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UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science
DOCTORAL OF PHILOSOPHY IN NURSING

INCIDENCE AND CLINICAL PREDICTORS OF RISK FACTORS FOR
INAPPROPRIATE SHOCK IN PATIENTS WITH IMPLANTABLE CARDIOVERTER-
DEFIBRILLATORS

by

Shu-Ling Lo

A dissertation presented to the
FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE
UNIVERSITY OF SAN DIEGO

In partial fulfillment of the
requirements for the degree
DOCTOR OF PHILOSOPHY IN NURSING

August 2005

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ABSTRACT

Incidence and Clinical Predictors of Risk Factors for Inappropriate Shock in Patients with Implantable Cardioverter-Defibrillators

Shu-Ling Lo

Sudden cardiac death (SCD) is a major unresolved medical problem worldwide. Although Implantable Cardioverter-Defibrillators (ICD) are highly effective in diagnosing and treating life threatening arrhythmias, inappropriate shock therapy (IST) occurs in approximately 5-20% of ICD recipients. IST results in pain, anxiety, induction of ventricular arrhythmias, decreased battery longevity, and even death. Researchers studying clinical predictors of IST have drawn findings based on single case studies with small samples or with out-dated data. This study filled this gap by describing the incidence and co-existing clinical predictors of IST.

Methodology

This descriptive, retrospective study analyzed the incidence and clinical predictors of IST in ICD adult recipients by utilizing a five-year retrospective review ICD interrogation records and medical charts at a university hospital.

Results

During a mean follow-up period of 24.1 ± 16.2 months, 20 out of 119 ICD recipients received appropriate shock, and IST occurred in 13(9%) out of 119 ICD recipients. A total of 16 IST experiences occurred among these 13 patients. Eight subjects received IST for atrial fibrillation (AF)/atrial tachycardia or sinus tachycardia/normal sinus rhythm, two for double counting, two for lead problems, and one for drug interaction. Of these, 12 out of 98 men received IST. One out of 21 women received IST. Using Chi-square and logistic regression analysis, results showed only AF as a significant predictor ($p=.002$ vs 0.001) and remains the main cause of IST. Although the variables of age, gender, NYHA class LVEF and structural heart disease showed no significant relationship. Trigger events occurred during clinical interventions and were noted in this study.

Conclusion

The clinical characteristics of patients prone to IST should be carefully considered when planning clinical interventions. With the rapid expansion of this patient population, a multisite expanded longitudinal study is indicated to confirm the results seen in this initial descriptive study.

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CHAPTER I

STUDY PROBLEM AND ITS SIGNIFICANCE

Background

Sudden cardiac death (SCD) is defined as death from abrupt, unexpected circulatory arrest occurring within a short period, generally less than an hour, following the onset of acute symptoms (Jeanne, Poole & Bardy, 2004). SCD occurs in about 450,000 people in the United States each year (American Heart Association, 2005). It also affects a significant number of people in many other countries (Connolly, Gent, Roberts, 2000; Spector, 2005). SCD is a major unresolved public health problem in the U.S. and throughout the world. It is often attributed to untreated, life threatening, ventricular arrhythmia (Bardy, 2004). Attempts to prevent SCD with antiarrhythmic agents have met with little success and may even increase mortality (Cardiac Arrhythmia Suppression Trial II Investigators, 1992). Some nontypical antiarrhythmic agents (e.g., β blockers), have demonstrated a reduction in arrhythmic deaths by reducing the ischemic burden. Revascularization is most often used as the first line of intervention for the reduction of sudden death risk in ischemic patients (Spector, 2005). However, the limited efficacy of SCD prevention and the failure of resuscitation from out-of-hospital cardiac arrest renders SCD a significant problem. The development of the implantable cardioverter defibrillator (ICD), which almost instantly detects and treats life - threatening ventricular arrhythmia has in recent years revolutionized the treatment of SCD (Mirowki, Reid, Mower, Watkins, & Gott, 1980).

The advent of the ICDs has resulted in a significant decrease in the rate of SCD from ventricular tachycardia (VT) and ventricular fibrillation (VF) in specific populations (Moss, Hall, Cannom, Daubert, Higgins, Kiel, et al., 1996). With the advent of monitoring capabilities from the ICD, there has been a tremendous change in the prevention of sudden arrhythmia death (Moss, Zareba, & Hall, 2002; Naccarelli, 2004). The ICD is responsible for sending electrical signals that satisfy programmed criteria and is highly effective in reverting such rhythms back to normal (Klein, Auricchio, Reck, & Geller, 1999). An appropriate shock was defined as a spontaneous ICD discharge that terminated with such clinical symptoms as palpitations, nausea, dizziness, light-headedness, or syncope (Schreieck, Zrenne, Kolb, Ndrepepa, & Schmitt, 2001). The ICD functions by delivering shocks in response to electrical signals that satisfy preprogrammed criteria, and it is highly effective in reverting VT and VF to normal rhythms (Klein, Auricchio, Reck, & Geller, 1999). Clinical trials have demonstrated that the ICD is superior to medication in prolonging the lives of individuals with a history of prior or inducible, sustained, ventricular arrhythmia (i.e., VT longer than 30 seconds; Antiarrhythmics Versus Implantable Defibrillators [AVID], 1997; Kuck, Cappato, Siebels, & Ruppel, 2000). With the completion of multiple randomized clinical trials, ICDs have emerged as the dominant therapy for the secondary and primary prevention of SCD (Bardy et al., 2005, Connolly et al., 2000; Kuck et al.; Moss et al., 2002; Sheldon, Connolly, Krahn, 2000). In addition to the secondary and primary prevention of SCD, ICDs have an emerging indication for dilated cardiomyopathy (DCM) (Bänsch, Antz, Boczor, Volkmer, Tebbenjohanns, Karlheinz et al., 2002). The current *“Practice Guidelines of Indications for Implantable Cardioverter - Defibrillator Therapy”*

(Gregoratos, Abrams, Epstein, Freedom, David, & Hayes et al., 2002) is based on the clinical trails (Appendix A) developed by the expert panel of ACC/AHA/NASPE in 2002 (Appendix B). Along with the therapies for the secondary and primary prevention of SCD, the ICD indications expanded to chronic heart failure and DCM (Abraham, 2003; Guidant Atrial Features Guide, 2001). A substantial increase in the implantation of ICDs is expected because of these expanded indications.

Statement of the Problem

ICDs are accurate and effective in the diagnosis and treatment of VT and VF. However, inappropriate shock therapy (IST), defined as shocks occurring in the absence of life threatening ventricular arrhythmias, occurs in approximately 5% - 20% of ICD patients (Grimm, Flores, & Marchlinski, 1993; Lauria, Glikson, Brady, Lexvold, Rasmussen, Hodge, et al., 2001, Rosenqvist, Beyer, Block, Den Dulk, Minten, & Lindemans, 1998; Theuns, Klootwijk, Simoons, & Jordaens, 2005). Inappropriate therapy shocks are hazardous because the consequences of IST are severe and have been reported in many studies (Messali, Thomas, Chauvin, Conmel and Leenhardt, 2004; Steinbrook, 2005).

Impacts of Inappropriate Shock

Physiological Impact

Patients have described the sensation of an inappropriate shock as a pain similar to being punched in the chest or kicked by a horse (Thomas, 2001). IST, apart from being painful, may also cause myocardial damage, as documented in animal and human studies (Epstein, Kay, Plumb, Dailey, Peter, & Anderson, 1998). Due to IST,

proarrhythmia is also a frequently reported event (Pinski & Fahy, 1995). Pinski and Fahy reported on death from IST, and Messali, Thomas, Chauvin, Coumel, and Leenhardt (2004) also recorded deaths in their research, with the rate varying from 0.4% to 8%. The risk for proarrhythmia appeared to be most common in situations with fast supraventricular rhythms with a concomitant increase in sympathetic discharge, rate-related disease in ventricular refractoriness, or myocardial ischemia (Pinski & Fahy, 1995).

Psychological Impact

Although the ICD is a lifesaving device, living with the possibility of receiving a defibrillating shock at any time can be emotionally devastating. One small study (Dougherty, 1995) and a national survey (Sears & Conti, 2002) found that patients receiving ICD shocks, along with their families, experienced more anxiety, anger, depression, and stress than patients and families who had not received shocks. A study of 57 patients (Luderitz, Jung, Diester, Marneros, & Manz, 1993) found that patients who had experienced five or more shocks from an ICD had a higher state of anxiety than those who experienced fewer than five shocks. In another study of the impact of ICD therapy (Godemann, Butter, Lampe, Linden, Schlegl, Schulth, et al., 2004), the results demonstrated that, in patients who have two or more ICD discharges annually, the incidence of panic disorders and agoraphobia were higher than in those who only received a single ICD discharge annually. Patients' level of psychological symptoms was correlated with fear of ICD malfunction, particularly anxiety, depression, and fear of death (Dougherty, 2004). The manner of how one's quality of life was affected by ICD

shock(s) has been reported in several studies (Sears, Eads, Marhefka, 2002; Carroll & Hamilton, 2005).

Economic Impact

Other major negative impacts of IST include the induction of ventricular arrhythmias and a decrease in life longevity of battery caused by frequent shocks (Lin, Dixit, Russia, & Hsia, 2004). As the results of these effects, the replacement of already expensive ICDs will require additional costs. In addition, the fees of diagnostic procedures, treatments, and frequent clinical visits' fees must be paid as well. The unfavorable cost effectiveness resulting from ISTs ultimately may become a financial burden for the health care system.

Predisposing Clinical Characteristically Factors Are Not Well Known

Many inappropriate ICD discharges are caused by supraventricular arrhythmias that are triggered by a problem with the ICD device, or that occur at a time when the environment interferes with the ICD (Pinski & Trohman, 2002; Rinaddi, Simmon, Bostock, Elliot, & Gill, 2004). However, patients and clinicians report that inappropriate shocks still occur with no identifiable causes (Champagne, Geelen, Philippon, & Brugada, 2005; Glikson, 2004). The literature review demonstrated that, in the majority of patients who are at risk for an IST, the clinical predictors of ISTs are not well known. In addition, neither the timing nor the circumstances under which an IST occurred (e.g., exercise, dehydration) were correlated to occurrence of inappropriate therapy (Healy, Ngarmukos, & Rosenthal, 2002). Many case studies, consisting of only one to four patients, provided in-depth information about the incidence of inappropriate shock (Healy, 2002; Messali, 2004; Peters, 1998). However, these findings cannot be generalized due to limited data

(Burns & Grove, 2004). As a result, there exists no exhaustive list of what may or may not affect an ICD. The multitude of variables makes it impossible to know how a device will respond to various sources of interference. Misinformation and outdated information perpetuated within the medical community cloud these issues.

Current Status of Intervention Programs

Many respected nursing researchers have explored the impact of ICD therapy, including interventions to promote the quality of life for ICD recipients and their families (Carlessen, Olesson & Hertervig, 2002; Shea, 2004; Sneed, 1997; Vitale & Funk, 1995). Educational intervention programming related to psychological aspects has also been discussed extensively (Dougherty et al., 2004; Higgins, 1990; Sneed, Fench, & Michel, 1997; White, 2002). However, care practices are likely to have evolved that do not encompass the physiological elements. Few studies have provided information regarding the experience of shock itself or have made distinctions between appropriate shock and inappropriate shock. Recently, an educational program developed by Dougherty et al. made suggestions for the educational intervention of ICD recipients. Their suggestions were based solely on the number of shock events and the level of pain experienced, which might not accurately reflect the seriousness of a shock event. For example, a patient could feel pain when he/she experienced a “phantom shock” in which no true shock occurred but the patient claimed to feel pain). Conversely, a patient might not feel pain due to his/her loss of consciousness from a high-energy shock. In a recent nursing care journal discussing the issues of patients with ICDs, Dunbar (2005) intended to discuss all areas of concerns from psychosocial aspect. However, it was not clear whether the author intended to give information to prevent an inappropriate shock or address

appropriate shock in the nursing care of patients with ICDs. The author stated that, “Known predictors of inappropriate shock are history of atrial tachyarrhythmia and recurrent ventricular tachycardia that have triggered appropriate therapy”(p.297). Moreover, there are still many other risk factors that could trigger inappropriate shocks and appropriate shocks. Hence, without sufficient published information, it would be difficult to provide effective educational programs. O’Brien, Langberg, Valderrma, Kirkendoll, Romeiko and Dunbar (2005) investigated patients and families involving ICD storms, where patients experience two or more appropriate and/or inappropriate shocks within 24 hours. This study provided great insight into the effects of an ICD storm and the management of shocks; however, intervention for preventing the occurrence of an inappropriate shock event remains an unsolved problem. Appendix C summarizes the last five years of nursing research related to care of the ICD recipients.

Future Technological Considerations

As ICDs become more complicated, the incidence of inappropriate shock is likely to increase (Rinaddi, Simmon, Bostock, Elliot, Bcknall, & Gill, 2004). In addition, there has been a corresponding increase in the number and complexity of patients seen in follow-up visits after ICD implantation. This increased visitation volume demands that clinical practice create alternative methods to safely and effectively monitor these patients. Recently, the internet-based remote monitoring service has allowed clinicians to remotely manage their patients' ICDs and chronic diseases. The network is comprised of a patient monitor, a secured server, and clinician and patient websites. Under clinical direction, patients interrogate their ICDs at home and transmit data to a secure server via standard telephone lines (Joseph, Wilkoff, Dresing, Burkhardt, & Khaykin, 2004).

Patients have become critical consumers of health care and are frequently using the internet as a resource for their health concerns and treatment options. Cardiovascular nurses have a unique opportunity to assist patients using this modality. Web pages provide interactive patient education, including behavioral interventions, for risk reduction management in ICD therapy. This study serves as an exemplar for how cardiovascular nurses can work with these valuable tools for patient care.

The Role of Cardiovascular Nurses in the Management of Inappropriate Shock Therapy from a Physiological Aspect

The nursing profession plays an important role in the delivery of health services, particularly for cardiovascular patients. Nurses are responsible for recognizing “cue complexes,” or syndromes, and for providing prompt emergency treatment (e.g., cardiac resuscitation). Nurses also provide appropriate information to the ICD recipients and their families regarding the diagnosis or plan of therapy following physician-nurse appraisal (Roger, 1971). One goal of advanced cardiovascular nurses is to integrate technology with patients’ everyday lives. Cardiovascular nurses can play a pivotal role in providing optimal care for ICD patients. Through effective nursing interventions utilizing current guidelines and updating information in a multidisciplinary forum, nurses can develop realistic, scientifically-based guidelines for ICD patients. To date, no study has systemically analyzed clinical conditions as risk factors predisposing patients to an inappropriate shock, and the phenomenon remains relatively unexplored. As nurse scientists, advanced cardiovascular nurses are taking leadership roles in major interdisciplinary organizations and need knowledge and skills to contribute in a

competitive, ever-evolving field. Therefore, it is imperative to investigate the clinical characteristics of ICD patients that may be predictive of inappropriate shock in a broad population.

