

Lawrence Kevin Woodrow, SHOCK 2010: ANALYSIS OF GLOBAL HEALTH INDICES AND QUALITY OF LIFE IN A WEB BASED NATIONAL ICD SAMPLE (Under the direction of Dr. Samuel F. Sears) Department of Psychology, April 2012.

The Implantable Cardioverter Defibrillator (ICD) has become the “gold standard” of care in reducing mortality in patients at risk for sudden cardiac death (SCD). However, there remain concerns about the psychosocial impact of the ICD on patients and particularly the effects of high-energy shocks. The present study examines the results of a survey that queried ICD patients on global health and quality of life indices. The primary aim of this study was to provide descriptive data on a large national sample of ICD patients on global measures of general health, quality of life (QOL), emotional health, family relationships, sense of security, disruptiveness of ICD shock, and shock anxiety. Analyses were also performed to assess the between-group differences for shock, sex and age. Key findings are that the great majority of ICD patients report good overall QOL. The majority of patients also report that their ICD has contributed positively to their overall QOL. There was also support for the view that shocks are strongly associated with ICD-specific shock anxiety levels with greater shocks associated with significantly higher levels of anxiety, $F(3, 439) = 43.25, p < .0005$. Information from this analysis may be used to provide clear, understandable, and relevant information to current and prospective ICD patients, as well as to clinicians and caregivers concerning the patient experience of living with an ICD.

Shock 2010: Analysis of Global Health Indices and Quality of Life in a Web Based
National ICD Sample

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CHAPTER I: INTRODUCTION

The implantable cardioverter defibrillator (ICD) has demonstrated a mortality advantage compared to treatment with medications for preventing sudden cardiac arrest in patients at risk. While research has shown that ICDs reduce mortality, research examining patient perspectives on quality of life have suggested that living with the potential of arrhythmias and ICD shocks can be problematic concerning QOL outcomes. The present study examined results from a survey that queried a large, national population of ICD patients on global health and quality of life indices. The information gathered from this survey may be used by clinicians to provide guidance and advice to prospective and current ICD recipients. It can also be used to develop psychoeducational literature so that persons indicated for an ICD may make informed decisions concerning whether an ICD is their best option. A more complete set of information for patients is especially important as they may be experiencing the stress of poor health and fear of death that may reduce their capacity to fully consider therapy options. For those who already have an ICD, this information will provide some normative information about health outcomes to serve as a comparison or benchmark to their own outcomes post-implantation.

The primary aim of this study is to provide descriptive data on a large national sample of ICD patients on measures of general health, QOL, emotional health, family relationships, sense of security, disruptiveness of ICD shock, and shock anxiety. The secondary aim is to examine potential between-group differences on these same measures for shock, sex, and age.

CHAPTER 2: LITERATURE REVIEW

Sudden Cardiac Arrest

Sudden Cardiac Arrest (SCA) is a condition in which the heart unexpectedly stops beating and is a consequence of a malfunction in the heart's electrical system that results from arrhythmias. If the arrhythmia continues without interruption, then sudden cardiac death (SCD) may ensue (National Heart, Lung, and Blood Institute, 2009). SCA as a result of arrhythmia occurs in between 184,000 to 462,000 Americans annually (Goldberger et al., 2008) depending on criteria and death certificate specifications.

Preventive treatment for SCA is often problematic because there may be either no prior symptoms or symptoms which are so mild they may be ignored. Initial symptoms may include tachycardia, bradycardia or irregular heartbeats. Prolonged arrhythmias may result in more serious symptoms of anxiety, fatigue, dizziness, lightheadedness, fainting, sweating, shortness of breath, heart pain and SCA (National Heart, Lung, and Blood Institute, 2009). Research has shown that ventricular tachycardia (VT) and ventricular fibrillation (VF) are the most common proximate causes of SCA (Goldberger et al., 2008). One of the most important risk factors for SCA is low (< 35) left ventricular ejection fraction (LVEF) which is the fraction of blood pumped out of the left ventricle with each contraction. Determining risk factors allows for early treatment of those at risk for SCA prior to an episode of SCA.

Implantable Cardioverter Defibrillator

The premier treatment for ventricular arrhythmias based on clinical trial data is implantation of an ICD. An ICD is a device that recognizes dangerous arrhythmias and delivers a shock to bring the heart back into normal rhythm. The ICD also records the

heart's electrical activity and gives information that may be used by medical personnel to set the device to work optimally. It was developed in the 1960s with first human implantation in 1980 (Mirkowski, 1985) and has become the premier treatment for patients with potentially life-threatening cardiac arrhythmias. The first ICDs were relatively large and required an invasive trans-thoracic surgery to implant abdominally. As a result of extensive research, modifications to ICDs have made them much smaller and they are normally implanted in the subclavian region with transvenous lead systems.

There are three different kinds of ICDs that provide protection against SCA (Bryg, 2009). In a single chamber ICD, a lead is attached to the right ventricle that allows for a simple "shock box" circuit to rescue a patient detected as having a potentially life threatening arrhythmia. These are indicated in patients who have no other cardiac conduction disease and are usually used for primary prevention of SCA. In a dual chamber ICD, leads are attached to both the right atrium and right ventricle. This two lead system allows for monitoring and discrimination between atrial and ventricular rhythms. The dual chamber system allows for potentially greater precision of determining which heart rhythms are dangerous. A shock is delivered to the heart if a ventricular arrhythmia is detected and confirmed. In a biventricular ICD, leads are attached to the right atrium, the right ventricle and the left ventricle. This type of ICD-lead configuration allows for a synchronization of the contractions of the left and right ventricle to potentially improve cardiac output and allow for cardiac reverse remodeling.

An ICD monitors heart rhythm at all times. When it identifies an abnormal rhythm, it attempts to disrupt the ongoing heart rhythm using electrical therapies such

as pacing and shock. In bradycardia pacing, small electrical impulses are initiated to increase the heartbeat when it is beating too slowly. In anti-tachycardia pacing, a series of small electrical impulses are delivered to restore normal rhythm to a heart that is beating too fast. In cardioversion, a low energy shock is delivered to correct fast or irregular heartbeats. Finally, in defibrillation, high-energy shocks are delivered to restore normal rhythm when the heart is beating dangerously fast. The ICD is designed to use tiered therapies with the least intense first.

The defibrillating shocks administered by an ICD may be painful and common descriptions patients give for a shock include: "putting their finger in a light socket;" "an earthquake;" "a knife in the heart;" "being hit by a truck;" "being hit with a baseball bat;" and "being kicked by a mule" (Ahmad, Bloomstein, Roelke, Bernstein, & Parsonnet, 2000). On occasion, unnecessary or inappropriate shocks may be delivered when non-dangerous arrhythmias occur but are misinterpreted by the ICD. In fact, up to 25% of all patients receive inappropriate shocks (Tung, Zimetbaum, & Josephson, 2008). Manufacturers continue to improve ICDs to be more adept at distinguishing between life threatening and non-life threatening arrhythmias. Nonetheless, the effects of high-energy, defibrillating shocks whether appropriate or inappropriate, remain a challenge for patients and providers.

Psychosocial Issues Related to Living with an ICD

While the ICD is the premier treatment for patients with potentially life-threatening cardiac arrhythmias, a continual concern is that no less than 20% of ICD patients experience diagnostic levels of psychological distress (Magyar-Russell et al., 2011). The delivery of high-energy ICD shocks has been associated with reduced scores on

mental and emotional scales health related quality of life (HRQL) as measured by version 1 of the 12-Item Medical Outcomes Study Short-Form Health Survey (SF-12) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Passman et al., 2007). Other studies have indicated similar reductions in QOL (Irvine et al., 2002; Lüderitz, Jung, Deister, Marneros, & Manz, 1993) with the most notable increases in distress in cases in which five or more shocks have been received.

