anonymous and completely voluntary.

There is no penalty for not completing the survey, responses are anonymous and names and addresses are only used for the mailing of the survey.

If you have any question related to the survey or to the research study, there is contact information below.

Don Pohorence  
donald.pohorence@rockets.utoledo.edu  
216-570-8112

Ajwad Ferah PA-C  
toledopac@gmail.com

Confidentiality  
Please do not identify yourself anywhere on the survey. This survey is completely anonymous. IP (internet protocol) addresses, names, and email addresses will not be identified upon return of a completed survey. The results obtained from this study may be used in publication. Results obtained from this study will be shared with the Zoll-LifeCor Corporation®.

Link to Online Survey  
http://www.surveymonkey.com/s/Y5ZRM7P  
-Type the web address in your URL bar, this will take you directly to the survey.

Association of Physician Assistants in Cardiology (APAC) website link  
www.cardiologypa.org  
-Type this web address into your URL bar and this will take you to the APAC homepage, there you will find a link to the survey titled "Physician Survey."
Practitioner Survey

What is your biggest concern when prescribing the LifeVest®?
- Patient Compliance
- Malfunction of the device
- Efficacy of the device
- Inappropriate shock

When you prescribe the LifeVest® to a patient, what is the most important factor you consider?
- Patient Compliance
- LVEF
- Markers of abnormal repolarization or electrical instability (TWA, SAECG, EPS studies)
- Non-sustained VT and ventricular ectopy
- Markers of abnormal autonomic balance
- Comorbid conditions

What indications do you prescribe the LifeVest®?
- 40 days after Myocardial infarction
- 90 days after CABG/PTCA intervention
- Recent diagnosis of non-ischemic cardiomyopathy
- NYHA class IV heart failure
- ICD explantation

Do you feel the indication for LifeVest® should be expanded?
- Yes
- No

Do you feel the indication for ICD should be expanded?
- Yes
- No

What is your level of satisfaction with the LifeVest®?
- Satisfied
- Somewhat satisfied
- Somewhat unsatisfied
- Unsatisfied

How do you feel patients benefit from the LifeVest®?
- Peace of mind
- Life saving properties from sudden arrhythmic death
- Patient does not benefit from the device
- Increases follow up for future ICD implantation

Do you know about reimbursement options from online monitoring?
- Yes
- No
Hi, my name is Don Pohorence, I am a physician assistant student at the University of Toledo. I am conducting a research study with a physician assistant in cardiology from ProMedica, evaluating patient and practitioner satisfaction with the wearable cardiac defibrillators (LifeVest®). The title of the research is Clinician perception and patient compliance with the wearable cardioverter defibrillator. Enclosed is a survey that will take no longer than 7-10 minutes of your time. There are 10 brief questions in which your response is greatly appreciated. You will be asked to answer questions regarding your specific use with the LifeVest® and also your views on the safety of the device. Responses from the survey will be completely anonymous and may be used in publication. Your participation is voluntary. The information obtained from completed surveys will be extremely valuable to my study and to the future use of wearable cardiac defibrillators.

You have received this survey either because you are currently wearing a Zoll LifeVest® or you have worn a Zoll LifeVest® during the period of January 1 to December 1, 2010. Your name and mailing address were taken from the Zoll-LifeCor Corporation® database. I approached the Zoll-LifeCor Corporation® after hearing about the LifeVest®, I wanted to learn more about patient compliance and also about the views of physicians who prescribe the LifeVest®. Understanding patients' views of the device and comparing it with physicians' views, we will be able to educate patients and health care providers of the utility of the LifeVest® and help to reduce the incidence of sudden cardiac death.

In order to achieve this goal, I ask for your effort in completing the enclosed survey. For your convenience a return envelope is enclosed for you to return the completed survey. There is no postage necessary. In addition, the survey is available to you online. The survey can also be found at the Association of Physician Assistants in Cardiology website at www.cardiologypa.org. It is only necessary to complete one survey, you can choose to complete the survey online or use the paper form as provided for you. Furthermore, if you are uncomfortable answering a question you may leave it blank or simply skip that question. Again, your response is anonymous and completely voluntary. Survey's can be returned at any time. The electronic version of the survey will only be active for 4 months from the date of mailing of this letter.