Purpose of the Study

The overall purpose of this study was to describe the incidence of appropriate and inappropriate shock occurrence and to investigate the clinical predisposing factors for an inappropriate shock in a group of ICD recipients treated at a university medical center in Southern California during the period from July 2000 to May, 2005. The specific aims were as follows:

Specific Aim # 1

To describe the incidence of appropriate and inappropriate shock occurrence in a group of ICD recipients who visited the university medical facility between July, 2000 and May, 2005 for emergent and routine follow-up visits.

Specific Aim # 2

To describe the relative risk relationships between age group and IST, gender and IST, heart disease severity and IST, structural/ non-structural heart disease and IST, and the history of atrial fibrillation and IST.

Specific Aim # 3

To describe the frequency of ISTs in a group of ICD recipients by risk factors (e.g., atrial fibrillation, lead problems, double counting) and the frequency and proportion of each risk factor associated with an IST.

Specific Aim #4

To investigate significant correlations between clinical factors and an IST, and, when taken in combination, to reveal any clinical predictability for the incidence of an IST. Clinical factors analyzed include demographic characteristics, history of previous underlying heart disease, ejection fraction, and medications taken at the time of the IST.

CHAPTER II

REVIEW OF LITERATURE

Inappropriate shocks from ICD therapy occur in a combination of events involving the interference of the patient, device and environment. Regarding the causes of IST, it is imperative to understand the foundation it is built upon. For this reason, the author has scrutinized the pathways that lead to IST.

This section begins with a review relevant arrhythmias of implantable Cardioverter-defibrillator. The concepts of reentry and defibrillation are discussed, because they play important roles in the events of IST. The author then proceeds to discuss the development of ICD, its multiprogrammable features and the function of this modern device. This section concludes with the significance of interrogation concerning ICD in follow-up visits.

The Relevant Arrhythmias of Implantable Cardioverter –Defibrillator Therapy:

Supraventricular Arrhythmias

Supraventricular Tachycardia.

Supraventricular tachycardia (SVT) is a rapid, regular heart rate, where the heartbeat ranges from 150 to 250 beats per minute in the atria. The condition can be caused by a number of factors, or it can occur spontaneously. As a result, the heart beats abnormally fast and the oxygen supply to the brain is reduced. Some people experience no symptoms, yet others may experience dizziness, syncope, shortness of breath, pale color, chest tightness, and chest pain (Ganz, 2002).

Atrial Fibrillation

Electrical signals in the atria are fired in a very fast and uncontrollable manner. Atrial signals create a pattern of rapid and chaotic beating that starts at 350 beats per minute and ranges higher. Instead of a single electrical signal followed by coordinated atrial contraction, there is quivering of the atrial muscle. Not all signals are conducted through the AV node. Ventricular rates may vary from 100 to 180. Atrial fibrillation (AF) may occur in a sustained manner or may occur episodically (Woods, Froelicher, Motzer, & Bridges, 2005).

Ventricular Arrhythmias

The two major types of the ventricular arrhythmias are ventricular tachycardia (VT) and ventricular fibrillation (VF). VT is a regular heartbeat arising in the ventricles. Ventricular fibrillation occurs when the ventricles go out of control, quivering and beating ineffectively, thereby stopping the pumping action. If a more normal rhythm is not restored promptly—within three to five minutes—the patient will suffer brain and heart damage and will die (Kastor, 2000; Woods, Froelicher, Motzer, & Bridges, 2005).

Ventricular Tachycardia.

Ventricular tachycardia occurs when the ventricles produce impulses that make the heart beat too quickly. With this disorder, the heart tries to beat 150 a minute or more. The heart does not fill with enough blood between beats to meet the body's needs. Symptoms include a pounding sensation, dizziness, and sometimes fainting occurs (Kastor, 2000). There are several categories that VT falls under. Please see Table 1.

Table 1
Ventricular Tachycardia Defined by Category

Category I Duration / Duration of Tachycardia	
Transient also called unsustained or nonsustained (NSVT)	Beats are no longer than 30 seconds, with a minimum of 3 consecutive ventricular beat and without cardiovascular deterioration.
Sustained in which the paroxysms last (SMVT)	More than 30 seconds, with cardiovascular deterioration, requires immediate treatment to prevent cardiovascular collapse.
Incessant	Most of the time.
Category II Electrocardiographic Appearance / QRS Form	
Monomorphic ventricular tachycardia	Each of the QRS complexes has identical or nearly identical.
Polymorphic ventricular tachycardia (also called Torsade de Point, TdP)	The morphology (form) of the QRS complexes change A particularly rapid, dangerous form of VT that often occurs as a result of certain medications or in patients with congenital Long QT syndrome.
Category III The Presence or Absence of Heart Disease/ Examples	
With heart disease	most often coronary or cardiomyopathic
Without structural heart disease or idiopathic.	Long QT syndrome, Brugada syndrome, short QT syndrome.

Source: Modified from Kastor, J. A. (2000). *Arrhythmias*. (2nd). Philadelphia : W. B.

Sunders, p.343.

Ventricular Fibrillation

Ventricular fibrillation (VF) is a chaotic heart rate resulting from multiple areas of the ventricles attempting to control the heart's rhythm. VF sometimes can occur spontaneously, but generally it is caused by heart disease, or when VT has persisted too long. When the ventricles fibrillate, they cannot contract normally, hence, they cannot effectively pump blood. The instant VF begins, effective blood pumping stops. VF quickly becomes more erratic, resulting in sudden cardiac arrest or sudden cardiac death. This arrhythmia must be corrected immediately via shock from an external defibrillator

or an ICD. The defibrillator can stop the chaotic electrical activity and *restore* normal rhythm (Ganz, 2002; Kastor, 2000).

Mechanisms of Fibrillation and Defibrillation

The Role of Reentry

The available clinical and experimental evidence suggests that instability in VT leading to the degeneration of the VT into VF is a phenomenon of re-entry, which is a disorder of impulse conduction (Singer, 1994). The restitution hypothesis suggests a mechanism for the development of instability in re-entry that may explain the predisposition for degeneration to fibrillation (Adgey, Spence, & Walsh, 2005; Spector, 2005).

Re-entry is a continuous electrical activity in which each wave re-circulates to produce the next wave. For activation waves to propagate continuously, two paths for conduction separated by unexcitable tissue are required. Activation must spread around one side of the unexcitable tissue allowing the other side time to recover from inactivation in order to re-excite the tissue when the wave front returns. Tissue refractory periods limit re-entry: the conduction time around the circuit must be greater than the refractory period of each component of the circuit. Therefore, decreased conduction velocity or a decreased refractory period facilitates re-entry by decreasing the likelihood that the activation wave front will encounter its own refractory tail, ending the tachycardia (Woods, Froelicher, Motzer, and Bridges, 2005)

In clinical practice, re-entrant circuits can occur in two circumstances. First, a fixed re-entry is the site of an anatomic conduction block that resulted from scar tissue

and frequently occurs in the setting of ischemic cardiomyopathy (Adgey, Spence et al., 2005).

The second circumstance during which functional re-entry may occur is in the absence of anatomic obstacles. In this instance, the circuit path is determined by tissue refractoriness. Factors leading to the correct conditions that favor such re-entry mechanisms include increased heart size through hypertrophy or dilatation, drugs that alter the length of the refractory period, and areas of cardiac disease. A group of transiently unexcitable cells (i.e., secondary to refractoriness) creates an obstacle to the conduction around which a circuit can form (Adgey, Spence et al., 2005).

The Electrophysiological Concepts of Ventricular Defibrillation

The mechanism of ventricular defibrillation has been extensively investigated over many decades. However, the definite mechanism of defibrillation is still unclear and many hypotheses have been proposed. The most influential was the *critical mass hypothesis*. First proposed by Garrey in 1914 (Spence, 2003), it was supported by several other electrocardiologists. Garrey found that a fibrillating heart would no longer fibrillate when the myocardial mass decreased into small pieces (Adgey, Spence et al., 2005). The studies from Schunder, Stoekle, Gold, West, & Denniston (1973) and Miroski, Mower, Gott, Brawley, & Denniston (1973) showed that successful defibrillation could occur when low energy shocks were delivered through a transvenous catheter. This result suggested that the shock might need to defibrillate only the critical mass of the ventricles to get a successful outcome. In 1975, Zipes, and his colleagues provided further validation for this idea by demonstrating that the chemical depolarization of a critical mass of ventricular myocardium (~75%), using selective infusion of potassium chloride

into the left coronary artery, would successfully abolish ventricular fibrillation. Therefore, if a sufficient voltage potential gradient could be generated by a shock to halt the fibrillation activation fronts in the myocardium, defibrillation could occur (Adgey, Spence et al., 2005).

Historical Development of the of Defibrillator

Development of practical defibrillators began in the 1920s with response to an increasing number of electrical shock accidents and deaths. In 1947, Beck et al. performed the first successful human defibrillation using specially designed internal cardiac paddles to resuscitate a 14-year-old boy who had become pulse-less during elective chest surgery. In 1956, Zoll et al. performed the first successful human external defibrillation using a 15-amp AC current that produced 710 volts applied across the chest for 0.15 seconds. In 1961, Alexander, Kleiger, and Lown first described the use of AC current for terminating VT. Work by Lown et al. in the early 1960's demonstrated the superiority and safety of DC over AC for defibrillation. Ambulance-transported Belfast physicians first performed successful pre-hospital defibrillation in 1966. Defibrillation by emergency medical technicians (EMTs) without the presence of physicians was first performed in Portland, Oregon, in 1969 and was reported in 1972. (Bocka, 2005)

The Implantable Cardioverter Defibrillator

In the 1960s, Mirowski (1985) conceived of the idea of an automatic implantable defibrillator. The first ICD was implanted in a young woman as a prophylaxis against SCD in 1980. The U.S. Food and Drug Administration approved the device in 1985.

The earliest devices weighed up to 300 grams, had a battery life of three years, and were implanted in the subcutaneous layer of the abdomen with epical screw-in leads, and were sutured to the pericardium (Wolfe, Kosinski, & Grubb, 1998). A second generation of devices, developed in the mid-1980s, did not require thoracotomy, but used a transvenous defibrillating lead. These second generation ICDs employed cardioversion, were programmable, detected ventricular arrhythmias better, and delayed electrical therapy. In the 1990's, the third generation ICDs had multiple features, tiered therapies, enhanced programmability, and increased sophistication, as well as being designed to target energy delivery. Additionally, these advanced devices weighed less than 40 milligrams and had a battery life of eight years (Fetzer, 2003).

Components of Current ICDs

The current ICD consists of a pulse generator and one or more leads. An epoxy resin header at the top of the generator connects pacing and defibrillation electrodes (DiMarco, 2003; Zipes, Libby, Bonow, & Braunwald, 2005).

The newer models provide a daily rhythm history with as many as 150 certain therapy events stored in their memory. The devices that store a graphic image of a patient's arrhythmia, called an electrogram (EGM), are ready for interrogation by an external analyzer. However, if events go beyond the capacity of storage, the oldest rhythm would be discarded and the newest would be stored instead (DiMarco, 2003).

An ICD battery usually functions between four and eight years, depending on the number of shocks and/or the pacing it sends. When the battery runs down, a new ICD must be implanted (DiMarco, 2003; Fetzer, 2003; Zipes, Libby, Bonow, & Braunwald, 2005).

The leads are responsible for capturing the electrical activity that goes toward internal sensing, provide a site for pacing and defibrillating. Recent technological improvements in electrode design have led to improved features. The transvenous leads have decreased the amount of energy required to defibrillate. This decrease in energy has rendered the need for the larger epicardial patches and electrodes rendering sternotomy incisions obsolete. Therefore, these transvenous leads are now accepted as a standard (Seidl & Senges, 2003). Currently, the following models are available: (a) a single chambered, ventricular-only device that is usually placed in the right ventricle; (b) a dual-chambered atrial and ventricular device with leads placed in the right ventricle and atrium; and (c) a biventricular ICD, whose leads are attached in the right atrium, the right ventricle and the left ventricle. These techniques help the heart beat in a more balanced way and are specifically used for patients with heart failure.

Functions of Implantable Cardioverter-Defibrillator

The ICD has three major functions: monitoring, detecting and delivering. The ICD program monitors the R wave of the electrocardiogram and counts the number of QRS complexes per minute on a beat-to-beat basis (Fetzer, 2003). The ICD determines when the ventricular rate exceeds the programmed limit. Many ICDs have a VT zone (e.g., 150-200 beats per minute [bpm]) and a VF zone (e.g., > 200 bpm). When the ICD has detected the ventricular rate and QRS morphology abnormalities that exceed its programmed limits, the program triggers the antitachycardia pacing therapy (ATP). When the heart beats too fast, a series of small electrical impulses are delivered to the heart muscle to restore a normal heart rate and rhythm for VT, or delivers a shock to terminate VF (Clemo & Ellenborg, 2001; DiMarco, 2003).

When the shock program has been initiated, the device can be programmed to deliver a first shock from a minimum of 1 joule to a maximum of 41 joules, depending on the energy level required; traditionally starting at 10 joules. The charging time can take 0.1 to 7 seconds. After delivering the first shock, a 5 to 25 second delay is programmed to allow the ICD to detect any continuing dysrhythmia and recharge. Second, third, fourth, and fifth shocks are delivered at the maximum energy level if needed. Newer ICD models can be programmed for six shocks, and some will deliver a maximum of eight shocks.

Figures 1
Appropriate shock

Interrogation of the ICD

The interrogation procedure is typically done every three months in a specialized pacemaker/ICD follow-up clinic. A cardiac electrophysiologist, assisted by a trained technician or senior cardiovascular nurse, performs the procedure. Interrogation is also performed as the device approaches elective replacement or in response to symptomatic events (e.g., shocks).

During ICD interrogation, a “wand” is passed over the device and is attached to a programmer for communicating by means of electromagnetic coupling. Thus, the electrophysiologist is able to determine what electrical therapies have been experienced. The interrogation process checks lead integrity and battery status. Based on the revealed information, the device can be adjusted to optimize detection and therapy parameters. Most ICDs record the patients’ electrocardiographic tracing at the time of arrhythmia detection. This information can be analyzed at follow-up visits to determine the nature of the arrhythmia and the efficacy of the electrical therapy that was given (Groh & Foremn, 1998).

An implantable defibrillator, prescribed for people whose hearts beat dangerously fast, operates differently from a pacemaker. When a defibrillator detects a fast heart rate, it delivers electrical therapies to restore a normal rhythm. Depending on the patient's condition, these therapies can begin mildly and become progressively stronger as needed (ATP). The highest energy therapy is called defibrillation, and it provides treatment similar to defibrillation paddles used by medical personnel (Fetzer, 2003). Over 250,000 defibrillators have been implanted worldwide since 1985 (Metronic, 2005).

Review of Literature on Inappropriate Shock

The ICD has achieved a preeminent role in the treatment of life-threatening, ventricular arrhythmias. The most common arrhythmias-related complaint among ICD patients is the subjective feeling of shock. The variant causes of inappropriate shock therapy remains a major clinical problem and the contributing factors remain unclear. Weber, Boecker, Block(1996) reported that the causes of IST are many, including: AF, the most frequent cause of IST; lead over sensing due to lead failure; sinus tachycardia; problems with environmental interference; and other unknown factors. Studies in which the incidence of ISTs has been examined have documented single, multiple, or repetitive shocks from a variety causes in ventricular ICDs. However, studies investigating atrial ICDs that cardiovert atrial fibrillation with a slow ventricular rate are no longer available and are beyond the scope of this review. Therefore, the topic of atrial ICDs will not be addressed.