Recently, the direct link between shock and psychosocial distress has been questioned. Pedersen, Van den Broek, Berg, and Theuns (2010) propose that the progression and severity of patient's heart failure, as well as their psychological profile, have a larger impact on patient outcomes than ICD shock. They highlight perceived, inconsistent findings in seven large primary or secondary prevention trials concerning the association between ICD shocks and quality of life in support of their position. In an accompanying editorial, Sears and Kirian (2010) suggested that the inconsistency of findings might be partially attributed to differences in the timing of post-shock assessment by patients. They note that the further removed the assessment is from the time of the shock, the less the measured effect may be. They emphasize that patient report of the effect of shock in clinical settings is undeniable. They also suggest that another plausible explanation for seemingly inconsistent findings on the effect of shock on patient outcome may also be attributed to the various "generic" tools used to measure QOL in the different studies. Sears and Kirian also draw attention to the large number of studies that support the view that shock is a critical event and argue the effect of shock remains important.

The debate between these researchers highlight the importance of better understanding patient assessment of the role of their ICD, as well as the effect of ICD shock on psychosocial outcomes such as QOL. While the exact effect of shock may be debated by some, studies indicate many ICD patients experience a wide array of concerns that affect QOL and three of the most notable are device acceptance, anxiety, and depression.

Device Acceptance

Device acceptance may be understood as the ability to understand and psychologically accommodate the benefits and drawbacks of an ICD (Burns, Serber, Keim, & Sears, 2005). While the ICD has improved and become smaller and more reliable, studies continue to show that as many as 24% of patients have difficulty adjusting to living with this technology (Ladwig, Disenhofer, Simon, Schimitt & Baumert, 2005). Among the device specific concerns patients endorse are reliance and acceptance of living with technology (Burns et al., 2004), coping with ICD shock storms (Kuijpers, Honig, & Wellens, 2002; Sears & Conti, 2006), dealing with recall (Cucili, Herzig & Kobza, & Erne, 2006; Stutts et al., 2007), body image (Sowell, Kuhl, Sears, Klodell, & Conti, 2006), and sexual function (Steinke, Gill-Hopell, Valdez, & Wooster, 2005; Vazquez, Sears, Shea, & Vazquez, 2010). The concept of ICD acceptance has grown in importance because brief psychosocial interventions, while not likely to ameliorate more general personality or psychopathological conditions, may be efficacious in facilitating adjustment to the ICD specifically. More precise conceptualization and measurement of device specific adjustment may be a more sensitive and specific construct to evaluate.

Anxiety

Anxiety disorders occur in 13-38% of ICD patients (Bilge et al., 2006; Hegal, Griegel, Black & Goulden, 1997; Sears, Todaro, Lewis, Sotile, & Conti, 1999) with general or ICD-specific anxiety experienced by 24-87% of patients post-implantation (Sears, Matchett, & Conti, 2009). The exact nature of this anxiety can take the forms of various anxiety disorders (e.g. Generalized Anxiety Disorder, Panic Disorder) but recent attention has increasingly focused on post-traumatic stress disorder (PTSD) (Sears, Hauf, Kirian, Hazelton, & Conti, 2011). PTSD appears to develop in approximately 20% of ICD patients as a consequence of the threat of death due to heart failure combined with exposure to powerful electrical shock (Ladwig et al., 2008). Moreover, Ladwig et al. found that ICD patients diagnosed with PTSD had a 77.5% greater chance of dying before patients without PTSD at five year follow-up.

Other recent work has focused on the measurement of ICD specific shock anxiety. Shock anxiety is defined as “the fear or anticipation of an ICD shock that often results in increased heart-focused anxiety symptoms as well as the development and maintenance of avoidance behaviors to minimize patients’ perceived risk of shock” (Kuhl, Dixit, Walker, Conti, & Sears, 2006). This increasingly disease specific approach to shock anxiety allows for a targeted assessment and intervention to the unique contributions of the ICD and shock to the patient experience versus acute general anxiety approaches.

One consequence of ICD shock may be the development of avoidance behaviors among patients. This development may be understood initially in terms of classical conditioning where the unconditioned stimulus of an aversive shock is paired with a

previously neutral stimulus (e.g. any behavior, or activity in which the patient was engaged in at time of shock) (Sears & Conti, 2003). As the patient develops an association between the shock and behavior/activity, he/she may become anxious when engaging in it or decide to abandon it all together. Unfortunately, if the patient remains shock-free following this change in behavior, then he/she may attribute this desired outcome to their change in behavior, thus reinforcing it. In this way the model moves from a classical one for conditioning to an operant model for sustaining such choices. Avoidance of people, places, and activities have been found in approximately 55% of ICD patients (Lemon, Edelman, & Kirkness, 2004).

Maladaptive thought processes have also been noted in ICD patients. Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, and Kühlkamp (1999) found that ICD patients who had “catastrophic cognitions” regardless of whether they had been shocked or not were more likely to interpret physical symptoms negatively and to experience concern that their lives were at risk. ICD patients also may develop a “sickness scoreboard” mentality that interprets their health in terms of a scoreboard where received shocks indicate worsening health and a more perilous condition (Sears et al., 1999). They may also experience death anxiety as they either have survived a near-death experience due to heart problems or are at risk for such an event. Receiving a recommendation for and ultimately receiving an ICD may be interpreted as a sign of their own mortality and can lead to catastrophic thinking (Matchett, Kirian, Hazelton, Brumfield & Sears, 2008).

Depression

Depression is also a common experience among ICD patients and rates of depressive symptoms are equivalent to cardiac patients in general and range between 18-41% (Bilge et al. 2006; Sears et al., 2000; Sears & Conti, 2003; Whang et al., 2005). The severity of depression has been associated with the number of shocks received and has also been found to be a predictor for increased shocks (Goodman & Hess, 1999; Whang et al., 2005). ICD shock can lead to “learned helplessness” in patients arising from their lack of control over receiving a shock thus leading to poor coping (Goodman & Hess, 1999; Sears et al., 1999). Pedersen, van Domburg, Theuns, Jordaen, and Erdman (2004) have suggested that personality factors such as Type D (distressed) may partially explain rates of depression, as it is a primary risk factor for poor psychosocial outcomes in ICD patients. Type D personality consists of high negative affectivity (e.g., worry, irritability, gloom) combined with social inhibition including a tendency to not share emotions and is a personality style associated with higher rates of depression (Denollet, 2005). Physiologically, Type D thinking is also associated with higher cortisol levels which are an indicator of chronic stress (Pedersen & Denollet, 2006).

Risk Factors for Psychosocial Adjustment Difficulties in ICD Recipients

Several ICD-specific risk factors have been associated with problematic psychological outcomes. One risk factor is young age (< 50) (Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008; Sears et al., 1999; Vazquez et al., 2008). Sears et al. suggest that younger recipients experience more distress because a heart condition is more surprising and unexpected because of their relative youth. In addition,

it is perceived to be more disruptive to “normal” living, as evidenced by young patient’s concerns about how the ICD may affect clothing fit, ability to socialize, and sexual activity (Dubin, Batsford, Lewis, & Rosenfeld, 1996). Female gender is another risk factor with gender specific concerns about body image after implantation (Vazquez et al., 2008), higher sensitivity to bodily sensations (Versteeg et al., 2010), and child bearing (Natale, Davidson, Geiger, & Newby, 1997). Patients who experience a high number of shocks have also been shown to be at greater risk for adjustment difficulties such as anxiety and/or depression (Irvine et al., 2002; Passman et al., 2007; Redhead, Turkington, Rao, Tynan, & Bourke, 2010; Sears et al., 1999). There are other general heart disease risk factors that are factors in ICD patients, such as significant history of psychological problems, poor social support, and increased medical severity of patient condition (Sears et al., 1999). Pedersen and Denollet (2006) found that patients with elevated scores on negative affectivity and social inhibition (i.e., Type D personality) have increased morbidity and mortality.

Survey Methodology

The Shock 2010 survey queried a nationwide sample of ICD patients on global health and quality of life indices. This survey was designed to measure health by using single item questioning on several key indices. Sloan, Aaronson, Cappelleri, Fairclough, and Varricchio (2002) detailed several advantages for the use of single item compared to summated scores in measuring quality of life. A single item index is useful for its ease in administration and for measuring items that are unambiguous. Single items are also useful for describing quality of life at a particular point in time. However, they note that reliability is better with multi-items tests because there are more questions about

the underlying concept. Common questionnaires that use single item questions to measure QOL include the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLC-C30) which asks, "How would you rate your overall quality of life during the past week?" with responses ranging from very poor to excellent. The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) asks, "In general, would you say your health is excellent, very good, good, fair, or poor"? (Sloan et al., 2002). Similar question formats were employed in this study.