There is no penalty for not completing the survey, responses are anonymous and names and addresses are only used for the mailing of the survey.

Confidentiality
Please do not identify yourself anywhere on the survey. This survey is completely anonymous. There is no return address necessary on the return envelope. If you decide to complete the survey online, there will be no identification information available to us when you return the survey (ie. IP addresses, email). The results obtained from this study may be used in publication. Results obtained from this study will be shared with the Zoll-LifeCor Corporation®. If you have any question related to the survey or to the research study, there is contact information below.

Thank you for your time and attention.

Don Pohorence
donald.pohorence@rockets.utoledo.edu
216-570-8112

Ajwad Farah PA-C
toledopac@gmail.com

Link to Online Survey
http://www.surveymonkey.com/s/M25CYNN
-Enter this link into your URL bar; this will take you directly to the survey.

Additional Link to Survey through Association of Physician Assistants in Cardiology (APAC)
www.cardiologypa.org
-The link will be on the homepage (click Patient Survey).
Patient Survey

Please fill in the information below, and mark one box for each question

Indication (Why were you prescribed the Zoll LifeVest®):

- □ Recent heart attack
- □ Recent Cardiac Surgery
- □ Inherited Arrhythmic disorder
- □ Implantable defibrillator complications (e.g. Infection), awaiting re-implantation
- □ Other (otherwise not specified, or don't know why)

1. Can you carry out all desired activities throughout the day while wearing your LifeVest®?? (Excluding bathing)
   - □ Yes
   - □ No
   - If you answered No, please specify the activity or activities that you are unable to carry out in the space provided

2. Do you feel the LifeVest® provides adequate protection for you and your heart?
   - □ Yes
   - □ No

3. What is your comfort level while wearing the LifeVest®??
   - □ Very Comfortable
   - □ Comfortable
   - □ Neutral (Don't Mind It)
   - □ Somewhat Uncomfortable
   - □ Uncomfortable

4. How protected do you feel while wearing the LifeVest®?
   - □ Very Protected
   - □ Somewhat Protected
   - □ Neutral
   - □ Somewhat Unprotected
   - □ Unprotected

5. How many hours a day do you wear the LifeVest®?
   - □ 0-5 hours
   - □ 5-10 hours
   - □ 10-15 hours
   - □ 15-20 hours
   - □ 20-24 hours

6. Have you had any events in which the Lifevest® was utilized to cardiovert (shock) your heart?
   - □ Yes
   - □ No

7. How long have you been wearing the LifeVest®?
   - □ 1-4 Weeks
   - □ 4-6 Weeks
   - □ 6-8 Weeks
   - □ 8-10 Weeks
   - □ >10 Weeks

8. Please mark the statement that best describes your current status.
   - □ Currently wearing (prescribed) LifeVest®
   - □ Have received an Implantable Cardioverter Defibrillator (ICD) after wearing the LifeVest®
   - □ Not currently using either device

9. Do you know that your physician can monitor your wearing compliance?
   - □ Yes
   - □ No
Abstract

**Background:** Sudden cardiac arrest is a major public health concern. Ventricular arrhythmias are the most common cause of sudden cardiac arrest. The wearable cardioverter defibrillator (WCD) is an alternative approach for prevention of sudden cardiac death.

**Objective:** To collect data on patient compliance and satisfaction with the WCD. Also to collect data on practitioners' satisfaction and concerns with the WCD.

**Methods:** A survey to 78 patients concerning their comfort level and compliance of the WCD, and to 100 practitioners about their prescription of the WCD was given. Data was collected and descriptive statistics were analyzed.

**Results:** Six practitioners responded along with 14 patients. Total response rate was 10.85%. Compliance among patients was 93%. Practitioners’ largest concern with the WCD is patient compliance.

**Conclusion:** Patients comfort level with the WCD is low, but there compliance rate is high. Practitioners are satisfied with the WCD but are concerned about patient compliance.