Overall Factors Contributing to IST

The first large scale study reviewed by Grimm et al. (1992), retrospectively analyzed the incidence and causes of documented cases of spontaneous electrocardiography (ECG), and ICD discharges in the absence of VT and VF in 241 patients. During the follow-up period (24 ± 20 months), records of electrogram storage demonstrated that 54 of 241 patients (22%) received a total of 132 spontaneous ICD charges in the absence of VT or VF. The researcher further found that the most frequent cause of these ISTs was AF with rapid ventricular response ($n = 30$ patients). ISTs caused by lead problems occurred in eight patients. The rest of events of IST were caused by generator malfunction VVI programming, and by T-wave oversensing.

Nunain, Roelke, Trouton, Kim, Sosa-Suarez, and Brooks (1995) performed a descriptive study examining the problem(s) of third generation ICD therapy. One hundred and fifty-four patients with monomorphic sustained ventricular tachycardia (MSVT), VF, or syncope, with inducible VT not suppressed by antiarrhythmic drug therapy, and implanted with ICDs, were recruited for the study. In the mean follow-up period (15.3 ± 9.7 months), 30 of 154 patients had non-thoracotomy lead systems. The 26% rate of IST was similar to that reported for an earlier generation (Grimm et al., 1992). Thirty-two patients (21% of subjects) received ISTs for either sinus tachycardia or AF with rapid ventricular response. In this study, AF remained the primary cause of IST, with lead problems as the second major cause ($n = 3$). Nunain et al. acknowledged that the success of ATP therapy could reduce the need for shock in the third generation ICD device.

Klein, Raitt, and Wilkoff (2003) expanded the number of subjects to evaluate the incidence and characteristics of arrhythmia events that triggered ICD therapy in the Antiarhythmics Versus Implantable Defibrillator (AVID) Trial. Four hundred ninety-two of 1016 participants in this trial were examined. The results demonstrated that inappropriate sensing, ICD malfunction, and electrode failure rarely triggered ICD therapy in the AVID trial. AF and other sustained ventricular tachycardia (SVT) were responsible for attempted therapy in 11 patients and for all 13 treated episodes. Patients who received IST were slightly younger (63 ± 11 vs. 66 ± 11 , $p < .05$). Since approximately one-third of all patients in the AVID Trial received no syndrome preceding the delivery of the therapy, Klein et al. concluded that clinical or electrophysiologic parameters could not predict IST accurately.

A prospective study, conducted by Russo, Nayak, Verdino, Springman, Tenfeld, et al. (2003), examined the occurrence of ICD shock events in 51 patients ($M_{\text{follow-up}} = 16$ months). IST occurred in four patients. Shock therapy was delivered for SVT in four patients; one IST delivery was related to AF; and one IST was related to T-wave oversensing. Russo et al. concluded that the low incidence of IST (8%) might be related to vigilant device programming. However, the follow-up period utilized in this study was limited.

Nanthakumar, Dorian, Paquette, Greene, Edwards, Heng, et al (2003) retrospectively analyzed the single chamber ICDs' recipients with a history of AF or NYHA Class I to identify patients most at risk for receiving inappropriate shock. Of 299 patients, 261 completed data for analysis. All received ICDs in 1990 using single chamber, third generation, tiered device therapy. Results confirmed that 116 of the 261 patients (44%) received one or more inappropriate therapies and 73% of patients received inappropriate therapies within 2 years of receiving their device. The causes ISTs were: (a) ST = 58 (50%); (b) AF = 38 (33%); and, (c) noise events = 20 (17%). Seventy-one percent of the patients received shocks within two years of device implantation. Significant predictors of inappropriate therapy with AF and NYHA Class I versus Class II-IV. Age, gender, and coronary artery bypass graft (CABG) did not increase the risk of receiving an IST. The type of medications taken upon hospital discharge was also not a predictor of events. Nanthakumar et al. supported the suggestion that ICD recipients with a previous history of AF should be considered "at risk" for the occurrence of IST. However, the hypothesis that NYHA Class I should not be considered a risk factor, since the development of IST remained unsupported.

Recently, Rinaddi, Simmon, Bostock, Elliot, Bcknall, and Gill (2004) intended to assess whether the occurrence of IST would be reduced by the diagnostic enhancements of the ICD device. Rinaddi et al. retrospectively analyzed the data from 171 patients over 17 years of IST experience. Based on the records with full data (n =155 patients), results showed that IST occurred in 22 patients (14%), predominantly for atrial arrhythmias (18 patients with IST for atrial flutter/AF or ST). The occurrence of IST in the remaining four patients was related to problems with lead fractures. The three independent predictors of IST identified by these researchers were pre-existing atrial tachyarrhythmias, co-existent medication therapy, and a single chamber device. Data also showed dilated cardiomyopathy (DCM) and high incidences of IST (50%). AF incidence was also high (80%) and in high proportion (78%). Rinaddi et al. stated that the finding of increased coexistent medication therapy was not entirely clear, but might reflect poorer left ventricular functioning that is often associated with an enhanced use of medication therapy. Similarly, AF itself might be predisposed to ventricular arrhythmias. As for DCM patients, the researchers posited that the high incidences of IST were likely related to their increased incidence of AF.

Most recently, a prospective study by Theuns, Klootwijk, Simoons, and Jordaens (2005). collected clinical and functional variables for each patient. This study evaluated whether clinical characteristics could predict inappropriate ICD therapy due to atrial tachyarrhythmias. The observations noted in this study were: (1) a history of atrial tachyarrhythmias is an independent predictor of inappropriate therapy; and (2) recurrent VT with a C33L ≥ 350 ms that triggered device therapy was associated with an increased

risk for first inappropriate therapy. However, this study was not thorough enough to adequately to address the clinical associates.

Individual Factors

Lead Failure and Related Problems

Dorwarth, Frey, Dugas, Matis, Fiek, Schmoeckel, et al. (2003) retrospectively analyzed the incidence and clinical presentation of transvenous ICD lead failures during long-term follow-up and their clinical mode of presentation (n = 261). These patients had a transvenous ICD lead systems that were implanted between 1990 and 1998. Seventy patients had an implantation site on the abdomen, whereas 191 patients had implantations on the pectoral site. Patients who had experienced lead dislodgement were excluded. The results demonstrated that 31 of 261 subjects' lead malfunction had inappropriate detection, with IST occurring in 19 of 31 patients who had received 1 to 11 shocks. A high number of malfunctions (48%) was observed within the first year after device replacement due to battery depletion, with battery depletion occurring after $4.6 \pm .07$ years. Dorwarth et al. recommended that clinicians carefully monitor the lead status in any ICD recipient with a transvenous lead for more than four years.

Lead Hyperpolarization

Healy, Goyal, Browing, Robotis, Ramaswamy, Rofino-Nadoworany, et al. (2004) did a case study of another aspect of a lead problem. The patient involved did not experience any symptoms prior to being first shocked 16 months after implantation. He received the shock at a time when he was climbing the stairs. The initial shock occurred after an AF provoked an episode of VF. This VF was terminated by an appropriate shock,

but due to lead hyperpolarization and T wave oversensing, the device continued to deliver five inappropriate therapies at 30 joules. The mechanism behind this phenomenon was unclear, but might have involved an interaction at the lead/myocardium interface at the time this patient climbed the stairs. Healey, et al. proposed that the mechanisms for proarrhythmic effects of shock might be caused by an increase in QT dispersion. Increasing sotalol from 40 mg bid to 80 mg bid resulted in no further shocks.

Lead Connection: Header and Set Screw-Related Problems

Picket, Saaverdr, Ali, Darbar, and Rottman (2004) reported four cases (i.e., *three* males and one female) of device malfunction due to the mechanical failure of a header connection within the a single device family over a limited time. The patient in Case 1 received one shock on the day after the procedure and 15 shocks occurred three days post implantation within one and a half hours. Repeated chest X-rays revealed an incomplete penetration of the right ventricular terminal pin in the header. Two ISTs occurred in Patient 3 as the left ventricular lead could not be placed due to increasing dyspnea at the time of implantation. After the device was replaced, no further problems were reported. The other two patients, as described by Picket et al., did not receive any ISTs. These cases shared a common element of defective connections between the header post and the right ventricular pace/sense terminal pin that required intervention and reconnection. Picket et al. posited that such lead connection problems would increase as ICD devices became more complex.

Double Counting

Biventricular pacing emerged as a modality for the treatment of patients with heart failure. Combined biventricular pacers and ICDs offered treatment for heart failure

as well as protection from a sudden cardiac death. Tachycardia detection in first-generation biventricular pacemaker-implantable cardioverter defibrillators (BiV ICD) occurred through both the right ventricular (RV) and left ventricular (LV) leads, creating the potential for inappropriate detection and therapies (Al-Ahmad, Wang, Homoud, Estes, and Link, 2004).

Case studies done by Schreieck, Zrenne, Kolb, Ndrepepa, and Schmitt (2001) and Liu, Villareal, Hariharan, Rasekh, and Massumi (2003) presented three patients who had all received IST from biventricular ICD therapy. Al-Ahmad, Wang, Homoud, Estes, and Link (2004) performed another study related to the problem of double counting. Al-Ahmad et al. retrospectively analyzed the ICD records from a group of 23 patients receiving biventricular ICD therapy. Within the follow-up period (3.7 ± 2.6 months), the results showed that 15 ISTs out of 33 shocks in five patients were caused by double sensing. All episodes resulting in shock occurred because of sinus tachycardia or a supraventricular tachycardia (SVT) higher than the upper-programmed pacing rate of the device with resultant AV conduction and double sensing of the non-paced ventricular depolarization. Al-Ahmad et al. concluded that double sensing of the R-wave was a common and clinically important cause of inappropriate ICD detection and shock in patients with biventricular ICDs. New generation devices with inappropriate detection in patients with a first-generation BiV ICD was common and often resulted in inappropriate ICD therapy. The most common mechanism of inappropriate detection was double counting, often creating the need for additional procedures. Although devices in which tachycardia detection occurred only through the RV lead were now available, RV/LV output and double counting should therefore not occur. However, close follow-up of the

patients who received a first-generation BiV ICD was necessary (Chugh, Scharf, Hall, Cheung, Good, Horwood, et al., 2005)

Generator Malfunction Issues

Generator malfunction constitutes another type of device limitation that could also cause an inappropriate shock. De Meester and Gilles (2001) reported a case study of IST that related to the ICD malfunction caused by excessive defibrillation of charge time twice (22 seconds and 19 seconds). Suspected were the gradual decline in battery voltage and increase of battery resistance, and the consequence of excessive charge time of the electric capacitors device was affected by highly variable and ineffective capacitors. Therefore, a new generator was implanted. De Meester and Gilles stated that, to avoid similar events from recurring, long-term follow-up would be needed to investigate the predisposing factors related to a malfunction of the capacitor's elements. Because of this potentially serious effect, the manufacturer recommended that ICDs with a charge time longer than 14 seconds should be monitored every month. They also suggested that, if a charge time exceeded 60 seconds, an immediate replacement was needed.

Diaphragm Myopotential

Three case studies were reported by Peters, Cooklin, Brockman, Steven, Shorofsky, & Michael, (1998). The patient in case 1 had received all asymptomatic shocks, which were not triggered by VT. But noise and oversensing were present during normal sinus rhythm (NSR) at a moment when the subject was performing the Valsalva maneuver. After decreasing the sensitivity in the device, the researchers noted that no further shocks occurred in the ensuing month of follow-up. Peters et al. stated that in all three cases, the lead was initially positioned in the right ventricular apex. It is presumed

that the sensing of diaphragmatic potentials was directly related to the proximity of the lead to the diaphragm. Peter et al. also recommended that the possibility of sensed DMP should be considered at the time of ICD implantation, especially during ventricular pacing, so that the appropriate preventive measures can be taken.

In a larger prospective study, Schulte, Sperzel, Carleson, Dursh, & Erdogan, et al (2001) investigated the incidence of diaphragmatic myopotential (DMP) in a cohort of 384 ICD recipients from 1991 to 1999. One hundred and thirty-nine nonadequate episodes of arrhythmia due to the oversensing of diaphragmatic myopotentials were observed in 33 out of 384 patients. Eleven out of these 33 patients had a total of 32 high energy shocks. The majority of nonadequate arrhythmia detections were during intrinsic bradycardia pacing. Electrical lead failure was ruled out in every patient. In 90% of ICD recipients provided with programmable maximal sensitivity ($n = 16$), the reduction of maximum sensitivity was effective in preventing further episodes of nonadequate arrhythmia deduction. Schulte et al. recommended that the clinical use of provocation maneuvers to examine the oversensing of DMP, (i.e., using the induction of DMP oversensing to distinguish far field oversensing from electrical lead failure,) can prevent an unnecessary surgical lead revision.

Electromagnetic Interference

Anfinsen, Bernsten, Kongsgaard, & Amlie (2002) reported the experience of an ICD recipient who had been implanted with an ICD endocardial lead post MI with VF. Two ISTs occurred during an MRI of the brain in this patient. These authors proposed that electromagnetic noise induced during the MRI may be detected as VF and

subsequently cause IST. Anfinssen et al. Suggested that clinicians should consider inactivating the ICD before an MRI procedure.

Anifinsen et al. went on to describe EMI occurring in four other patients with ICDs. Patient A received one shock while she was cleaning a lamp that connected to a 230 V 50Hz alternating current. Patient B received an IST when he was using a vibrator for genital and anal stimulation. Patient C experienced two ISTs while being treated by electronic muscle stimulation of the gluteal region. Patient D was using a percussion drill when he experienced two episodes of VF detection during sinus rhythm.

The incidence of IST caused by EMI has been estimated as < 1% per patient/per year (Kolb, Zrenner, and Schmitt, 2001). However, some episodes may have gone undetected. Thus, the overall incidence of EMI might be underestimated in the literature. The improvement of EMI detection algorithms and advances in lead technology are necessary to minimize the risk of EMI-related IST in ICD patients.

The interference between ICD function and the use of a washing machine was documented by Chan and Ho (2005). These authors also reported an instance of IST occurring when a subject wore a pair of cotton gloves to operate a power drill during a rainy day. Therefore, Chan and Ho suggested that EMI due to 50 Hz alternating current leak could be avoided by giving detailed advice on the handling of electrical appliances to ICD recipients.

Drug Interactions

The concomitant administration of antiarrhythmic drug therapy remains common in patients with ICD. The potential influence of antiarrhythmic drugs on the defibrillation threshold (DFT) is the most significant issue. Class III agents (except amiodarone) can be

safely administered in conjunction with ICD patients as long as the interaction between these therapeutic modalities is monitored (Sergo, & Gerard, 1995).