Concerning, the value of self-assessed health instruments, Idler and Benyamini (1997) noted several advantages including simplicity, directness, and the ability to obtain patient's perceptions of health using broad criteria. They reviewed 27 studies using self-ratings of health and determined that "... self-ratings represent a source of very valuable data on health status" and that "... global rating represents an irreplaceable dimension of health status and in fact, that an individual's health status cannot be assessed without it." (p. 34)

Two advantages of using single-item indices questioning are that it allows for limited survey length and increased ease of administration, important factors for a voluntary, email-distributed survey that relies completely on voluntary participation. Answers to these questions reveal valuable patient opinions on their experience of living with an ICD although there is a potential consequence of decreased validity and reliability.

Issues Related to Web-based Surveys

Modern communication strategies allow for the use of new methods of data collection that have assets and liabilities. Advantages of web-based surveys include

cost savings, speed in obtaining results, and reduction in human error concerning data entry (Menachemi, 2011). Menachemi also cites limitations that include the possibility that computer users may not be representative of the population of interest, incorrect email accounts, and that web-based surveys may have lower response rates than paper surveys. They also note there may be a problem in estimating response bias.

Couper (2000) discussed four major sources of error in electronic surveys. They view coverage error as the biggest threat to drawing inference from Web surveys. Coverage error occurs when there is a mismatch between the target and frame population. The target population is the group to which inference is going to be made, while the frame population is the subset of that population that is accessible for surveying (e.g. people who have Medtronic ICDs and who have provided Medtronic with email addresses). Coverage error in the case of this study refers to the fact that not everyone is able to be surveyed because they do not have web access or an email address or a Medtronic ICD. Sampling error may occur when the results gathered from the frame population do not match the results that would be obtained if the entire frame population were surveyed. On subsequent surveys, new frame populations may produce different results. Non-response error is a third problem that occurs as a result of people not being willing or able to complete the survey. Possible explanations for non-response rates with email surveys may be technical difficulties and confidentiality concerns. Measurement error is a fourth problem and is the deviation of respondent answers from their true values on the measure. Examples of respondent factors to measurement error include such things as lack of motivation, lack of comprehension, and haste in responding. Examples of instrument factors include poor wording, design

flaws, and technical flaws.

In the current study, the target population is all ICD recipients, while the frame population is people who were listed on the Medtronic ICD recipient database and who are literate and capable of completing an electronic survey. There is no apparent reason to believe that Medtronic patients are different in any systematic way than the patients of other ICD makers. Regardless of brand, all patients face similar challenges in adapting to living with an ICD. The use of a web-based survey in the current study made it possible to reach a broad, national sample of ICD patients that could not have been reasonably reached otherwise. While there are limitations in conducting a web-based survey, there remains good evidence that results will reveal valid, reliable data that will help better understand patient experience in living with an ICD (Coderre, St. Laurent, & Mathieu, 2004).

Exploratory Items in the Shock 2010 Survey

The specific concept of “security” as it relates to the ICD patient experience appears to have received limited focus in ICD studies although researchers have noted that sense of security is “likely” one of two main purposes of an ICD from the patient perspective (Sears, Matchett, & Conti, 2009). Bolse, Hamilton, Flanagan, Carroll, and Fridlund (2005) conducted semi-structured and open-ended interviews with a small population ($n = 14$) of patients with the goal of identifying and describing patient experience of having an ICD. They concluded that patients experience a sense of security due to the ICD and that the sense of security increases over time. In another small study ($n = 15$) by Goldstein et al. (2008), researchers led focus groups of ICD patients in discussions on whether patients would choose to deactivate their ICD as

their health changed. Over the course of these discussions, it became apparent that patients had developed a “complex psychological relationship with their ICD unlike other interventions” and that it provided them with a sense of security like “an insurance policy” or “a trusted friend” (p. 11). Ricci et al. (2010) surveyed patient acceptance and satisfaction with remote control systems of implantable devices. Ninety-two percent of patients ($n = 119$) reported that their device provided them with a sense of security. However, only a small number ($n = 24$) of the total study population had ICDs, while the remainder had pacemakers. Thus, while some research has investigated the concept of security in ICD populations, Shock 2010 may provide the largest population surveyed to date on this specific topic. The increased focus on security represents an effort to examine positive psychological factors for the ICD patient that go beyond the examination of psychopathology.

An alternative single item construct of interest with similar implications is the construct of “sense of lifestyle disruption.” In the current study, patients were queried about the sense of disruption that ICD shock entails. This is a novel item for which there does not appear to be any previous discussion in ICD literature. Sense of disruption as it is related to shock represents a non-life threatening consequence of an ICD but a potentially important construct for daily living with an ICD. Ideally, medical treatments could provide security without disruption.

The Common Sense Model of Illness Representation

As the evidence above shows, ICD patients may experience psychosocial distress that affects patients both emotionally and behaviorally. The Common Sense Model of Illness Representation as described by Diefenbach and Leventhal (1996)

postulates that people mentally appraise the meaning of somatic stimuli based on such aspects as location, duration, and severity. Interpretations of stimuli are influenced by such things as past medical history, knowledge of illness, and societal expectations. This appraisal forms a representation of the illness that may affect their emotional state that, in turn, may influence an action or coping procedure they take to respond to their symptoms.

The Common Sense Model views the individual as an active problem solver dealing with a perceived health threat and their emotional reactions to this threat. The model maintains that illness is represented by five distinct attributes that form an illness representation. *Identity* is the disease label that the individual assigns to their symptoms or condition. *Timeline* is the belief about the expected duration of the disease; its chronicity or acuteness. The *causal* attribute refers to the perceived cause of the condition (e.g., if abdominal pain occurs after a heavy meal it may be attributed to overeating while if it is reoccurring pain it may be attributed to an ulcer). *Controllability* refers to the degree to which the individual believes the condition can be cured or managed and the measure to which he can influence it. Finally, *consequences* are the beliefs about how their condition will affect them in such ways as economic hardship, emotional upheaval, or lifestyle.

Hagger and Orbell (2003) conducted a meta-analytic review of 45 empirical studies that were based on the Common Sense Model and found that the attributes of illness identity, timeline and consequences were negatively associated with psychological well-being (e.g., the more negatively perceived the illness identity, the worse the psychological well-being). Perceived controllability was significantly

associated with problem-focused coping and cognitive reappraisal. Perceived controllability was also positively related to adaptive outcomes such as psychological well-being while negatively related to psychological distress. Their findings support the model's hypothesis that the way in which individuals perceive their illness, its timeline, their control and the consequences of the disease, is associated with psychological outcomes.

Information from Shock 2010 will provide normative information about health outcomes that may influence patient concepts concerning the consequence attribute of the Common Sense Model. By learning about the experiences and opinions of other ICD recipients they may formulate their personal expectations concerning living with an ICD. The knowledge gained from these results may educate and influence healthcare providers concerning the unique experiences of ICD patients and provide guidance on information that should be disseminated to their patients to increase the likelihood of favorable outcomes (i.e. consequences). For example, the shock experience may be explained as a possibly distressing event while helping patients plan for (thus increasing controllability) and understand (thus informing identity) the potential consequences of such an experience. Hopefully, this knowledge will enable them to form a more accurate understanding of their condition and better outcomes.

Summary, Aims and Hypotheses

The ICD has become the premier device in reducing mortality in patients at risk for SCD. However, psychosocial issues in ICD patients remain a concern with prior research indicating increased levels of anxiety and depression, as well as concerns with device acceptance. While previous research has indicated that increasing number of

shocks (> 5) are associated with problematic patient outcomes, that notion has recently been questioned by some who suggest that personality type is the issue of concern rather than number of shocks (Pedersen et al., 2010). The present study examined the results of an email survey that queried patients on global health and quality of life indices in a national population of ICD patients.

Specific aim #1: Provide descriptive data on a large national sample of ICD patients on measures of general health, quality of life (QOL), emotional health, family relationships, sense of security, sense of lifestyle disruption as a result of shock, and shock anxiety.

Specific aim #2: Examine potential between-group differences on measures of general health, quality of life (QOL), emotional health, family relationships, sense of security, and shock anxiety for four different levels of shock frequency.