Due to the psychological impact of ICD therapy, patients with these devices often had symptoms of anxiety or depression (Dougherty, 1995, Burg, Lampert, Joska, Batsford, & Jain, 2004). Pickworth, Votolato, and Raman (2004) reported a 35-year-old woman with depression. After implantation, the ICD was tested by delivering a shock on the T wave to induce VF. It was not terminated by one 15 joules and one 20 joules shock, but terminated by an additional seven external shocks of 360 joules. After evaluating the patient's drug regimen, a suspected drug to device interaction was discovered between Venlafaxine and ICD. After discounting Venlafaxine, an antidepressant with cardiac sodium, channel blocking activity was identified as a potential contributor to her elevated defibrillation threshold. The ICD was able to successfully defibrillate the patient. Carners et al. (2004) suggested that clinicians should be aware of this potential adverse drug-device interaction. Further studies are needed to determine the clinical significance of Venlafaxine therapy in patients with ICDs.

In a case reported by McBride, & Klucger (2004), an ICD recipient consumed two to three doses of Metabolife 356, a dietary weight loss supplement. The patient received four ISTs within 3 days. Device interrogation revealed atrial tachycardia. The patient stopped taking Metabolife 356 and took increasing doses of Sotalol instead. The patient remained event free for 18 months. The researcher suspected that the Metabolife 356 induced atrial tachycardia resulted in multiple discharges. This author proposes that ICD recipients concomitantly consuming alternative pharmacotherapy may have an enhanced risk of inappropriate ICD functioning.

Clinical Characteristics and Other Factors

Authorities propose that IST is most often the result of SVT, lead/device malfunction, or oversensing. Other situations leading to the occurrence of IST have been reported as well (Healy, Ngarmukos, and Rosenthal, 2002).

Healy, Ngarmukos, and Rosenthal (2002) described a case experiencing an IST associated with improper timing. This 58 year-old man with a history of ICM underwent ICD implantation after having an EPS positive for inducible SMVT. One IST occurred at one week post implantation. Electrograms revealed that a run of NSVT had caused the ICD to charge. The device appropriately detected the rhythm abnormality and charged. However, after charging, a premature ventricular contraction (PVC) with a short coupling interval was detected during the second look window and a shock was delivered to the patient while in sinus rhythm. Thus, Healey et al. stressed that while algorithms are being developed to deliver appropriate therapy for life-threatening ventricular arrhythmias, an algorithm that allowed for continued sensing during the charge period might have saved this particular patient.

Recently, it has been proposed that a congenital short QT interval is associated with an increased risk for arrhythmias and SCD (Schimpf et al, 2003). At present, the ICD is the only therapeutic option. Schimpf et al. recruited five patients from two unrelated European families who had structurally normal hearts, excessively shortened QT intervals, and strong positive family history of SCD. ICDs were placed for primary and secondary prevention. Mean QT intervals were 252 ± 13 ms (QTc 287 ± 13 ms). In the follow-up 30 ± 26 days, Schimpf et al. observed that three of five patients received ISTs for T wave oversensing. After reprogramming their generators of ICDs by lowering

sensitivities, no further episodes of IST were noted. Schimpf et al. concluded that an increased risk for IST is inherent, due to the detection of short-coupled and prominent T waves.

Idiopathic VF patients had a high recurrence rate of ventricular arrhythmias. ICD prevented SCD from this population; the clinical outcome of the ICD recipients with solely a diagnosis of Idiopathic VF was lacking. Champagne, Geelen, Philippon, and Brugada, (2005) conducted a prospective cohort study (from 1992 to 2000) to examine the clinical and electrophysiological characteristics of consecutive SCD survivors from idiopathic VF. In this study, after excluding those patients with LQTS, Brugada syndrome, right ventricular dysplasia and no history of CAD from 445 ICD recipients, 18 patients with idiopathic VF were studied. Six participants had syncope associated with self terminated TdP or VF, and 12 subjects survived an episode of SCD with VF. All of the subjects had left ventricular ejection fraction of >50% and a mean age of 42 (ranging from 20 to 70). At the mean follow-up at $41 \pm$ months, 7 out of 18 patients received a total of 27 shocks, and 8 of 18(44%) subjects received IST for a total 21 discharges. The causes included AF in 12 of 21 (57%) episodes in 14 patients (mean age 53 ± 14 years); sinus tachycardia in 6 of 21 episodes in 4 patients (mean age of 31 ± 13 years); lead malfunction 3 of 21 episodes in 2 patients (mean age unknown); and 6 of 21 episodes in 2 patients had experienced IST from AF. Data also demonstrated that the presence of the ICD prevented SCD from idiopathic VF, and only treated the final manifestation of unknown diseases. IST remained a major concern in this young population.

Death Events Related to Inappropriate Shock Therapy

Messali, Thomas, Chauvin, Conmel and Leenhardt (2004) reported that the cause of death of one ICD recipient was related to IST. This patient was a 49 year-old man, with a 15-year history of NIDCM and an LVEF of 40%. The patient had a history of two cases of SCD and DCM in his immediately family. A syncopal SMVT was performed in 1991, with an initial ICD implantation in 1991 in the abdominal site. The generator was replaced in 1995 and in 2000, but the same atrial and ventricular leads from the original ICD implantation were retained. This patient received six shocks and experienced SCD in 2000. Data storage of the fatal event showed an episode of ventricular oversensing during sinus rhythm that was improperly designated as VF because of some short cycle lengths < 300ms. This false detection triggered the first shock as well as five subsequent shocks within two minutes. The sixth shock induced a true, untreatable VF. Inappropriate shocks were delivered due to noise oversensing originating from a ventricular lead with an insulation defect. In the interrogation of the device, it was also revealed that the patient had experienced an IST nine days earlier due to the same type of oversensing and multiple NSVT that might have been oversensing in the 12 days before death. Messali et al. posited that the event of noise oversensing could be caused by an insulation defect of the ventricular lead that was caused by prolonged used and repeated episodes of shock. However, other studies have demonstrated that oversensing could have occurred without structural lead failure (Dorwarth, et al, 2003). Therefore, the abdominal location and coaxial body design may be predictors for long-term structural failure of the ventricular lead. Messali et al. emphasized the need for careful follow-up for patients with ICDs and the performance of interrogation as soon as possible following a shock delivery.

A recent tragic event occurred, caused by a generator malfunction, to a 21 year-old college student with HCM, according to a manufacturer's report. An autopsy revealed no clinically significant pathology beyond a massive left ventricular hypertrophy. An ICD was shown to be almost successful in preventing SCD for this young man. When the manufacturer analyzed the ICD, it was revealed that the device had short-circuited internally while trying to deliver high voltage therapy, thereby permanently disabling itself. Its memory had been destroyed, making the time of failure impossible to pinpoint (Gornic, Hauser, Almquist, Maron, 2005; Steinbrook, 2005). Since this defect was not detected at the patient's previous regular follow-up, the safety and the reliability of these life-saving devices triggered a broad discussion. The FDA and Heart Rhythm Society will plan to develop the guidelines regarding ICD recalls for manufacture – notification standards and will decide when to replace the ICD devices.

Summary and Conclusions

Despite the rapid evolution of the ICD device and algorithms designed to reduce IST, the reported incidence of IST ranges from 5% to 20% and continues to be a major problem associated with the use of ICD. Although spurious discharges are most commonly caused by supraventricular arrhythmias, especially AF, IST can be triggered by device malfunction, such as lead failure due to battery depletion, and problems related to header and set screw connections, double counting, lead hyperpolarization and generators. Other factors, such as an oversensing of diaphragmatic myopotential, electromagnetic interference, and interactions between antiarrhythmic medications and the ICD device are also frequently reported by researchers.

There is also a growing consensus that structural heart diseases, such as ischemic cardiomyopathy and heart failure, which induce the development of AF, contribute to the occurrence of IST. In addition, non- structural heart diseases, such as T wave oversensing, occurred in patients with short QT syndrome. In some situations, researchers suspected the underlying pathology may contribute to IST, although the exact nature of the relationship of cardiac pathology to IST remains to be explored.

As the above literature review demonstrates, current documentation of the IST phenomenon in ICD patients is limited to either case studies or descriptive research investigations with mostly small numbers of subjects. Hence, the knowledge base in this area is at an initial stage. While it is a definite limitation that the proposed study is based on single-case studies and limited research, it is an appropriate next step in the development of knowledge to examine further the factors which experts suspect may play a significant role in contributing to the occurrence of IST. Table 2 refers to the risk factors of IST in the above studies.

Therefore, given the available evidence regarding the complex factors contributing to IST, the researcher has examined the incidence of appropriate shock and inappropriate shock occurrence and has investigated the clinical predisposing factors of inappropriate shock in a group of ICD recipients from a major medical center located in Southern California, which also serves as a tertiary referral hospital.

Table 2

Inappropriate Shock Therapy Events in ICD Studies with Varying Criteria (Studies are Chronological Order)

A. Overall Factors with AF as a Primary Cause			
Author(s) /year	Subjects (N = Total)	Research Design	Finding (s) R/T IST # & Cause(s)
Grimm et al /1992	N = 241	Retrospective Analysis	54 of 241 patients (22%) received a total 132 spontaneous ICD charges to the absence of VT or VF AF RVR: 30 Magnet misdirect 1 - T wave oversensing 1 - Generator malfunction 1 - Sensing lead malfunction 1 - Lead 1 - Loose set screw 1 - Lead adaptor break 1
Nunain et al /1995	N =154	Descriptive study	<ul style="list-style-type: none"> • IST experience : 36 (28%)Patients • AF : 32 (21%) SVT (AF or Sinus tachycardia) excess autogain in 2 patients. •Lead problem : 1
Nanthakumar et al /2003	N =261	Retrospective study	116/261 patients received IST <ul style="list-style-type: none"> • Causes: - ST : 58 (50%), - AF: 38(33%) - Noise events: 20(17%) • Predictors of increasing risk of receiving IST -Previous Hx of AF & NYHA FcI received single chamber had high risk of develop IST 2-4 =1.3:1 •Age, sex, & CABG did not increase the risk of receiving IST

Klein, et al /2003	N = 492 from AVID trail	Secondary analysis	<ul style="list-style-type: none"> • AF and other SVT were responsible for attempting therapy in 22% of patients • Patient received IST slighter younger (63 ± 11 vs 66 ± 11, $p < .03$). • Approximately 1/3 of all patients received no syndrome preceding delivery of therapy
Russio et al/2003	N=51	Prospective study	<ul style="list-style-type: none"> • IST occurred in 4 patients. • Causes of IST: <ul style="list-style-type: none"> - SVA : 4 (8%) - AF :1 -T wave oversensing : 1,
Rinaldi et al/ 2004	N=155	Retrospective study	<ul style="list-style-type: none"> • IST : 22 (14%) patients • Causes - <ul style="list-style-type: none"> -Atrial flutter/AF, or ST:18 - Lead fracture: 4 • 3 Independent predictors of IST – <ul style="list-style-type: none"> - Pre- existing atrial tachyarrhythmias: - Coexistent appropriate therapy - IST more common with single chamber than double chamber • DCM had high incidence of IST (50%). AF incidence was also high (80%) and high proportion (78%)
Theuns et al/2005	N=261	Prospective study	<p>IST : 14%</p> <p>Causes:</p> <p>(1) a history of atrial tachyarrhythmias is an independent predictor of inappropriate therapy and</p> <p>(2) recurrent VT with a $CL \geq 350$ ms that triggered device therapy was associated with an increased risk for first inappropriate therapy.</p>

B. Inappropriate Shock Therapy Events in ICD Studies with Varying Criteria /Lead Problems			
Author(s) /year	Subjects (N=total)	Research Design	Finding (s) R/T IST # & Cause(s)
Dorwarth et al/ 2003	N = 261	Retrospective analysis	<ul style="list-style-type: none"> •31/261 subjects lead malfunction had inappropriate detection •IST occurred 19/31 patients •3± (1-11) shocks /patient <p>X- ray did not show lead fracture in any of patient. Only one case had subclavian crush syndrome. S/P the association with battery depletion secondary to old lead (>4years)</p>
Healey et al /2004	N =1	Case Report	<ul style="list-style-type: none"> - Initial IST AF - the subsequently 6 ISTs : T wave oversensing secondary to lead hyperpolarization.
Pickett III et al /2004	N = 4	Case report	<p>Case 1: 15 shocks, -ray revealed incomplete penetration to the RV terminal pin in the header.</p> <p>Case 2: no shock although it was found that the terminal pin penetration beyond the set screw</p> <p>Case 3: Case 3- 2 ISTs due to the LV lead could not placed because of increasing dyspnea at the time of implantation</p> <p>Case 4 –no shock, terminal pin failed to extend beyond the set screw.</p> <p>These cases shared a common element of defective connections between the header post and the right ventricular pace/sense terminal pin that required intervention and reconnection</p>

C. Double Counting			
Author(s) /year	Subjects (N=total)	Research Design	Finding (s) R/T IST # & Cause(s)
Schreieck et al /2001	N = 1	Case study	An IST due to double detection of ventricular premature beats.
Liu. et al /2003	N = 3	Cases study	<p>Case 1 - one IST occurred at 3 weeks after implantation</p> <p>Case 2 - 4 ISTs occurred during 3 days after 2 weeks implantation.</p> <p>Case 3 - one IST occurred 2 months after implantation</p>
Al-Ahmad et al/ 2004	N = 23	Retrospective study	<ul style="list-style-type: none"> • 15 IST /33 IST episodes in 5 patients • 7/33 (21.7%) due to double sensing. • 4 patients(17.4%) had aborted shocks due to double sensing

D. Generator Malfunction & Other Problems			
Author(s) /year	Subjects (N=total)	Research Design	Finding (s) R/T IST # & Cause(s)
De Meester et al /2001	N = 1	Case study	•Two years after implantation Patient suffered from a recurrent syncope. Interrogation of the device revealed ICD malfunction caused by excessive defibrillation charge time -22 seconds in 02/99 and 19 seconds in 03/99. * [manufacturer company recommend charge time of >14 seconds needs to be follow up every month].
Healy et al/ 2002	N = 1	Case study	One IST occurred at one week after implantation. Electrograms revealed that a run of NSVT had ICD to charge. Further inspection revealed that a critically timed PVC during the "second look" interval resulted in delivered therapy.

E. Oversensing of Diaphragmatic Myopotentials			
Author(s) /year	Subjects (N=total)	Research Design	Finding (s) R/T IST # & Cause(s)
Peters et al /1998	N = 3	Case report	Case 1- All several asymptomatic shocks were not triggered by VT. noise & oversensing during NSR with deep inspiration & valsalva maneuver. Case 2 - Received several shocks during AF & multiple arrhythmia detection's during NSR at the time of patient's defecating. Case 3 An asymptomatic shock was demonstrated during valsalva maneuver
Schulte et al/2001	N = 384	Prospective study	139 non adequate episodes of arrhythmia due to oversensing of diaphragmatic myopotentials were observed in 33 patients. •11 /33 patients had a total 32 high energy shock occurred. ***The oversensing of diaphragmatic myopotential to be distinguished from lead failure.

F. Interferences with Environment			
Author(s) /year	Subjects (N=total)	Research Design	Finding (s) R/T IST # & Cause(s)
Groh et al /1999	N = 169	Post only design	<ul style="list-style-type: none"> • G1: No any negative response in routine exposure (10-15 seconds) • G2: 3 subjects experienced inappropriate tachyarrhythmia detection, • G3: 19/126 showed evidence of oversensing. • no ICD reprogramming was observed in any of the ICDs in all 3 groups.
Kolb et al /2001	N = 4/341 patients	Retrospective Study	<p>Case 1, one shock delivered at the time she cleaned the lamp that connect to 230V, 50Hz alternating current.</p> <p>Case 2, one IST when using a vibrator for genital and anal stimulation</p> <p>Case 3, was treated by electronic muscle stimulation of the gluteal region , EMI lead to detection of VF and response shock twice.</p> <p>Case 4, 2 episodes of detection of VF during sinus rhythm with a normal rate recorded by device at the time patients was using a percussion drill.</p>
Anfinson et al /2002	N = 1	Case study	2 ISTs occurred during brain MRI procedure.
Kolb et al/2002	N = 1	Case study	<p>a defibrillation shock without warning symptoms at the moment patient touched washing machine.</p> <p>-Hemodynamic instability.Ruled out sensing problems, No myopotentials;</p> <p>-Rule out lead and pulse generator malfunction by the evidence of X-ray and interrogation data (history). -S/P washing machine was not properly grounded.</p>
Chan et al /2005	N = 2	Case study	<p>Case 1, received one IST at the time he operating power drill while it was raining and he wore a pair cotton gloves.</p> <p>Case 2 , received one IST while He used his wet hand to touch the old washing machine, which current was leaked.</p>

G. Interaction with Drug			
Author(s) /year	Subjects (N=Total)	Research Design	Finding (s) R/T IST # & Cause(s)
Capoferri et al /2004	N = 100	Prospective observation study	<ul style="list-style-type: none"> •19 (19%) patients experienced inappropriate therapy. 12/19 received shock. • Causes of IST : Atrial tachycardia : 8; Sinus tachycardia : 9; T wave oversensing : 2. • No significant difference of the incidence rate of IST in primary prevention and secondary prevention groups.
Carnes et al/2004	N = 1	Case study	Venlafaxine, an antidepressant with cardiac sodium channel blocking activity, was identified as a potential contributor to patient's elevated defibrillation threshold.
Mcbride et al/2004	N = 1	Case study	After consuming 2 to 3 doses of Metabolife 356 (a dietary weight loss supplement), patient received 4 IST within 3 days. Device interrogation revealed atrial tachycardia.

H. Specific Clinical Characteristics			
Author(s) /year	Subjects (N=total)	Research Design	Finding (s) R/T IST # & Cause(s)
Schimpf et al/ 2003	<ul style="list-style-type: none"> • N =5 from two families • structurally normal hearts, • excessively shortened QT intervals & positive family Hx of SCD. 	Case study	<ul style="list-style-type: none"> • 3 of 5 patients received ISTs for T wave oversensing. • Schimpf et al concluded that increased the risk for IST is inherent due to the detection of short-coupled and prominent T wave.
Glikson et al/2004	<ul style="list-style-type: none"> • N = 82 • stable VT • mean age : 66.2 ± 11.3, • stable VT 	Retrospective analysis	<ul style="list-style-type: none"> • 29 (35%) patients had at least one IST. • Hemodynamically stable VT were at considerable risk for subsequent unstable VT • No description of the events of IST. But Glikson et al suggested that degree of the structure of heart disease may be as or more important than absence or presence of arrhythmia symptoms for predicted death.
Champagne et al /2005	N =18 idiopathic VF out of 445 ICD recipients	Prospective cohort study	<p>7/18 patients received a total of 27 shocks.</p> <ul style="list-style-type: none"> • 8/18 (44%) subjects received IST for a total 21 discharges. • Causes: <ul style="list-style-type: none"> -AF: 12/21 (57%) episodes in 14 patients, these patients are older. mean age 53 ± 14, -Sinus tachycardia : 6/21 episodes in 4 patients with a mean age of 31 ± 13 years. -Lead malfunction : 3/21 episodes in 2 patients. -Unknown : 6/21, episodes in 2 patients & had experienced IST for AF.

I. Specific Clinical Characteristics			
Author(s) /year	Subjects (N=Total)	Research Design	Finding (s) R/T IST # & Cause(s)
Messali et al /2004	N = 1	Case study	6 shocks on 03/31/00, SCD on 06/29/00. Data storage of fatal event showed an episode of ventricular oversensing during sinus rhythm that was designed as VF because of some short cycle lengths < 300ms. This false detection triggered the first shock and the five subsequent shocks within 2 minutes, the 6 th shock induced a true VF that could not be treated because the end of therapeutic procedure had been reached.
Steinbrook /2005	N=1	Case Study	Subject died suddenly, EGM revealed the device had short-circuited internally while trying to deliver high voltage therapy, it was permanently disabled. More over, its memory had been destroyed, making the time of failure impossible to pinpoint.

CHAPTER III

METHODOLOGY

Research Design

This five-year retrospective study was designed to analyze the incidence of appropriate and inappropriate shock and the clinical predictors for inappropriate shock in a group of ICD recipients from a university medical center. This study was carried out by reviewing ICD interrogation records and medical charts.

A retrospective method was chosen primarily because the knowledge base regarding factors that contribute to IST is currently at the descriptive level. It is known that the events contributing to IST include multiple intrinsic and extrinsic factors; however, there are many gaps in current knowledge regarding these clinical characteristics and their associations to IST. A retrospective method examining 5 years of patient data was used to capture a variety of salient factors related to the incidence of IST. However, this investigation may still have been confounded by the possibility of two problems: first, that the observed time period was too short to provide enough information; and second, that rapidly changing technological and pharmaceutical developments in devices and treatments may have rendered data difficult to evaluate on a cohort basis. With these possible problems in mind, the

current study was based on data gathered over a five-year period, a moderate amount of time that can provide sound results for analyzing the maximum strengths and minimal weaknesses of a cohort.

Research Setting

This study was conducted at the Arrhythmia Clinic at the University of Medical Center in Southern California, USA. This university medical center serves the surrounding metropolis and participates as a tertiary, regional, referral center for the area's cardiovascular patients. Although the majority of patients were local residents at the time of ICD implantation and follow-up, some patients came from areas outside of the region. Therefore, this study has the benefit of being based on results from a diverse group of participants. This hospital has well established systems in its Arrhythmic Clinic. Patients who undergo ICD implantation receive follow-up care in the clinic, including interrogation procedures to examine the ICD device function. Interrogation allows electrophysiologists to determine effects from specific forms of electrical shock therapy that a patient received since the previous clinic visit. Lead integrity and battery status are also checked. The ICD device can then be adjusted to optimize detection and therapy parameters. Most ICDs record the patient's electrocardiographic tracing at the time of arrhythmia detection. This

the patient's electrocardiographic tracing at the time of arrhythmia detection. This information can then be analyzed at follow-up visits to determine the nature of the arrhythmia and the efficacy of the electrical therapy that was given.

The cardiac electrophysiologist, along with a trained technician and/or a cardiovascular nurse, typically conducts an interrogation once every three months. An interrogation is also conducted as the device approaches elective replacement, as well as at any time of symptomatic events (e.g., shock occurrence).

Sample

Criteria for Sample Inclusion/Exclusion

The target group consisted of ICD recipients who underwent follow-up examinations in the Medical Center Arrhythmic Clinic from January of 2000 to May of 2005.

The following inclusion criteria were utilized for this study:

- 1) Persons age 18 and above who had received an ICD and attended one or more ICD clinic visits at the medical center;
- 2) The documented occurrence of an appropriate shock (i.e., a shock delivered in the presence of VT or VF), and/or an inappropriate shock (i.e., a shock delivered in the absence of VT or VF).

- 2) An incomplete chart record regarding pertinent study data.

Data Collection

Data Collection Instrument

The data collection form was designed by the researcher and reviewed by two electrophysiologists for content validity (see Appendix D). Each item was designed to obtain appropriate demographic information and clinical characteristics. In addition, indications for ICD implantation, clinical history, underlying diseases, and prescribed medications were recorded. Device information and the history of shock events were integrated as well.

Validity and Reliability of the ICD Records and Charts

Records from medical charts and ICD records offer objective evidence (Eder, Fullerton, Benroth, & Lindsay, 2005). Descriptions of events reported by patients and their families were recorded by an examining physician shortly after the actual IST events. Therefore, error variance in research conclusions should be minimized by the short time interval between the occurrence of the event and its report.

To minimize the variability and increase the precision of measurements, all data were collected by the researcher and confirmed by an electrophysiologist. Thus, concerns of inter-rater reliability have been minimized.

concerns of inter-rater reliability have been minimized.

Data Collection Procedures

Following appropriate IRB approval from the major university medical center in Southern California that served as the data collection site, the researcher collected data from the clinical charts of ICD recipients who had attended ICD clinics from January 1, 2000 to May 31, 2005. The researcher examined the charts to confirm that the criteria for study inclusion were met. Once the established criteria were met, the researcher recorded the data of applicable subjects on the collection sheet (Appendix E).

Data Analysis

This study utilized descriptive statistics, correlations, and regression models to perform the required statistical analyses. Calculations were performed by using SPSS 13 for Windows (SPSS, Inc., 2005).

For the purposes of this study, appropriate shock was defined as a shock developing in the presence of VT or VF, and inappropriate shock therapy (IST) was defined as a shock developing in the absence of VT or VF. For data analysis purposes, the occurrence of inappropriate shock therapy was considered as the dependent variable. Independent variables included sex, age, NYHA Functional Class, LVEF, structural / nonstructural heart disease, and AF/atrial tachycardia.

two groups: ages < 65, and ages ≥ 65 . The convention within medical literature is to present LVEF by range. Thus, the researcher utilized the three levels of classification of LVEF ranges utilized in the literature: normal $\geq 50\%$, moderately depressed: 35-49%, severely depressed $\leq 34\%$. Therefore, in this analysis, ordinal variables (e.g., NYHA functional class, LVEF) and age group were used in chi-square procedures to test the frequencies of categorical variables related to IST.

The following statistical analyses were performed to achieve the specific aims of this study. Continuous data, such as age and follow-up months, were expressed as a mean and standard deviation ($M \pm SD$). Categorical data were compared utilizing a chi-square test. Predictors of risk factors were determined by multivariate logistic regression analysis. The alpha level for this study was established at 5% ($p = .05$). Correspondingly, when the probability of making an alpha error was equal to or less than 5% ($p \leq 0.05$), the result was considered as statistically significant.

To achieve Specific Aim #1 (to describe the incidence of appropriate and inappropriate shock occurring in a group of ICD recipients seen at the specified university medical facility between January 2000 and May 2005 for emergent and routine follow-up visits), variables were analyzed and the following descriptive statistics were performed.

Calculation of the following factors required special attention: the total number of appropriate shock occurrence(s) and the total number of inappropriate shock occurrence(s); and the percentage of appropriate shock and inappropriate shocks per total number of patients. These rates of appropriate and inappropriate ICD shock therapies were determined by dividing the number of therapies experienced by the total number of patients, by the number and percentage of men and women experiencing inappropriate shocks.

To achieve Specific Aim #2 (to describe the relative risk between IST and specific factors i.e., age, gender, heart disease severity, structural heart disease, non-structural heart disease, atrial fibrillation) the following steps were taken:

- 1) The frequency and proportion of each clinical risk factor associated with an IST was first calculated.
- 2) The researcher then analyzed the relationships between each risk factor and the frequency of ISTs, using chi square testing. Following that, the researcher applied a logistic regression model to identify the clinical predictor(s).

Post hoc testing was employed to detect significant differences among the causes of an IST. If no significant differences were detected, the next step was to use another procedure to further investigate any relationships between the frequency of inappropriate shock therapy and certain variables and/or risk factors by adding a covariate in the event that another variable was confounding the results.

To achieve Specific Aim #3 (to describe the frequency of ISTs in a group of ICD recipients by risk factors (e.g., atrial fibrillation, lead problems, double counting) and the frequency and proportion of each risk factor associated with an IST, the following procedures were utilized. The number of ISTs for each risk factor (i.e., the presence of atrial fibrillation, lead problems, double counting) was divided by the number of IST events experienced per patient, and by the total number of patients over time.

To achieve Specific Aim #4 (to investigate any significant correlations between relevant clinical factors and the occurrence of IST), an analysis examined the relative risks between structural heart disease, non-structural heart disease, heart disease severity and the incidence of an IST. The clinical factors examined included antiarrhythmic medications taken, device mode, model, and device programming at the time of the inappropriate shock event.

Human Subjects

This study was a retrospective chart review with limited access to identifying personal information. Therefore, with the authorization of an HIPPA Waiver (i.e., waiver of consent), in accordance with the HIPPA Privacy Rule, 45 CFR 164, section 512 (I), the need for signed informed consent was waived. IRB approval was obtained from USD (Appendix E) and from UCSD Medical Center

(Appendix F) prior to data collection. The direct risks to participants in the study were minimal and every effort was made to protect confidentiality. Only a code number was used to identify participants, and no patient identifiers appeared on any data collection sheet. All data were stored in a locked file cabinet at the researcher's residence and only accessible to the researcher. All data were kept for a minimum of five years before being destroyed. Results were only reported through unidentifiable or aggregated means.

Risk Management

Only the researcher had access to the anonymous subject data throughout the research process. Prior to analysis, all subjects were assigned a case number. The protected health information of each patient was not reused or disclosed for any purposes other than that of the study.

Potential Benefits

There were no immediate, specific benefits to any individual subjects. However, the potential benefits of this research to the society were significant. An enhanced understanding of the predisposing factors related to inappropriate shock can potentially assist health care professionals in providing more effective patient education and clinical interventions. In addition, such descriptive research can

provide a basis for future research that ultimately may enhance the well being of all ICD patients.

Risk/Benefit Ratio

Thus, from the discussion above, the potential benefits of this research outweighed the minimal risks to subjects in this study.

CHAPTER IV

RESULTS

Subjects and Sample Characteristics

Two hundred and twelve patients were listed on the Electrophysiology laboratory's ICD roster. Out of that group, one minor patient (i.e., under 18 years old) was excluded. Also excluded were patients who came to the electrophysiology laboratory solely for ICD device implantations, generator changes, or lead replacement procedures. The researcher was unable to locate 22 charts and noted key data missing from the records of another 43 patients. The remaining 119 patients had sufficient data for analysis and review. Figure 3 illustrates the schematic summary of subject inclusion.

Using the period from January 1, 2000 to May 31, 2005, data from 119 patient records were included in this study; a total of 2,868 months were analyzed. The mean follow-up period was 24.1 ± 16.2 months (ranging from 1 to 53 months). Patients with 53 months of follow-up had received ICD implantations at an earlier time than in 2000.

Subject demographic and clinical characteristics are displayed in Table 3. The researcher's chart reviews uncovered a variety of indications for ICD implantation, with many patients having more than one type of heart pathology diagnosed. In examining the patients and their characteristics, the majority of participants were male ($n = 98$; 82.4 %); were NYHA Functional Class II ($n = 39$; 32.8 %); and had experienced a severe decrease in LVEF ($n = 90$; 75.6%). Only three subjects had nonstructural heart disease. With regard to age, there were slightly more patients in the elderly group ($\text{age} \geq 65$, $n = 67$; age

<65, n = 52), but this difference was not statistically significant ($\chi^2 = 1.891$, $p > .05$).