Hypothesis #2: There will be between-group differences with patients with higher number of shocks reporting lower ratings on measures of general health, quality of life (QOL), emotional health, family relationships, and sense of security. They will also report higher levels of shock anxiety.

Specific Aim #3: Examine potential between-group differences on measures of general health, quality of life (QOL), emotional health, family relationships, sense of security, and shock anxiety for gender.

Hypothesis #3: There will be between-group differences with females reporting lower ratings on measures of general health, quality of life (QOL), emotional health, family relationships, and sense of security. They will also report higher levels of shock anxiety.

Specific Aim #4: Examine potential between-group differences on measures of general health, quality of life (QOL), emotional health, family relationships, sense of security, and shock anxiety for three levels of age (under 50, 50-64, 65 and older).

Hypothesis #4: There will be between-group differences with the under 50 group reporting lower ratings on measures of general health, quality of life (QOL), emotional health, family relationships, and sense of security. They will also report higher levels of shock anxiety.

Chapter III: Method

Participants

This study was conducted with a sample of 443 people with an ICD who responded to an email notification. Five-thousand people listed on a nationwide Medtronic electronic database were sent an email invitation to participate in the survey and of those emails, 563 were opened. Four-hundred and forty-three participants granted consent and completed the surveys for a participation rate of 78.7% of opened emails and 8.9% of all possible sent emails. The only minimum requirement was that the participant must be an ICD recipient. This study received IRB approval from East Carolina University (ECU). None of the participants were compensated for their participation.

Demographic Data and Shock History

Of the total of 443 ICD patients who completed the survey, 81% of the study sample ($n = 359$) were male and 19% ($n = 84$) were female. Ninety-five percent ($n = 421$) of the study sample were White, 1.8% ($n = 8$) were Black/African-American/Caribbean-American, 1.1% ($n = 5$) were Asian, .9% ($n = 4$) were Hispanic/Latino, .7% ($n = 3$) listed "other" for their race, and .5% ($n = 2$) selected "don't know/refused".

The age distribution of participants was 5.6% ($n = 25$) under age 50, 26.2% ($n = 116$) between age 50-64, and 68.2% ($n = 302$) were 65 or older. Concerning highest attained level of education, 2.7% ($n = 12$) had some high school, 12.2% ($n = 54$) were high school graduates, 5.9% ($n = 26$) had attended technical school, 23.9% ($n = 106$) had some college, 30.5% ($n = 135$) were college graduates, and 24.8% ($n = 110$) had

attended graduate school. The income level of participants is displayed in Table 1.

Table 1.

Yearly Household Income of Participants

Income Level	<i>n</i>	Percentage
\$0 to \$9,999	1	.2
\$10,000 to \$19,999	13	2.9
\$20,000 to \$29,999	36	8.1
\$30,000 to \$39,999	40	9.0
\$30,000 to \$49,999	41	9.3
\$50,000 to \$74,999	93	21.0
\$75,000 to \$99,999	55	12.4
\$100,000 to \$149,999	66	14.9
\$150,000 and above	43	9.7
Missing/Don't know/refused	55	12.4
Total	443	100.0

Of the total population, 50.3% ($n = 223$) had never been shocked, 30.5% ($n = 135$) had been shocked 1-4 times, 8.8% ($n = 39$) had been shocked 5-10 times, and 10.4% ($n = 46$) had been shocked more than 10 times. Just over half (50.1%, $n = 180$) of the male participants and 47.6% ($n = 40$) of the female participants had been shocked.

Procedure

The survey sample was drawn from a Medtronic database of ICD recipients who had indicated prior willingness to be contacted for research purposes. The sample was

notified via email of the opportunity to participate in a survey and needed to click on a link embedded in the email to begin the survey process. There were no exclusion criteria. Informed consent was obtained before the survey was made electronically available to the participant. As part of the consent process, potential participants were informed that the purpose of the study was to examine patient attitudes, beliefs, and experiences with their ICD, including ICD shock. Following informed consent, patients were asked to complete the survey. At the end of the survey, patients had the opportunity to list any feelings or comments related to ICD therapy that had not been asked. No compensation was provided to any of the participants.

Measures

Participants completed a 42-question survey (See Appendix B) that used both standardized and exploratory non-standardized measures to assess the experience of patients living with an ICD. Questions of interest in this study were those concerning standard demographics, number of shocks received and questions designed to ascertain overall quality of life and ICD-specific anxiety. Patients rated the following items on a scale that offered from three to seven response choices depending on the question: "Today, how would you describe your general health?"; "Overall, how much has the ICD affected your general health? Is your general health now..."; "Today, how would you describe your quality of life?"; "Overall, how much has the ICD affected your quality of life? Your quality of life is now..."; "Today, how would you describe your general emotional health?"; "Overall, how much has the ICD affected your emotional well-being? Is your emotional well-being now..."; "Overall, how much has the ICD affected your relationship with your family? Is your relationship now..."; "How would you

rate your sense of security with your overall health on a scale of 1 to 7, where 7 means 'very secure' and 1 means 'not at all secure?'; "Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?"; and "How disruptive was the overall shock event to your life." The question items not reported here are reported in another study.

The *Florida Shock Anxiety Scale* (FSAS) was used to measure ICD-specific anxiety and had been previously validated (Kuhl, Dixit, Walker, Conti, & Sears, 2006). Examples of questions from the FSAS include, "I am afraid of being alone when the ICD fires and I will need help", "It bothers me that I do not know when the ICD will fire", and "I worry about the ICD firing and creating a scene." The diverse items on the scale form a single construct termed "shock anxiety" (Ford et al., 2011). The FSAS total score correlates well ($r = -0.65$, $p < 0.01$) with the Multidimensional Fear of Death Scale (MF-DOS) total score (Kuhl et al., 2006). Lower scores on the MF-DOS indicate greater fear of death while higher scores on the FSAS indicate higher anxiety levels.

Statistical Analysis

The number of responses to each possible answer for every question of interest along with the percentage of participants who selected that response was determined to meet the first primary aim. The second through fourth primary aims was answered by conducting analysis of variance to explore the impact of each independent variable (age, gender, number of shocks) on ratings of measures of general health, quality of life (QOL), emotional health, family relationships, sense of security and shock anxiety.

The Tukey HSD post hoc test was employed to reduce Type I errors and no Bonferonni adjustment to the alpha level was made. It was deemed inappropriate to

use the Bonferonni adjustment for three primary reasons. One, there were *a priori* hypotheses that there would be between-group differences on the variables under study. Secondly, use of Bonferonni adjustment would increase the possibility of a Type II error. Thirdly, for comparisons that have statistically significant differences, effect sizes were computed to determine the proportion of variance explained by the independent variable. Calculation of effect size was included in analyses so that significant differences were interpreted in context.

CHAPTER IV: RESULTS

Descriptive Data

Descriptive data from the sample on measures of general health, quality of life (QOL), emotional health, family relationships, sense of security, sense of lifestyle disruption as a result of shock, and shock anxiety are reported below.

General Health

A majority (72.2%) of the sample reported their general health as at least "good" (see Table 2). Of particular note is that 59.9% ($n = 262$) believed that their ICD had improved their general health and, in fact, 34.3% ($n = 152$) believed that their general health was "much better" (see Table 3). Only 3% ($n = 13$) believed that their ICD had worsened their general health.

Table 2.

Today, how would you describe your general health?

	<i>n</i>	Percent
Excellent	34	7.7
Very good	114	25.7
Good	172	38.8
Fair	103	23.3
Poor	20	4.5
Total	443	100.0

Table 3.

Overall, how much has the ICD affected your general health? Is your general health now...?

	<i>n</i>	Percent
Much better	152	34.3
Somewhat better	111	25.1
About the same	167	37.7
Somewhat worse	10	2.3
Much worse	3	.7
Total	443	100.0

Quality of Life

A large majority (87.5%, *n* = 388) of the sample reported their QOL as at least “good” (see Table 4). Of particular note is that 59.4% (*n* = 263) believed that their ICD had improved their QOL and, in fact, 31.2% (*n* = 138) believed that their QOL was “much better” (see Table 5). Only 4.3% (*n* = 19) believed that their ICD had worsened their QOL.

Table 4.

Today, how would you describe your quality of life?