Figure 3 Schematic Summary of Subject Inclusion

Table 3

Demographic and Clinical Characteristics of Subjects

Variable	Outcome (%)
Sex	
Men	98 (82.4%)
Women	21 (17.6%)
Age	
Mean (in years)/Range	65.4 ± 15 (29 – 89)
< 65	51.0 ± 9.6
≥ 65	76.6 ± 6.4
Implant Indications	
SCD	9 (7.6%)
VT/VF	29 (24.4%)
ICM	42 (35.3%)
DCM	35 (29.3%)
HCM	2 (1.7%)
AVRD	2 (1.7%)
Heart Disease	
Structural	116
Non Structural	3
NYHA Functional Class	
I	27 (22.7%)
II	52 (43.7%)
III	39 (1.0%)
IV	1 (0.8%)
LVEF n = 118	
50%	10 (8.4%)
35-49%	18 (15.1%)
<35%	90 (75.6%)

ARVD= Right Ventricular Dysplasia, HCM = Hypertrophy Cardiomyopathy

DCM = Dilated Cardiomyopathy, ICM = Ischemic Cardiomyopathy,

SCD = Sudden Cardiac Death.

VT/VF= Ventricular Tachycardia/ Ventricular Fibrillation

Data Analysis Related to the Aims of This Study

Specific Aim #1

Specific aim # 1 of the study was to describe the incidence of appropriate and inappropriate shock occurrence in a group of ICD recipients, as well as to account for the incidence of appropriate shocks and inappropriate shocks for patients who visited the medical facility between January 2000 and May 2005 for emergent and routine follow-up visits.

Descriptive statistical analysis was performed to determine the profiles of shock occurrence in this study group. In this follow-up period, with a mean time follow-up of 24.1 ± 16.2 months (range of 1- 53 months), there were 90 subjects who had not experienced any shock treatment. Sixty shock events occurred for 29 (24.4%) patients; 16 (13.4%) patients received 44 appropriate shocks and 13 (10.9%) patients received 16 inappropriate shocks. Thirteen out of 119 patients (11 %) experienced IST, and 12 out of 13 IST subjects were men. Shock profiles are displayed below in Table 4

Table 4

Shock Profiles

Shock Type	Number of patients (%) N = 119	Number of Shocks
No Shock	90 (75.6)	0
Appropriate Shock(only)	16 (13.4)	44
Inappropriate Shock (only)	9 (7.6)	16
Coexisting Shock	4 (3.4)	-
Appropriate Shock Total	20 (17)	
IST total	13 (11)	
Male	12 (10)	
Female	1 (.8)	
Shock Total	29 (24.4)	60+

See Table 5 for other demographic information concerning the IST patients.

Table 5

Inappropriate Shock Therapy Patients Profile

Variables	Outcome (Number of Patients)		
Gender	Male (12)	Female (1)	
Age	< 65 (6)	≥ 65 (7)	
NYHA Class	I(4)	II(2)	III(7)
LVEF	>50% (2)	35- 49 %(1)	<35% (9)
Structural HD	Yes = 13	No = 0	
Hx of AF	Yes = 10	No = 3	

Specific Aim #2

The second specific aim of this study was to describe four associations: the relative risk relationships between age group and IST; gender and IST, heart disease

severity and IST; structural/ non-structural heart disease and IST; and the history of atrial fibrillation and IST.

To test the relationship between heart disease severity and IST, the researcher examined whether the incidence of inappropriate shock correlated with ICD recipients' severity of disease according to left ventricular ejection fraction (LVEF; i.e., very severe $\leq 35\%$, moderate severe 36-49%, normal $\geq 50\%$). Additionally, the NYHA functional classes (i.e., I, II, III, IV) of structural heart disease were examined to identify any significant correlations with the ICD recipients' non-structural heart disease.

Chi-square analysis was chosen to compare the IST group to the non-IST group in terms of the frequencies of ordinal variables (i.e., NYHA functional class, LVEF) and categorical variables (i.e., structural heart disease and non structural heart disease) as related to an inappropriate shock. These findings are displayed in Table 6

Table 6

Inappropriate Shock in Chi-Square Comparisons between IST and Non-IST patients

(N = 119)

Potential Clinical Predictors (N)	IST		χ^2	p
	Yes	No		
Sex Male (98) Female (21)	12 1	86 20	1.242	.537
Age Group < 65 (52) ≥ 65 (63)	6 7	46 59	.809	.667
NYHA Class I II III IV	4 2 7 0	22 50 32 1	8.731	.189
LVEF > 50 % 35-49 % < 34 %	2 1 9	8 17 80	1.792	.774
Structural HD Yes (115) No (4)	13 0	102 4	.410	.815
Atrial Fibrillation Yes (13) No (10)	10 3	3 70	11.993	.002*

df = 2, *p < .01

To characterize patients who were prone to develop an inappropriate shock, the researcher did the following: 1) comparison of clinical variables; 2) analysis of characteristics, including demographic information; 3) examination of subjects' histories of atrial arrhythmia, underlying heart disease, and ejection fraction; and 4) examination of the clinical characteristics of each qualifying arrhythmia. None of these variables was predictive of a future development of IST, except atrial tachycardia arrhythmia. To

account for the difference in the relationship between these potential risk factors, regression models were used; however, no predictive variables were identified. Details of the comparison of variables between the IST and non-IST groups are summarized in

Table 7.

Table 7

Likelihood Ratio Tests

Effect	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood of Reduced Model	Chi-Square	df	p
Intercept	37.080	.000	0	
Age Group	38.487	1.407	2	.495
Gender	38.489	1.409	2	.494
NYHA Class	47.543	10.463	6	.106
LVEF	38.146	1.066	4	.900
Structural	37.187	.107	2	.948
AF /Atachy	51.959	14.879	2	.001*

*p = .001.

As depicted in Table 6, atrial fibrillation was significantly correlated with the incidence of IST ($\chi^2 = 11.993$, $p = .002$). However, gender ($\chi^2 = 1.242$, $p = 5.37$), age ($\chi^2 = .809$, $p = .667$), NYHA ($\chi^2 = 8.731$, $p = .189$), LVEF ($\chi^2 = 1.792$, $p = .774$), and structural

heart disease ($\chi^2 = .410$, $p = .815$) were not statistically significant identifiers for IST.

These same variables were repeated using a logistic regression analysis, and results were similar. In this analysis, atrial tachyarrhythmia demonstrated an even higher significance in the regression analysis ($\chi^2 = 14.879$, $p = .001$) than in the chi square analysis ($p = .002$).

Specific Aim #3

This study's third specific aim was to describe the frequency of ISTs in a group of ICD recipients by risk factors (e.g., atrial fibrillation, lead problems, double counting). Thus, descriptive statistics evaluating the frequency and proportion of each risk factor associated with an IST were performed.

The number of ISTs for each independent variable (e.g., atrial fibrillation, double counting) is reported and divided by the number of inappropriate shock therapies experienced per patient and by the total number of patients over time.

IST's occurred in eight patients in the presence of atria arrhythmias (i.e., flutter, fibrillation) or sinus tachycardia. In one subject, an IST occurred following a missed dose of mexiletine. Other concurrent clinical events included double counting and T-wave over-sensing secondary to an imbalance of electrolytes. Table 8 displays the incidence of

IST by variable factors.

Table 8

Incidence of ISTs by Variable Factors

	AF/ A tachy	ST /NSR	Double counting	Lead problem	Drug Interaction	Total
Number of subjects	8	2	2	1	1	13
Number of IST	10	2	2	1	1	16

NSR= normal sinus rhythm, ST = sinus tachycardia

Specific Aim #4

The study's fourth specific aim was to investigate significant correlations between clinical information and an IST, and, taken in combination, to reveal any clinical predictability for the incidence of an IST. Variables analyzed include demographic characteristics, histories of previous underlying heart disease, ejection fraction, and medications taken at the time of the IST.

Medical charts and ICD follow-up records were reviewed for the clinical characteristics of the presenting arrhythmia. All information regarding episodes of stored arrhythmias were recorded at the discretion of the physician treating the individual patient. The elements recorded in the subject record as possible predisposing factors triggering ISTs are discussed below.

Most patients at risk for an IST had severe chronic heart disease and multiple independent risk factors for atrial fibrillation. More than 70% of the ICD patients had significant coronary artery disease, and most had severe left ventricular dysfunction with an ejection fraction of less than 30%. A minority of ICD patients ($n = 3$) had normal coronary arteries and electrically compromised, right ventricular dysplasia, mitral valve prolapse, or hypertrophic cardiomyopathy (HCM). Most ICD patients were also at risk for potential triggers of inappropriate shock known to precipitate atrial fibrillation and lead to SCD if left unchecked. These triggers included hyperthyroidism, diabetes mellitus, and valvular heart disease.

Table 9

Characteristics of Subjects and Incidence of Inappropriate Shock Therapy

P t #	Age Sex	Implant Indica-tion	History of HD	N Y H A	E F	Cause of IST Event	Mode	AA Drug at time of Event	F- up (M)	Intervention
1	82 M	VT CHF	Chr AF CABG Syncope Hypothyroidism	II	35	One shock due to AF Charge time 6.55 sec.	VVIR	Metoprolol Lanoxin	49	Up grade to dual chamber ICD
2	68 M	VT ICM	NSVT PAF	I	58	Missing one dose of Mexiletine	DDD	Coreg Digoxin Amidarone	25	Monitor VT
3	48 M	DCM	NIDCM HTN ESRD	III	10	Lead dislodge	Biv DDD	Coreg Laoxin	18	Reposition lead
4	85 M	VT	MVP	I	N/A	Discharge for AF	VVI	Coreg Digoxin	53	_____
5	87 M	DCM	PAF	III	15	Double counting	Biv DDD	Digoxin	10	Expired

Pt #	Age Sex	Implant Indication	History of HD	N Y H A	E F	Cause of IST Shock Event	Mode	AA Drug at time of Event	F-Up (M)	Intervention
6	44 M	DCM	CHF MI LBBB	III	24	Sinus tachycardia as VT	Biv DDD	Coreg Digoxin	7	VT zone increased, VT onset, stab discrimination ON
7	48 M	HCM	AF RVR	II	34	One shock for AF	DDDR	_____	46	_____
8	71 M	DCM	CHF AF	I	18	One shock for atrial flutter	DDDR	Mexiletine Sotalol Lanoxin	22	Arrange DFT testing
9	74 M	VT	ICM	I	35	Shock for SVT and AF RVR Dehydration, Creatine ↑ K ⁺ ↑	DDDR	Sotalol Laoxin Amidarone Coreg	41	Coreg increase to 625 mg. DFT remained stable on amidarone w/no antiarrthmic event.

Pt #	Age Sex	Implant Indication	History of HD	N Y H A	E F	Cause of IST Shock Event	Mode	AA Drug at time of Event	F-Up (M)	Intervention
10	49 M	VT	TOF VHD	III	30	One shock for A Tachy secondary induced by exercise	DDDR	Coreg	10	Since ICD firing in VT zone during exercise induced ST. After VT turned off. VT Ablation
11	79 F	AVRD	NSVT SMVT PAF	I	72	Two shocks for sinus tachycardia	Biv DDD	Cozaar Amiodarine Norvasc	53	No evidence for reversible perfusion to suggest inducible coronary insufficiency
12	54 M	ICM NIDCM	Chr. AF	II	30	One shock due to double counting	Biv DDD	Coreg Digoxin	18	Rate increase to 175, VT interval decrease to 343 ms
13	48 M	NICM	Chr AF	III	22	4 shocks - 3 for VT VF 1 for AF RVR while performing stress test	Biv DDD	Coreg , Cozaar Digoxin	22	ICD normal function Recommend rate control

AF = atrial fibrillation

PAF = paroxysmal Atrial fibrillation

TOF = Tetralogy of Fallot

Description of 13 IST Patients

As presented in Table 9, in the IST group, all patients had structural heart disease. Twelve patients were men. Subjects aged 65 years and older were slightly more numerous than younger patients (7 vs. 6), but this difference was not statistically significant. Eleven out of 13 patients had LVEFs that were severely depressed (i.e., below 35%), but there were no patients experiencing IST that had moderately depressed LVEFs. Two patients had a normal LVEF: 1) a patient with an LVEF of 58% who had CAD NSVT; 2) another patient with an LVEF of 72% who had poor right ventricular function due to right ventricular dysplasia.

The major causative factor of IST in this group was atrial fibrillation (n = 8). Two patients had sinus tachycardia. Double counting occurred in two patients, one patient's IST was associated with lead dislodgement, and another patient's IST was caused by missing one dose of Mexiletine. This type of event has been posited to be associated with an increased defibrillation threshold (DFT) (Murakawa, Yamshita, Kanese, Omota, 1998; Rajawat, Patel, Gerstenfeld, Nayak, and Marchinski, 2004).

Regardless of a variety of indications and disease diagnoses (including two patients with congenital heart disease), 10 out of 13 subjects who experienced IST had coexisting chronic AF or paroxysmal atrial fibrillation (PAF). Finally, three patients had no history of chronic AF; however, they all had at least one inherited risk factor for developing AF.

Another finding from this group was the importance of occurrences of trigger events. In two patients (Patient 1 and Patient 4) the ICD device was suspected to lack the ability to discriminate between SVT and VT, and, after changing VVI mode to DDD,

there was no further IST. However, IST occurred in the remaining patients who were implanted with a dual chamber device (Patient 5) and a biventricular device (Patient 6 and Patient 8). According to chart records, a missed Mexiletine dose was suspected to be the trigger of the IST secondary to alternating defibrillation threshold for Patient 2.

Two subjects receiving ISTs had similar situations. Patient 10, who had atrial tachycardia, received an IST while he was performing extreme exercise, and Patient 13 received an IST while he was undergoing a stress test. The patient activity at the time of the lead dislodgement case (Patient 3) was not recorded. However, all of these three patients were males and in their 40s.

Summary

The major finding of this study was a significant correlation between the occurrence of atrial fibrillation and the incidence of IST. The trigger events precipitating IST were varied in this study population, and their salience as clinical predictors of IST are discussed in the next chapter.

Figure 3

Patient 10 received an IST while he was performing extreme exercise. An inappropriate shock from atrial fibrillation with rapid ventricular response.

Figure 4

Patient 13 received an IST while he was undergoing a stress test. Inappropriate shock from a sinus tachycardia that had a ventricular rate fast enough to be detected in the VT zone of the device

CHAPTER V

DISCUSSION

Overview

This investigation is an updated cohort study of inappropriate shock therapy. The study represents the first research findings from a nursing perspective on the physiological aspects of IST in ICD recipients. Unlike previous cohort studies that only present the rates of causes of IST, including the most recent such study by Thenus et al. (2005), this study explores underlying trigger events by incorporating these events at the time when IST occurred, as well as by correlating subjects' clinical histories.

The actual data collection period of Thenus et al.'s (2005) study is not indicated; but the observation period of this present study was specifically conducted at a teaching hospital as well as a tertiary referral hospital in Southern California from July 2000 to May 2005, with a mean follow-up period of 24.1 ± 16.2 months.