	<i>n</i>	Percent
Excellent	90	20.3
Very good	157	35.4
Good	141	31.8
Fair	49	11.1

Poor	6	1.4
Total	443	100.0

Table 5.

Overall, how much has the ICD affected your quality of life? Is your quality of life now...?

	<i>n</i>	Percent
Much better	138	31.2
Somewhat better	125	28.2
About the same	161	36.3
Somewhat worse	14	3.2
Much worse	5	1.1
Total	443	100.0

General Emotional Health

A majority (87.8%, $n = 389$) of the sample reported their general emotional health as at least “good” (see Table 6). Their ICD had positively affected the emotional well-being of 54% ($n = 239$) of the sample with 28% ($n = 124$) reporting that their emotional well-being was now “much better” (see Table 7). However, 6.1% ($n = 27$) believed that their ICD had worsened their emotional well-being.

Table 6.

Today, how would you describe your general emotional health?

	<i>n</i>	Percent
Excellent	114	25.7

Very good	161	36.3
Good	114	25.7
Fair	47	10.6
Poor	7	1.6
Total	443	100.0

Table 7.

Overall, how much has the ICD affected your emotional well-being? Is your emotional well-being now...?

	<i>n</i>	Percent
Much better	124	28.0
Somewhat better	115	26.0
About the same	177	40.0
Somewhat worse	22	5.0
Much worse	5	1.1
Total	443	100.0

Family Relationships

For the majority (67.5%, $n = 299$) of participants, their ICD had negligible effect on family relationships although for 30.0% ($n = 133$) the ICD had in some measure positively affected their relationship with their family (see Table 8). Only 2.5% ($n = 11$) indicated that their ICD had worsened their family relationships.

Table 8.

Overall, how much has the ICD affected your relationship with your family? Is your relationship now...?

	<i>n</i>	Percent
Much better	73	16.5
Somewhat better	60	13.5
About the same	299	67.5
Somewhat worse	10	2.3
Much worse	1	.2
Total	443	100.0

Sense of Security

A majority (88.7%, *n* = 393) of the sample reported their sense of security with their overall health was at least a “4” on a scale of 1 to 7 and 49.2% (*n* = 218) reported their sense of security as either a “6” or a “7” (see Table 9). A majority (73.4%, *n* = 325) reported that they felt more secure since receiving their ICD, while 5.2% (*n* = 23) felt less secure (see Table 10).

Table 9.

How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means “very secure” and 1 means “not at all secure”?

	<i>n</i>	Percent
1 – Not at all Secure	11	2.5
2	14	3.2
3	25	5.6

4	66	14.9
5	109	24.6
6	118	26.6
7 – Very Secure	100	22.6
Total	443	100.0

Table 10.

Since you've received your device, would you say you feel more secure, less secure, or the same about your overall health?

	<i>n</i>	Percent
More secure	325	73.4
The same	95	21.4
Less secure	23	5.2
Total	443	100.0

Lifestyle Disruption

Only 9.5% (*n* = 21) of shocked participants reported that their shock event was not at all disruptive while 90.5% (*n* = 199) found it at least somewhat disruptive (see Table 11).

Table 11.

How disruptive was the overall shock event to your life? Please rate the disruption on a scale of 1 to 7, where 1 means "extremely disruptive" and 7 means "not at all disruptive"?

	<i>n</i>	Percent
1 – Extremely Disruptive	48	21.8
2	17	7.7
3	27	12.3
4	40	18.2
5	31	14.1
6	36	16.4
7 – Not at all Disruptive	21	9.5
Total	220	100.0

Shock Anxiety

Finally, the mean FSAS score was 15.18, the median was 13, the mode was 10 ($n = 134$) and the standard deviation was 6.48 (See Table C1 in Appendix C). The range of possible scores was from 10 to 50 while the range of actual scores was from 10 to 40.

Effects for Shock on Individual Item Ratings

A one-way between groups analysis of variance was conducted to explore the impact of number of shocks on ratings of general health, ICD affects on general health, quality of life (QOL), ICD affects on QOL, emotional health, ICD affects on emotional health, ICD affects on family relationships, sense of security, ICD affects on sense of

security and shock anxiety (see Table 12 and Table 13). Subjects were divided into four groups according to number of shocks. (No shocks; 1-4 shocks; 5-10 shocks; Greater than 10 shocks).

There was not a statistically significant difference for the four groups in their response to the questions: "Today, how would you describe your general health?"; "Overall, how much has the ICD affected your general health? Is your general health now..."; "Today, how would you describe your quality of life?"; or "Overall, how much has the ICD affected your quality of life? Your quality of life is now..."

There was a statistically significant difference for the four groups in their response to the question, "Today, how would you describe your general emotional health?": $F(3, 439) = 3.085, p = .027$. Post-hoc comparisons using the Tukey HSD test indicated that the mean score for the 1-4 Shocks Group ($M = 2.12, SD = .978$) was significantly lower than the Greater than 10 Shocks Group ($M = 2.59, SD = 1.185$). Neither the No Shock Group ($M = 2.24, SD = .975$) nor the 5-10 Shocks Group ($M = 2.46, SD = .996$) differed significantly from any other group. Despite reaching statistical significance, the actual difference in mean scores between groups was quite small using guidelines proposed by Cohen (1988) that an eta-squared of .01 indicates a small effect size, .06 indicates a medium effect size, and .14 indicates a large effect size. The effect size for shock level on general emotional health, calculated using eta squared, was .02 (see Table 12).

There was not a statistically significant difference for the four groups in their response to the question: "Overall, how much has the ICD affected your emotional well-

being? Is your emotional well-being now..." or "Overall, how much has the ICD affected your relationship with your family? Is your relationship now..."

There was a statistically significant difference for the four groups in response to the question, "How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means 'very secure' and 1 means 'not at all secure'?: $F(3, 439) = 3.481, p = .016$. Post-hoc comparisons indicated that the mean score for the No Shock Group ($M = 5.42, SD = 1.427$) was significantly higher than the Greater than 10 Shocks Group ($M = 4.78, SD = 1.672$). Neither the 1-4 Shocks Group ($M = 5.27, SD = 1.443$) nor the 5-10 Shocks Group ($M = 4.87, SD = 1.418$) differed significantly from any other group. Despite reaching statistical significance, the actual difference in mean scores between shock level groups on sense of security was, again, quite small with a calculated effect size of .02 (see Table 12).

There was also a statistically significant difference for the four groups in response to the question "Since you've received your device, would you say you feel more secure, less secure, or the same about your overall health?": $F(3, 439) = 4.188, p = .006$. Post-hoc comparisons indicated that the mean score for the 1-4 Shocks Group ($M = 1.21, SD = .463$) was significantly lower than the Greater than 10 Shocks Group ($M = 1.54, SD = .780$). Neither the No Shock Group ($M = 1.32, SD = .548$) nor the 5-10 Shocks Group ($M = 1.38, SD = .633$) differed significantly from any other group. Despite reaching statistical significance, the actual difference in mean scores between shock level groups on ICD affects on sense of security was small with a calculated effect size of .03 (see Table 12).

Table 12.

Descriptive Data for Single-item Questions by Shock Groups

Question	Group	<i>n</i>	<i>M</i>	<i>SD</i>
Today, how would you describe your general health?	0	223	2.85	.984
	1-4 times	135	2.93	1.019
	5-10 times	39	2.95	.999
	More than 10 times	46	3.15	.868
	Total	443	2.91	.986
Overall, how much has the ICD affected your general health? Is your general health now...	0	223	2.10	.915
	1-4 times	135	2.02	.851
	5-10 times	39	2.18	1.023
	More than 10 times	46	2.26	1.124
	Total	443	2.10	.929
Today, how would you describe your quality of life?	0	223	2.33	.942
	1-4 times	135	2.39	.993
	5-10 times	39	2.46	.996
	More than 10 times	46	2.50	1.049
	Total	443	2.38	.973
Overall, how much has the ICD affected your quality of life? Your quality of life is now...	0	223	2.18	.932
	1-4 times	135	2.06	.862
	5-10 times	39	2.26	1.019
	More than 10 times	46	2.17	1.122
	Total	443	2.15	.940
Today, how would you describe your general emotional health?	0	223	2.24	.975
	1-4 times	135	2.12	.978
	5-10 times	39	2.46	.996
	More than 10 times	46	2.59	1.185
	Total	443	2.26	1.008

Overall, how much has the ICD affected your emotional well-being? Is your emotional well-being now...	0	223	2.22	.927
	1-4 times	135	2.21	.850
	5-10 times	39	2.46	.969
	More than 10 times	46	2.33	1.334
	Total	443	2.25	.958
Overall, how much has the ICD affected your relationship with your family? Is your relationship now...	0	223	2.53	.787
	1-4 times	135	2.53	.800
	5-10 times	39	2.64	.743
	More than 10 times	46	2.76	.874
	Total	443	2.56	.797
How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means "very secure" and 1 means "not at all secure"?	0	223	5.42	1.427
	1-4 times	135	5.27	1.443
	5-10 times	39	4.87	1.418
	More than 10 times	46	4.78	1.672
	Total	443	5.26	1.470
Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?	0	223	1.32	.548
	1-4 times	135	1.21	.463
	5-10 times	39	1.38	.633
	More than 10 times	46	1.54	.780
	Total	443	1.32	.567

Finally, there was a statistically significant difference for the four groups on the measure of shock anxiety: $F(3, 439) = 43.25, p < .0005$. There was a large calculated effect size of .23. Post-hoc comparisons indicated that the mean score for the No Shock Group ($M = 13.18, SD = 5.13$) was significantly lower than the 5-10 Shocks Group ($M = 18.95, SD = 7.63$) and the Greater than 10 Shocks Group ($M = 22.93, SD = 7.54$) but not for the 1-4 Shocks Group ($M = 14.74, SD = 5.27$). The mean score for the 1-4 Shocks Group was significantly lower than both the 5-10 Shocks Group and the

Greater than 10 Shocks Group. The mean score for the 5-10 Shocks Group was significantly lower than the Greater than 10 Shocks Group. These results suggest that shock anxiety is similar for ICD patients who have experienced 0-4 shocks but may pass a threshold at 5 or more shocks (see Table 13).

Table 13.

Descriptive Data for Shock Anxiety by Shock Groups

Question	Group	<i>n</i>	<i>M</i>	<i>SD</i>
Shock Anxiety	0	223	13.18	5.13
	1-4 times	135	14.74	5.27
	5-10 times	39	18.95	7.63
	More than 10 times	46	22.93	7.54
	Total	443	15.18	6.48

Effects for Gender on Individual Item Ratings

A one-way between groups analysis of variance was conducted to explore the impact of gender on ratings of general health, ICD affects on general health, quality of life (QOL), ICD affects on QOL, emotional health, ICD affects on emotional health, ICD affects on family relationships, sense of security, ICD affects on sense of security and shock anxiety (see Table 14 and Table 15). There was not a significant statistical difference for gender on ratings of any of the single-item questions (see Table 14).

Table 14.

Descriptive Data for Single-item Questions by Gender

Question	Group	<i>n</i>	<i>M</i>	<i>SD</i>
Today, how would you describe your general	Male	359	2.93	.986

health?	Female	84	2.82	.984
	Total	443	2.91	.986
Overall, how much has the ICD affected your general health? Is your general health now...	Male	359	2.13	.927
	Female	84	1.99	.938
	Total	443	2.10	.929
Today, how would you describe your quality of life?	Male	359	2.38	.978
	Female	84	2.37	.954
	Total	443	2.38	.973
Overall, how much has the ICD affected your quality of life? Your quality of life is now...	Male	359	2.15	.912
	Female	84	2.14	1.054
	Total	443	2.15	.940
Today, how would you describe your general emotional health?	Male	359	2.25	1.005
	Female	84	2.29	1.025
	Total	443	2.26	1.008
Overall, how much has the ICD affected your emotional well-being? Is your emotional well-being now...	Male	359	2.25	.934
	Female	84	2.29	1.059
	Total	443	2.25	.958
Overall, how much has the ICD affected your relationship with your family? Is your relationship now...	Male	359	2.56	.796
	Female	84	2.58	.810
	Total	443	2.56	.797
How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means "very secure" and 1 means "not at all secure"?	Male	359	5.29	1.416
	Female	84	5.15	1.690
	Total	443	5.26	1.470
Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?	Male	359	1.31	.547
	Female	84	1.35	.649
	Total	443	1.32	.567

There was a statistically significant difference for gender on the measure of shock anxiety: $F(1, 442) = 7.051, p = .021$. The mean score for females ($M = 16.86$,

$SD = 7.57$) was significantly higher than for males ($M = 14.79$, $SD = 6.14$). Despite reaching statistical significance, the actual difference in mean scores between genders on shock anxiety was quite small with a calculated effect size of .02 (see Table 15).

Table 15.

Descriptive Data for Shock Anxiety by Gender

Question	Group	<i>n</i>	<i>M</i>	<i>SD</i>
Shock Anxiety	Male	359	14.79	6.14
	Female	84	16.86	7.57
	Total	443	15.18	6.48

Effects for Age on Individual Item Ratings

A one-way between groups analysis of variance was conducted to explore the impact of age on ratings of general health, ICD affects on general health, quality of life (QOL), ICD affects on QOL, emotional health, ICD affects on emotional health, ICD affects on family relationships, sense of security, ICD affects on sense of security and shock anxiety (see Table 16 and Table 17). Subjects were divided into three age groups (Group 1: less than 50; Group 2: 50-64; Group 3: 65 and older).

There was not a statistically significant difference for the three groups in their response to the questions: "Today, how would you describe your general health?"; "Overall, how much has the ICD affected your general health? Is your general health now..."; "Today, how would you describe your quality of life?"; or "Overall, how much has the ICD affected your quality of life? Your quality of life is now...";

There was a statistically significant difference for the three groups in their response to the question, "Today, how would you describe your general emotional

health?": $F(2, 440) = 7.93, p < .0005$. Post-hoc comparisons indicated that the mean score for the Less Than 50 Group ($M = 2.92, SD = 1.22$) was significantly higher than both the 50 to 64 Group ($M = 2.38, SD = 1.06$) and the 65 and older Group ($M = 2.16, SD = .944$) (see Table 16). Despite reaching statistical significance, the actual difference in mean scores between age groups on general emotional health was small with a calculated effect size of .03. The difference between the 50 to 64 Group and the 65 and older Group was not statistically significant.

There was also a statistically significant difference for the three groups in their response to the question, "Overall, how much has the ICD affected your emotional well-being? Is your emotional well-being now...": $F(2, 440) = 3.25, p = .040$. Post-hoc comparisons however, indicated that there were no statistically significant differences between individual groups.

There was also a statistically significant difference for the three groups in response to the question, "How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means 'very secure' and 1 means 'not at all secure'?: $F(2, 440) = 10.78, p < .0005$. Post-hoc comparisons indicated that the mean score for the 65 and older Group ($M = 5.48, SD = 1.33$) was significantly higher than both the Less Than 50 Group ($M = 4.64, SD = 1.50$) and the 50 to 64 Group ($M = 4.84, SD = 1.67$) (see Table 16). The difference in mean scores between age groups on sense of security was small with a calculated effect size of .05. The difference between the Less Than 50 Group and the 50 to 64 Group was not statistically significant.

There was not a statistically significant difference for the three groups in response to the question, "Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?"

Table 16.