Overall, this study reveals that, in 13 (9%) out of 119 patients who received inappropriate shock, AF remained the major cause of IST. In addition, 12 out of 13 patients receiving ISTs were men. The researcher posits that ISTs may be related to men's increased risk for atrial fibrillation. However, given that 98 out 119 patients (82.4%) were men, this conclusion is based on a small sample size that failed to achieve statistical significance and must be viewed with caution ($\chi^2 = 0.995$, $p > .05$).

Incidence Rates

In previous cohort studies, incidence rates of 22% (Grimm et al., 1993) and 14% (Rinaddi et al., 2004; Thenus et al., 2005) were documented, and inappropriate ICD therapy was attributed to atrial tachyarrhythmias. However, it is unknown what percentage of total events atrial tachyarrhythmias constituted in Thenus et al.'s study. The incidence of ISTs in this present study was 11%. This lower incidence might be due to the following reasons: (a) continuous refinement in the ICD devices; (b) rigorous procedures for performing a follow-up visit. The incidence rate also may have been underestimated because of patients lost to follow-up (e.g., moving, traveling, inability to locate patient or chart). However, those events also occur in most retrospective cohort studies.

Age and Gender

As in previous studies (Grimm et al. 1993; Nanthakumar, 2003; Rinaddi, 2004; Thenus et al., 2005), the present study did not show any significant difference in age and gender between the IST group and the non-IST group. Even though 12 out of the 13 IST subjects were men, the large proportion of men receiving this form of treatment was not significantly different between the groups ($p = .537$).

Atrial Fibrillation

Previous studies have investigated whether clinical variables could predict the delivery of IST in ICD recipients. Rinaddi et al. (2004) and Nanthakumar et al. (2003) observed previous histories of AF at the time of implantation to predict the incidence of inappropriate shock for patients with single chamber ICDs. Since the first cohort study (Grimm et al., 1993), and despite the advent of DDD, AF still remains the major cause of

IST (Thenus et al., 2005).

NYHA Functional Class

Nanthakumar et al. (2003) also noted that NYHA Class I could predict IST. In this study, however, the subjects' statuses of function classes fluctuated and could not reflect the level of severity for heart disease. Therefore, it was not surprising that identification of significance was not achieved at the level of NYHA Functional Class.

Ejection Fraction

As in the work of Thenus et al. (2005) and the present study did not found any significant differences in this factor related to the development of IST. One explanation could be that, although the value of LVEF is more objective (e.g., measured by rest technetium-99m-methoxy-isobutyl-isonitril (MIBI), echocardiography, or by the guideline of indications in Gate Bayesian Reconstruction In Emission Tomography [SPECT]), most patients were amalgamated into the severely depressed LVEF category in order to receive ICD therapy.

Eleven out of 13 patients with at least one IST experience had severely depressed LVEFs. However, other subjects with severely depressed LVEF had *experienced* no IST event. Therefore, the data could not support this variable as a clinical predictor.

Structural Heart Disease

A previous study (Rinaddi et al., 2004) posited that, while DCM patients comprised 50% of the study participants, a higher incidence of IST (80%) occurred in these patients. Rinaddi et al. concluded that patients with DCM were more likely to be at increased risk for ISTs. In this study with expanded indications, a variety of diagnoses are shown to have been occurring in ICD recipients. Because most patients had multiple

forms of heart diseases as well as other disease processes, DCM could not be considered as an independent variable, or as a clinical predictor. However, after grouping heart disease into structural and non-structural categories, the results demonstrated that almost all ICD recipients had structural heart disease ($n = 116$). Therefore, the number of patients with non-structural heart disease ($n = 3$) was too small to utilize structural heart disease as a grouping variable to test for statistical significance.

Lead Problems

Lead problems are the second major cause of ISTs, as reported in many articles (Dorwarth, et al, 2003; Goyal, et al, 2004; Pickett et al, 2004). In the present study, only one patient had an IST related to lead dislodgement. While another patient did have a lead fracture; however the lead was replaced in a timely fashion by rigorous integration, which contributed to be the lowered occurrence rate IST, as the researcher noted in the ICD record.

Double Counting

In this study, IST caused by double counting occurred in two cases in an early observation with the first generation of BiV ICD. Although dedicated BiV ICDs are now available with tachycardia detection only occurring through a single (RV) channel, continued follow-up of the many patients who received first-generation devices is needed.

Drug Interaction

In the present study, a unique finding not found in previous cohort studies was that an IST can be caused by missing one dose of Mexitil (i.e., mexiletine). In this patient, population, mexiletine function in a fashion similar to lidocaine to reduce the development of ventricular tachycardia, as has been used in hybrid therapy of ICD

recipients (Rajawat, Patel, Gerstenfeld, Nayak, & Marchinski, 2004). However, animal studies had reported that treatment with mexiletine increases the defibrillation threshold. Thus, suddenly missing one dose led to altering the serum level of mexiletine, which then lead to an IST (Bride et al, 1997). As a result, the association of missing one does of Mexitil and IST, is suspected.

Electrolyte Imbalance

Another IST event occurred when a patient was hospitalization for VT/VF. Predisposed dehydration increased the serum level of creatine and potassium, as the interrogation revealed VT and AF with rapid ventricular response.

Events Occurring at the Time of Inappropriate Shock Therapy Episodes

In this study, eight patients' IST were found to be AF/atrial tachycardia or SVT. In one case, there was no recorded trigger event; and in another case, the patient's single chamber ICD was replaced by a dual chamber ICD to solve the problem. Another patient was asked to increase the dosage of antiarrhythmics. Yet another patient was asked to take anti-thyroid. Adjustment of the defibrillation threshold and ablation were performed for two different patients to solve the IST problem. For the remaining two patients in the IST group, one IST occurred at the time when the patient was undergoing a testing procedure, the other IST occurred at the time when the patient was performing extreme exercise. Therefore, the clinical characteristics of patients prone to IST should be incorporated into intervention plans.

Clinical Implications

Because ICDs are a lifesaving device, the unexpected failure of one can be catastrophic. Thus, the findings from this study may have clinical implications that relate to the safety of ICD recipients. The following are this researcher's suggestions:

1. Early identification of the etiology of unnecessary shocks to allow for the immediate institution of therapy to reduce the risk for subsequent events;
2. Careful monitoring of concomitant anti-arrhythmic drug (AAD) therapy in patients with ICD;
3. Reinforcement of the need for careful electrode lead and generator placement to reduce IST events;
4. Increased awareness that certain testing procedures (e.g., stress tests) may predispose the patient to IST;
5. Development of an updated and effective education program for nurses caring for ICD patients that incorporates current research findings regarding assessment for risk factors for IST and patient/family education regarding these factors.

Ultimately, the goal is to ensure that ICD recipients achieve optimal care and recovery status.

Limitations

This study has several limitations. One major limitation is that it is based on a retrospective design. Data were collected through chart reviews and ICD records. Some of the information that the researcher needed was difficult to obtain. For example, if a patient expired at another hospital, the cause of death was unknown and the researcher could not know if any relationship existed between the cause of death and ICD device.

Other patient records may have been lost or were taken elsewhere (e.g., a patient might move out of the area). In addition, without the ability to contact patients, the researcher was unable to know where missing charts were located or about the existence of charts in other facilities.

This preset study data did not address the role of the programming in the genesis of IST as different programming modalities can influence the effectiveness of shock therapy. In addition, the researcher was not able to record all medications taken by the ICD recipients, and medications can alter ICD therapy. Further, the researcher was unable to obtain all ICD records for review, especially in the event of an IST occurring outside of the study site. For these reasons, the researcher may not be in a position to clearly assess the effects of risk factors and can only note inappropriate therapy prevalence based on the ICD records.

The major limitation of this study is its related small number of subjects limited to a single-center ICD clinic registry. As such, the conclusions could be buttressed by using larger multi-center registries or prospective data from future ICD research. Especially important would be focusing on data issues and avoid any potential bias resulting from incomplete data. At the outset, this researcher considered IST as the most clinically relevant event. Inappropriate anti-tachycardia therapy (ATP) that resulted in no shock or appropriate shock therapy was not assessed. Reasons for not including ATP were primarily due to missing data secondary to the ICD's memory limitations, incomplete interrogation, or cleared memory. Inclusion of any of these data could provide a fuller understanding of IST phenomenon.

Suggestion for Future Research

Despite the technological evolution of ICD devices, AF/atrial tachycardarrhythmia remains the major cause of IST. Efforts in future research should include investigations into the events arising from AF/atrial tachycardarrhythmia and clinical histories that could predispose patients to AF/atrial tachycardarrhythmia. Thus, the responses of ICD patients to triggered heart-rate exercise should be carefully studied. Since antiarrhythmics have become an integral part of hybrid therapy, the alteration of the defibrillation threshold by these medications also should be a focus of future research. As an IST can be triggered by an electrolyte imbalance, there is a need to investigate the pathways by which an imbalance in specific electrolytes (e.g., potassium) are promoting the occurrence of IST. Because of the serious consequences of device malfunction (e.g., sudden death), providing a patient alert system, surveying the reasons for patients missing a follow-up appointment, and developing a the strategy to assist ICD recipients to continue regular follow – up should be encouraged. The early detection of device malfunction and immediate replacement could avert a tragedy from occurring.

In addition, little is known regarding undersensing as a contributing factor to IST , and future research should focus on this area. Although inappropriate antitachycardia pacing may not be as serious as an IST, the wrong detection information can significantly alter hemodynamic functioning. Future research studies that explore more fully all inappropriate discharges may be made possible as increased memory electrogram storage in the ICD expands.

Despite expanded indications for the use of the ICD, the percentage of women receiving ICD therapy has not increased. This continuing persistent gender differential in

ICD therapy may need to be investigated using qualitative and quantitative methods, as a complex set of physiological and contextual factors may be operant.

This study represents an initial step in the growing body of knowledge regarding an expanding patient population. In the future, a multisite expanded longitudinal study will be necessary to confirm the results seen in this study and more clearly elucidate the multi-factorial nature of inappropriate shock therapy.

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Appendix A

Trails of ICD Therapy for the Secondary Prevention of SCD

Table 1

Trails of ICD Therapy for the Secondary Prevention of SCD

Study /Study Period	Population Characteristics, N= total	End Point (s)	Key Finding(s)
AVID/1993-1997 Antiarrhythmics vs. Implantable Defibrillator	<ul style="list-style-type: none"> • N=1016 -Survival of VF, -SMVT with near syncope, -SMVT with EF $\leq$ 40% & symptoms. •ICD therapy vs Antiarrhythmic (Amiodarone, Sotalol) therapy 	<ul style="list-style-type: none"> •Total mortality •Mode of death •Quality of life •Cost benefit 	<ul style="list-style-type: none"> •The ICD group experienced a 39% reduction death in the first year with a 27% and 31% reduction in years two and three. • Enrollment was discontinued prematurely because of a significant improvement overall survival with ICD.
CIDS/ 1990-1998 Canadian Implantable Defibrillator Study	<ul style="list-style-type: none"> • N=659 •Resuscitated after out-of hospital cardiac arrest -documented VF -SMVT with syncope -SMVT with EF<35% •ICD (n=328) vs amiodarone (n=331) 	<ul style="list-style-type: none"> •Primary end point: All causes mortality •Secondary end point: arrhythmia death 	<ul style="list-style-type: none"> A relative reduction occurred in all cause mortality of 19.7% in ICD group. A 33% reduction occurred in amiodarone group(this reduction did not reach statistical significance). •Result supports ICD is better than Amiodarone in the treatment of patients with MSVT or resuscitated cardiac arrest.
CASH /1987-1998 Cadiac Arrest Study Hamburg	<ul style="list-style-type: none"> •N = 288 • Resuscitated after cardiac arrest secondary to documented ventricular arrhythmia •ICD (n=99) vs amiodarone (n=92), metoprolol (n=97), & propafenone (n=58, propafenone discontinued 3/92) 	<ul style="list-style-type: none"> •Primary endpoint: Total mortality •Secondary endpoints: Recurrences of cardiac arrest requiring CPR *Recurrences of unstable Angina 	<ul style="list-style-type: none"> Preliminary results showed that propafenone treatment is less effective than ICD treatment. Therefore, this arm was suspended. The ICD group experienced a 24% relative reduction in mortality with amiodarone /metoprolol (p=0.081), non significant.

Table 2
Summary of ICD Trails for the Primary Prevention of SCD

Trail / Study period	Study Population N=Total	Study Group	Endpoint(s)	Key Finding(s)
CABG Patch /1990-1997 Coronary Artery Bypass Graft patch trail	<ul style="list-style-type: none"> • N= 900, age < 80 • EF $\leq$36% & • Abnormalities on – average signal ECG - Randomly assigned in OR after CABG • CABG+ ICD, n=446 CABG alone, n=454 	ICD vs conventional medical therapy	Total mortality	<ul style="list-style-type: none"> • The trail was prematurely terminated because mortality was equal in the CABG plus ICD(101 deaths) compare CABG alone 95 deaths; demonstrated no benefit of the prophylactic insertion of an ICD in patients with an ischemic burden and a depression EF undergoing appropriated coronary revascularization.
MADIT I 1990-1996 Multicenter Automatic Defibrillator Implantation Trail	<ul style="list-style-type: none"> • N=196, age 25-80 • Prior MI, - NYHA class I-III - CHF, LVEF $\leq$35% - NVST, VT 3 to 30 beats; -Inducible and non suppressible VT/ VF on EPS, not suppressed by IV procainamide) • 101 drug therapy (80 on Amiodarone) - 95 ICD 	ICD vs conventional therapy (Antiarrhythmia Drugs)	Total mortality Cost - effectiveness	<ul style="list-style-type: none"> • 39 (39%) deaths in antiarrhythmic group vs 15 (21%) ICD group Hazard ratio, 0.46; CI, 0.26-0.82; p = 0.009) Significant reduction in death from all causes in ICD group • ICD cost effective

Trail / Study Period	Study Population N= Total	Study Groups	Endpoint(s)	Key Finding(s)
MUSTT /1990-1998 Multicenter Unstained Defibrillator Implantation	<ul style="list-style-type: none"> •N=704 •More than 1 week post MI, -NYHA class I, II, III - EF$\leq$0.40 - Inducible VT on EPS. - NSVT >3 beats, 	EP guided antiarrhythmic or ICD therapy) vs No antiarrhythmic therapy	Cardiac arrest or death from arrhythmia	<ul style="list-style-type: none"> •Significant reduction in rate of cardiac arrest or death from arrhythmia with EP guided therapy; nearly all benefit attributable to ICD implantation
MADIT II / 1998 - 2002 Multicenter Automatic Defibrillator Implantation Trail	<ul style="list-style-type: none"> •N=1232 • Inclusion criteria : -With MI $\geq$ 1 month -EF$\leq$35%, -NYHA class I, II, or III •Exclusion criteria : -CABG or non CABG revascularization < 3 months prior to enrollment •ICD (n=742), •Drug Therapy (n=490). 	ICD vs Conventional medical therapy	Total Mortality	<ul style="list-style-type: none"> •Mortality - Conventional Medical therapy (n= 97,19.8 %) ICD group (n= 105, 14.2%) •Hazard ratio 0.69 (95% CI, 0.51-0.93). ICD decreased mortality by 34%