Descriptive Data for Single-item Questions by Age

Question	Group	<i>n</i>	<i>M</i>	<i>SD</i>
Today, how would you describe your general health?	Less than 50	25	2.88	1.269
	50-64	116	2.94	1.007
	65 and older	302	2.90	.954
	Total	443	2.91	.986
Overall, how much has the ICD affected your general health? Is your general health now...	Less than 50	25	2.36	1.036
	50-64	116	2.18	.983
	65 and older	302	2.05	.895
	Total	443	2.10	.929
Today, how would you describe your quality of life?	Less than 50	25	2.52	1.295
	50-64	116	2.40	.950
	65 and older	302	2.36	.953
	Total	443	2.38	.973
Overall, how much has the ICD affected your quality of life? Your quality of life is now...	Less than 50	25	2.52	1.046
	50-64	116	2.28	1.053
	65 and older	302	2.07	.872
	Total	443	2.15	.940
Today, how would you describe your general emotional health?	Less than 50	25	2.92	1.222
	50-64	116	2.38	1.060
	65 and older	302	2.16	.944
	Total	443	2.26	1.008
Overall, how much has the ICD affected your	Less than 50	25	2.60	1.155

emotional well-being? Is your emotional well-being now...	50-64	116	2.36	1.042
	65 and older	302	2.18	.898
	Total	443	2.25	.958
Overall, how much has the ICD affected your relationship with your family? Is your relationship now...	Less than 50	25	2.80	.577
	50-64	116	2.63	.808
	65 and older	302	2.52	.806
	Total	443	2.56	.797
How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means "very secure" and 1 means "not at all secure"?	Less than 50	25	4.64	1.497
	50-64	116	4.84	1.673
	65 and older	302	5.48	1.334
	Total	443	5.26	1.470
Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?	Less than 50	25	1.52	.770
	50-64	116	1.36	.665
	65 and older	302	1.28	.501
	Total	443	1.32	.567

There was a statistically significant difference for the three groups for the measure of shock anxiety: $F(2, 440) = 17.57, p < .0005$. Post-hoc comparisons indicated that the mean score for the Less Than 50 Group ($M = 20.12, SD = 8.07$) was significantly higher than both the 50 to 64 Group ($M = 17.01, SD = 6.72$) and the 65 and older Group ($M = 14.01, SD = 5.89$) (see Table 17). There was a moderate calculated effect size of .07. The difference between the 50 to 64 Group and the 65 and older Group was not statistically significant, however.

Table 17.

Descriptive Data for Shock Anxiety by age

Question	Group	<i>n</i>	<i>M</i>	<i>SD</i>
Shock Anxiety	Less than 50	25	20.12	8.07
	50-64	116	17.01	6.72
	65 and older	302	14.07	5.89
	Total	443	15.18	6.48

Therefore, in summarizing these findings on age, while the Less Than 50 Group reports about the same general health than the older groups, they have worse general emotional health, worse sense of security and greater shock anxiety than the oldest group.

Chapter V: Discussion

General Findings

The current study demonstrated that the great majority of ICD patients report good overall quality of life and also report that their ICD has contributed positively to their overall quality of life. Second, there is support for the view that shocks are strongly associated with ICD-specific shock anxiety levels. This data indicated that 23% of the variance in shock anxiety is attributed to the number of shocks received with greater shocks associated with significantly higher levels of anxiety. Third, comparisons of number of shocks, gender or age all found significant differences in the measure of shock anxiety. Thus, this supports the use of the FSAS as a sensitive tool for measuring this construct as previous research has supported the view that there are shock-related, gender and age differences in how patients cope with an ICD. Fourth, there is overall support for the view that younger ICD patients have unique difficulties in coping with living with an ICD compared to older recipients. While effect sizes were generally small and there were not significant differences in several measures, there was an overall trend that indicated younger recipients did not fare as well as older recipients. Specifically, while the Less Than 50 Group reports about the same general health than the older groups, they have worse general emotional health, worse sense of security and greater shock anxiety than the oldest group. Fifth, there is support for the view that shocks are a critical event for ICD patients. While effect sizes were generally small and there were not significant differences in several measures, there was an overall trend that indicated ICD patients who received more than 10 shocks fared more poorly than ICD patients who received fewer shocks. Specifically, they reported poorer

general emotional health, poorer sense of security, poorer perceived improvement to their sense of security post-implantation, and greater shock anxiety. Sixth, questions concerning security detected significant differences between both gender and shock groups. This unique measure of an aspect of overall QOL previously unresearched in ICD patient studies may be an important area for further study to include development of a life security scale for use with ICD patients and/or other patients with chronic conditions. Finally, counter to some previous research, gender differences were minimal on all measures except for shock anxiety and even then the effect size was small.

Findings from Descriptive Statistics

Analysis of descriptive data from Shock 2010 found that the majority of this sample reported current levels of general health, QOL, general emotional health to be “good”, “very good”, or “excellent.” The majority also reported their sense of security to be at least relatively good. The most favorable rating was for general emotional health of which 87.8% reported favorable ratings. Very few members of this sample reported ratings of “poor” in any of these areas with the highest percentage of “poor” responses for the question on general health (4.5%) and the lowest report of “poor” for QOL (1.4%). One benchmark for comparison is from a US national survey of ICD patients ($n = 450$) and spouses (NSIRSO, as cited in Sears and Conti, 1999) which found that 45% of ICD patients reported their global QOL as unchanged post-implantation while 46% reported that QOL had improved. This compares to the results from Shock 2010 of 36.3% reporting global QOL as unchanged post-implantation while 59.4% report improved QOL.

Only 30% of participants reported improvements in family relationships post-implantation, however. "Family relationship" is a more specific construct than the other questions related to QOL. While family relationships did not seem to improve for the majority of ICD recipients when compared to other areas, they also declined the least in this area indicating that ICD implantation has minimal effects on this somewhat specific aspect of living.

Effect of Shock

The effect of shock history on health and QOL was statistically significant on three of the nine individual global health and QOL measures (i.e. general emotional health, overall sense of security, and change in sense of security post-implantation). In all three cases, however, effect sizes were small. It is interesting that in two of the cases (general emotional health and change in sense of security since receiving their ICD) the only significant differences were between the group that had received 1-4 shocks and the group that had received more than 10 shocks. One possible explanation for this is that the group that had received only a small number of shocks had experienced the life-saving advantage of an ICD without experiencing the possible negative side effects that might occur with multiple shock experiences. The group that had received more than 10 shocks, while experiencing the benefits of the life saving qualities of the ICD, may also have had to wrestle with concerns about why they have received multiple shocks (e.g., questioning the soundness of their heart/health) or heightened anxiety that has occurred due to receiving so many shocks. In fact, the largest effect size found in the study concerned the relationship between number of

shocks and shock anxiety with 23% of the variance attributed to number of shocks. In this case, shock anxiety significantly increased at every level of shock history.

The greatest effect size found in this study concerned the relationship between number of shocks and shock anxiety with 23% of the variance attributed to number of shocks. This is consistent with previous research which has found elevated anxiety in patients with greater number of shocks (Irvine et al., 2002; Passman et al., 2007; Redhead, Turkington, Rao, Tynan, & Bourke, 2010; Sears et al., 1999). This finding provides support for the shock experience to continue to be considered a “critical event” (Sears, Matchett, & Conti, 2009) worthy of management and care by health care providers and continued emphasis by ICD manufacturers to minimize inappropriate shocks.

It is interesting that concerning general emotional health and change in sense of security, the group who received no shocks was not significantly different from the more than 10 shock group. It is possible that for many ICD patients, particularly those who receive an ICD for primary prevention, until the ICD has provided a lifesaving, tangible shock, there is no strong emotional connection to the benefits on emotional health or improvement in sense of security.

Similar results have been found in at least one other study (Ladwig et al., 2005). Patients who had been shocked 1-4 times reported greater treatment satisfaction with their ICD (viewing their ICD as a “life extender”) than patients who had not been shocked at all as well as those who had been shocked five or more times. These researchers suggested that the group that had not been shocked at all may be less satisfied “presumably because of doubts about the genuine necessity for the

defibrillator” (p. 511), while the benefits of an ICD in the group shocked 5 or more times diminishes when experiencing continually greater number of discharges.

Concerning one question that was only asked of those who had been shocked, it was reported that shock was extremely disruptive for 29.5% of participants. About an equal percentage (25.9%) found shock to be only minimally disruptive. This indicates that shock impacts individuals differently and that individual differences must be considered by clinicians when educating and treating ICD patients. This question is unique to Shock 2010 and may provide a benchmark for future studies on this aspect of the shock experience.

Effect of Gender

The effect of gender on health and QOL was not statistically significant on any of the nine individual global health and QOL measures. In fact, mean ratings on several measures were strikingly similar. The one area on which differences were significant was on shock anxiety with women reporting higher levels than men. Even in that area, however, the effect size of .02 was quite small indicating that only 2% of the variance can be explained due to gender differences.