Trail / Study Period	Study Population N= total	Study Groups	Endpoint(s)	Key Finding(s)
DEFINITE/ 2000-2003 Defibrillator in Nonischemic Cardiomyopathy Treatment Evaluation	N = 458 •Symptomatic CHF+ nonischemic cardiomyopathy [EF≤35%] >10 PVCs/hr or NSVT •Optimal medical therapy, n =229. • Optimal therapy + ICD therapy, n=229.	ICD vs conventional medical therapy (Drug Therapy only)	•The Primary End Point: Total mortality •The Secondary end point : All kinds of death	• Death from any cause; in -ICD group(n=28), -Conventional medical therapy (n= 40) •Sudden death from arrhythmia in -ICD group (n=3), -Conventional medical therapy (n= 14) *Significant reduction in overall mortality in ICD group. ICD decreased mortality by 34%
COMPANION (01/2000-11/2002) Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure	1520 patients Heart failure patients (NYHA class III-IV) with EF ≤ 35%, QRS ≥ 120 ms, PR interval > 150 ms	Three patient groups (randomized 1:2:2) 1. Optimal Pharmacologic Therapy (OPT) 2. OPT + CRT-P 3. OPT + CRT-D	•Combination of all-cause mortality or first hospitalization n * as measured by time to first event	• A pacemaker with CRT capabilities (CRT-P), in combination with OPT, reduced the risk of all-cause mortality or first hospitalization* by 19% when compared with OPT alone. • A defibrillator with CRT capabilities (CRT-D), in combination with OPT, reduced the risk of all-cause mortality or first hospitalization* by 20% when compared with OPT alone. • CRT-D, in combination with OPT, reduced the risk of all-cause mortality by 36% when compared with OPT alone

Trail / Study Period	Study Population N= total	Study Groups	Endpoint(s)	Key Finding(s)
SCD – HeFT/ 1997-2003 The Sudden Cardiac Death Heart Failure Trail	N =2521 NYHA II-III, CHF, EF≤35% ICD and conventional therapy(n= 829), Amioderone and conventional therapy (n= 845). Placebo and conventional therapy (n=847)	ICD and conventional therapy (n= 829) vs Amioderone & conventional therapy (n=845) vs Placebo & conventional therapy(n=847)	Total Mortality	<ul style="list-style-type: none"> •Amiodarone has no favorable effect on survival. single lead. •Shock only ICD therapy reduces overall mortality by 23 %. <p>Conclusions: NIDCM treated with ACE inhibitors and beta-blockers, the implantation of a cardioverter–defibrillator significantly reduced the risk of SCD from arrhythmia and was associated with no significant reduction in the risk of death from any cause.</p>

Abbreviations:

CAD = coronary artery disease; CHF= congestive heart failure;

EPS = electrocardiophysiology Study; ICD = Implantable Cardioverter- Defibrillator;

EF (LVEF) = left ventricular ejection fraction; NYHA = New York Heart Association Functional Class;

NIDCM = nonischemic dilated cardiomyopathy;

NSVT = non sustained ventricular tachycardia; PVC= premature ventricular contraction;

SMVT= sustained monomorphic ventricular tachycardia; VT= ventricular tachycardia.

CRT- P = cardiac resynchronization therapy – pacemaker

CRT-D = cardiac resynchronization therapy – defibrillation

Appendix B

2002 Indications for Implantable Cardioverter - Defibrillator Therapy (ACC/AHA/NASPE) Practice Guidelines

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful / effective and in some cases may be harmful.

Class I indications per level of A, B or C

A. Data were derived from multiple randomized clinical trials involving a large number of subjects.

B. Data were derived from a limited number of trials involving comparatively small of patients from well designed data analysis data analysis of nonrandomized studies or observational data registries.

C. Consensus of expert opinions was the primary source or recommendation.

Class III indications are patients in whom ICD therapy is no appropriate.

CAD, coronary artery disease; EP, electrophysiology

Class I

1. Cardiac arrest due to VF or VT not due to a transient or reversible cause. (*Level A*)

2. Spontaneous sustained VT in association with structural heart disease. (*Level B*)

3. Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiologic study when drug therapy is ineffective, not tolerated, or not preferred. (*Level B*)

4. Nonsustained VT in patients with coronary disease, prior MI, LV dysfunction, and inducible VF or sustained VT at electrophysiologic study that is not suppressible by a Class I antiarrhythmic drug. (*Level A*)

5. Spontaneous sustained VT in patients without structural heart disease not amenable to other treatments. (*Level C*)

Class IIa

Patients with left ventricular ejection fraction of less than or equal to 30% at least 1 month post myocardial infarction and 3 months post coronary artery revascularization surgery. (*Level B*)

Class IIb

1. Cardiac arrest presumed to be due to VF when electrophysiologic testing is precluded by other medical conditions. (*Level C*)

2. Severe symptoms (e.g., syncope) attributable to ventricular tachyarrhythmias in patients awaiting cardiac transplantation. (*Level C*)

3. Familial or inherited conditions with a high risk for life-threatening ventricular tachyarrhythmias such as long-QT syndrome or hypertrophic cardiomyopathy. (*Level B*)

4. Nonsustained VT with coronary artery disease, prior MI, LV dysfunction, and inducible sustained VT or VF at electrophysiologic study. (*Level B*)
5. Recurrent syncope of undetermined origin in the presence of ventricular dysfunction and inducible ventricular arrhythmias at electrophysiologic study when other causes of syncope have been excluded. (*Level C*)
6. Syncope of unexplained origin or family history of unexplained sudden cardiac death in association with typical or atypical right bundle-branch block and ST segment elevations (Brugada syndrome). (*Level C*)

Class III

1. Syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease. (*Level C*)
2. Incessant VT or VF. (*Level C*)
3. VF or VT resulting from arrhythmias amenable to surgical or catheter ablation; for example, atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, right ventricular outflow tract VT, idiopathic left ventricular tachycardia, or fascicular VT. (*Level C*)
4. Ventricular tachyarrhythmias due to a transient or reversible disorder (e.g., AMI, electrolyte imbalance, drugs, or trauma) when correction of the disorder is considered feasible and likely to substantially reduce the risk of recurrent arrhythmia. (*Level B*)
5. Significant psychiatric illnesses that may be aggravated by device implantation or may preclude systematic follow-up. (*Level C*)
6. Terminal illnesses with projected life expectancy less than 6 months. (*Level C*)
7. Patients with coronary artery disease with LV dysfunction and prolonged QRS duration in the absence of spontaneous or inducible sustained or nonsustained VT who are undergoing coronary bypass surgery. (*Level B*)
8. NYHA Class IV drug-refractory congestive heart failure in patients who are not candidates for cardiac transplantation. (*Level C*)

From "ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: Summary article," by G. J. Gregoratos, J. Abrams, A. E. Epstein, , 2002, *Circulation*, 106, pp. 2145–2161.

Appendix C

Nursing Research Related to Care of ICD Recipients (Studies are presented in Chronological Order)

Author/Year	Purpose	Study Design	Subjects N= total	Major Findings/Suggestions R/T Education
Fridlund et al /2000	Patients with ICDs and their conceptions of their life situations	A 12-month descriptive longitudinal study was carried out during a period of 48 months. fibrillator Questionnaire	N = 46 ICD recipients	Overall uncertainty showed a decrease over time. A statistically significant difference was found within the domain "uncertainty" related to information, suggesting the need for more education in teaching skills for health care personnel.
Cowan et al /2001	To evaluate the effects of biofeedback training used in cardiovascular health education	Experimental study on bio-feedback training used in cardiovascular health education Follow-up = 2 years	N= 133 Experimental group (n=67) Usual care (n=66)	Psychosocial therapy significantly reduced risk of cardiovascular death in SCD survivals.
Flemme et al /2001	To describe changes in the life situation of patients with an ICD over a period of 1 year	Descriptive longitudinal study	N= 56 Consecutive ICD recipients	Regarding their overall life situations, patients expressed increased satisfaction as well as less uncertainty and fear. The research indicates that patients need more information about typical changes in patients' life situations after ICD implantation.

Author /Year	Purpose	Study Design	Subjects N= Total	Major Findings/Suggestions R/T Education
Carlsson et al /2002	To describe how well the ICD recipients cope with their situations when they have the support of a nurse, and contrast this data with that from a control group receiving conventional information given by physicians.	Experimental study questionnaire, interviews, and observations.	N=20 Experimental group- Support by nurse (n=10). Control group- Received conventional patient education by a physician (n = 10).	Sleep disturbances were the greatest problem in both the study group and the control group before ICD implantation. The control group showed need for more information regarding the function of the ICD device. By means of a questionnaire, interviews and observations, the study revealed great need for information, and therefore that planning ways to create this kind of education is important.
Albarran et al. /2004	To explore the nature of patients' partners' experiences from the pre-ICD implantation phase up until a maximum of 20 months at home.	Qualitative study based on a semi-structured schedule	Eight partners cohabiting with a recipient of an ICD	Four themes representing 11 categories conceptualized the partners' experiences, including: Acknowledging the patient's need for the device, reactions to the device, Feeling grateful, Waiting for the shock, Knowing what to do to safeguard the patient, and Returning to normality.

Author/ Year	Purpose	Study Design	Subjects N=Total	Major Findings/Suggestions R/T Education
Dougherty et al /2004a	<p>1) To describe the domains of concerns of intimate partners of sudden cardiac death (SCD) during the first year after ICD implantation;</p> <p>2) To outline the strategies used by partners of SCD survivors in dealing with the concerns and demands of recovery during the first year after ICD implantation.</p>	Secondary analysis of interview data collected for the primary study entitled, "Family Experiences following Sudden Cardiac Arrest"	N = 15 families who met the inclusion criteria (sudden cardiac death survival)	<p>Eight domains of concerns : <i>1) Care to ensure survival; 2) The partner's self-care; 3) The relationship; 4) The ICD;</i> 5) Money matters; 6) The future; 7) Health care providers and family, or, education & support sources; 1) Information on the function of the ICD; 2) Normal progression of physical and emotional recovery experiences; 3) Safety and maintenance of the ICD; 4) Activities of daily living with the ICD; 5) Strategies to assist with the partner's self-care.</p>
Dougherty et al /2004b	To evaluate the effects of a short-term intervention for the initial ICD recipients	Experimental. A structured telephone intervention delivered during the first 8 weeks after ICD therapy by expert cardiovascular nurses	N = 168 Individuals who had experienced a first SCA or life-threatening ventricular arrhythmia requiring ICD implantation	Decreased ICD related physical symptoms and anxiety, and increased SCA knowledge over 3 months.

Author/Year	Purpose	Study Design	Subjects N=Total	Major Findings/Suggestions R/T Education
Kamphuis et al /2004	To explore how ICD recipients perceive their lives during the first year after ICD implantation	Qualitative study. Semi- structured interview	N = 21 ICD recipients	Physiological deterioration, cognitive changes, perceived social support, dependency, <i>feelings regarding the possibility of receiving a shock, and confrontation with mortality.</i>
O' Brien et al /2004	Provide an update for clinicians on the effects of ICD storm* on patients and family members. * Storm = a series of two or more ICD shocks (appropriately or inappropriately triggered) in succession within a 24 – hour period.	Case report. Literature review and interviews with patients who have experienced ICD storm	N = 6 Low number (4 or less) of ICD storm shocks (n=3) High number (more than 4) of storm shocks(n=3)	1) Qualitative of life was negatively affected only in subjects who received more than 4 shocks. 2) Pain and fear are major concerns requiring psychological counseling. 3) There is a need for knowledge about the purpose of the ICD and self care methods effective in reducing the occurrence of ICD storms.
Tagney et al /2004	To explore nurses' confidence and competence in preparing patients for having an ICD implanted and for life at home.	Survey. A 28-point postal questionnaire to explore knowledge of the device and its impact.	N=152 nurses. A purposive sample from cardiology departments in 4 large teaching hospitals.	Knowledge of the ICD and its effects appeared poorly understood by all nurses. irrespective of additional qualifications, length of time since qualifying or area of work.

Appendix D

ICD INAPPROPRIATE SHOCK THERAPY STUDY DATA SHEET

Demographic and Clinical Characteristics

Patient Information

Subject Code

Age_____

Sex M___ F___

Diagnosis / Indication

SCD___ VF/VT ___ MUSTT/MADITII___ DCM___ NIDCM___ CHF_____

Other _____

History

Clinical History / Cardiac History before

Underlying Disease

a. Heart disease - i) Other structural heart disease ii) Non structure heart disease

b. Heart disease severity

i) Left ventricular ejection fraction

ii) NYHA Functional Classes

c. Other significant disease

Device Information

Manufacturer : Guidant(G) ___ Medtronic(M)___ St. Jude (S)___

Implantation date(s)

mode

model

Programmer

Shock Episode (s) History

Incidence of Shock

Appropriate shock _____

Inappropriate shock _____

Description(s) of Inappropriate Shock(s)

1. Energy of shock Joul

2. How was device programmed at the time of shock

3. Drug(s) (Medications) at the time of inappropriate shock

a. Anti Antiarrhythmic Therapy (AA medications)

b. Amiodarone

4. Symptoms during at the time of inappropriate shock

5. Factors of inappropriate shock

Termination of inappropriate shock

APPENDIX F

Approval Letter From the Committee of Human Research - University of California San Diego
Medical Center

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Dr. Ulrika Birgersdotter-G Mailcode: 8411

RE: Project #051123X
Incidence and Clinical Predictor of Risk Factors for Inappropriate Shock in
Patients With Implantable Cardioverter-Defibrillators (ICD)

Dear Dr. Birgersdotter-Green:

The above-referenced project was reviewed and approved on 9/1/2005 by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. The IRB determined that waiver of informed consent may be granted for this project as it meets the requirements outlined in 45 CFR 46.116(d). This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval. In addition, a waiver of individual authorization for use of Protected Health Information (PHI) was granted by the Institutional Review Board as stipulated by the HIPAA Privacy Rule, 45 CFR 164 section 512(I).

The Institutional Review Board determined that the proposed research satisfies following criteria:

1. The use or disclosure of PHI involves no more than minimal risk.
2. Granting of waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.
3. The project could not practicably be conducted without a waiver.
4. The project could not practicably be conducted without use of PHI.
5. The privacy risks are reasonable relative to the anticipated benefits of research.
6. An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal.
7. An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.
8. The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.

The PHI for which use has been determined to be necessary by the IRB includes:

1. Medical records of Implantable Cardioverter-Defibrillators (ICD) recipients who underwent follow-up examination at 3 month intervals from January 1, 2000 to May 31, 2005 at UCSD Medical Center.

This waiver was granted using expedited review procedures.

This study was reviewed by the IRB through expedited review procedure as authorized by 45 CFR 46.110 and 21 CFR 56.110 and falls under the following research category: (5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

/af
Mamie Gonzalez, Acting Director
Human Research Protections Program
Mailcode 0052 Phone: 858-455-5050
E-mail: hrpp@ucsd.edu

Note: All Human Subject research conducted at the VA facility and/or utilizing VA/VMRF funds MUST BE APPROVED by the VA Research and Development Committee prior to commencing any research. In addition, please ensure that the clinical trial agreement or other funding is appropriately in place prior to conducting any research activities. IRB approval does not constitute funding approval.

Approval release date: 9/15/2005