These results appear counter to previous research which has reported female gender to be a risk factor for reduced QOL in ICD patients (Bilge et al., 2006; Natale, Davidson, Geiger, & Newby, 1997; Sears & Conti, 2002; Vazquez et al., 2006; Versteeg et al., 2010). A review by Bostwick and Sola (2007) however found that there was inconsistency in ICD studies which suggest female gender is a risk factor by highlighting contradictory findings. Inconsistency in findings, however, could be partially attributed to

small sample sizes as most studies (Shock 2010 included) have far fewer female participants than males.

Effect of Age

The effect of age on health and QOL was statistically significant on three of the nine individual global health and QOL measures. There were significant differences in how the groups rated their general emotional health and overall sense of security. There were also age differences on the shock anxiety scale. Effect sizes were small except in the case of shock anxiety which had a moderate effect size. In all cases, the younger than 50 group reported less positive ratings than the 65 and older group. These results are consistent with other research that has demonstrated young age as a risk factor for less favorable QOL outcomes (Dubin, Batsford, Lewis, & Rosenfeld, 1996; Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008; Sears et al., 1999; Vazquez et al., 2008).

Future Implications

While the scope of this study does not enable us to draw conclusions concerning the relative importance of shock on patient outcomes and QOL compared to such other important patient factors like progression and severity of patient heart failure or psychological profile (e.g., Type D), it certainly provides support for the view that shock is a significant event that contributes to increased anxiety for ICD patients. These findings add supporting evidence to the results of many other studies which have established shock as a critical patient event that can detrimentally effect psychosocial outcomes. This information supports efforts by device makers and physicians to continue to find better ways to reduce shocks. Also, research should continue to

search for better ways to educate, prepare, and treat ICD patients concerning the possible effects of shock episodes on mental and emotional well-being.

Findings from the survey provide possible support for a view that global questions may not be sensitive enough to detect differences in the experiences of ICD patients. While there were differences for age, gender, and number of shocks for shock anxiety as measured by the 10 question FSAS, differences on specific measures were not as distinguishing. An examination of means for many of these measures indicated overall trends that younger ICD patients and ICD patients with greater number of shocks tended to report less satisfaction than others. It may be that more sensitive QOL measures (like the FSAS for measures of shock anxiety) would indicate significant differences that single-item global measures were unable to detect. This remains a possibility for future research to determine.

Future research is also indicated to gain a better understanding of the value of sense of security as an important benefit to ICD patients. Information that needs to be gathered includes identifying the importance of security to patients, its relative importance to other factors, how best to increase sense of security (e.g., education, personal experience/history living with an ICD), and how it may be diminished (e.g., problematic shock history, lead failure, comorbid health/psychological problems).

Clinical Significance of Findings

Descriptive statistics indicate that the majority of ICD patients experience overall satisfaction with their ICD. This information should be provided to prospective ICD recipients so that they have a better understanding of the ICD experience as well as those who currently have an ICD so that they can benchmark their experience. The

significance of shock episodes and education on how to manage ICD shocks should be provided to patients so that they may be as prepared as possible for possible psychosocial distress. In addition, information addressing unique issues that younger patients (< 50) and/or women may experience should be provided to patients and health professionals.

Strengths of Study

This study has several strengths. First, results are from a large, nationwide sample size which is somewhat unique for ICD studies. Second, there was minimal participant burden as the survey was very brief and questions were clear, concise, direct and non-invasive. Third, use of email contact and a web-based survey allowed for rapid gathering of data and computerized computation of results thus minimizing the chance of human error. In addition, the financial cost of research was minimized by using electronic means for notification survey completion.

Weaknesses of Study

There are several limitations in the study. First, all the data provided was self-reported with no possibility for external validation. Second, representativeness was likely compromised in this study as there was a lack of demographic heterogeneity in the sample. The sample was predominantly older, white, and male and results may not generalize to other groups. Third, the sample was restricted to only those ICD recipients who had email and internet access. Fourth, the survey did not define "shock" for patients and it is possible that some patients may consider a shock storm to be only one shock while in reality they may have experienced a number of shocks in a very compressed time period. Fifth, the no-response rate for sent and opened emails was

21.3% thus there was possible response bias. Sixth, one important question concerning the shock experience that was not included concerned time since last shock. Time periods greater than 30 days since last shock have been associated with reduced anxiety levels. Seventh, there was no means to determine if shock experience reported was real or “phantom.” Again, this is related to the limitation of Shock 2010 as a self-report measure. Phantom shocks are experienced by ICD patients frequently but can only be identified through device interrogation. Finally, measures of health and QOL were single item questions and by their nature cannot provide subtle distinctions on unique aspects of health and QOL that may have been problematic.

Conclusions

Results from the Shock 2010 survey indicate that the great majority of ICD patients report good overall quality of life and also report that their ICD has contributed positively to their overall quality of life. The effects of shock, particularly concerning ICD-specific shock anxiety, however, remain a concern. Results from this survey may provide a benchmark for prospective and current ICD patients, as well as health care providers to better understand the experience of living with an ICD. Hopefully, this information will enhance the psychosocial potential provided by an ICD as it remains the premier standard of care in reducing mortality in patients at risk for SCD.

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APPENDIX A: IRB DOCUMENTATION

UMCIRB #:

RECEIVED

UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD REVISION FORM

OCT 08 2010

UMCIRB

UMCIRB #: 10-0322

Date this form was completed: 10/08/10

Title of research: SHOCK 2010: The United States National Survey of Attitudes and Experiences of Shocks in ICD Patients

Principal Investigator: Samuel F. Sears, Ph.D.

Sponsor: Medtronic, Inc.

Fund number for IRB fee collection (applies to all for-profit, private industry or pharmaceutical company sponsored project revisions requiring review by the convened UMCIRB committee):

Fund	Organization	Account	Program	Activity (optional)
		73059		

Account number is pending final approvals.

Version of the most currently approved protocol: Version 1 - approved on 08/09/10

Version of the most currently approved consent document: Version 1- 09/24/10

CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:

- | | |
|--|--|
| <input checked="" type="checkbox"/> East Carolina University | <input type="checkbox"/> Beaufort County Hospital |
| <input type="checkbox"/> Pitt County Memorial Hospital, Inc | <input type="checkbox"/> Carteret General Hospital |
| <input type="checkbox"/> Heritage Hospital | <input type="checkbox"/> Boice-Willis Clinic |
| <input type="checkbox"/> Other | |

The following items are being submitted for review and approval:

- Protocol: version or date
- Consent: version or date Version 1: 9/24/10: no change
- Additional material: version or date Version 1: 10/08/10

Complete the following:

- Level of IRB review required by sponsor: full expedited
- Revision effects on risk analysis: increased no change decreased
- Provide an explanation if there has been a greater than 60 day delay in the submission of this revision to the UMCIRB. n/a
- Does this revision add any procedures, tests or medications? yes no If yes, describe the additional information:
- Have participants been locally enrolled in this research study? yes no
- Will the revision require previously enrolled participants to sign a new consent document? yes no

Briefly describe and provide a rationale for this revision An introduction was needed to guide participants more clearly.

This text will be added following approval from IRB:


"The survey you are about to take is part of a medical research study on patient experiences with ICDs. As such, we need your consent to take part in this study. On the next screen you will see a detailed consent which tells you more about the survey and ensures your confidentiality. Please read the consent on the next page and check "I Agree" at the bottom if you'd like to continue."

Principal Investigator Signature

Print

Date

Box for Office Use Only

The above revision has been reviewed by:		
<input type="checkbox"/> Full committee review on _____	<input checked="" type="checkbox"/> Expedited review on <u>10/12/2010</u>	
The following action has been taken:		
<input checked="" type="checkbox"/> Approval for period of <u>10/12/2010</u> to <u>8/3/2011</u>		
<input checked="" type="checkbox"/> Approval by expedited review according to category <u>45 CFR 46.110</u>		
<input type="checkbox"/> See separate correspondence for further required action.		
Signature	Print	Date
	<u>Michelle Eldre</u>	<u>10/12/2010</u>

APPENDIX B: SHOCK 2010 SURVEY

Medtronic Protecta Survey
Penn Schoen Berland
October 2010

PURPOSE: THE PURPOSE OF THIS SURVEY IS TO GAIN A BETTER UNDERSTANDING OF THE PATIENT EXPERIENCE LIVING WITH AN ICD.

PRE CONSENT

/* DISPLAY */ The survey you are about to take is part of a medical research study on patient experiences with ICDs. As such, we need your consent to take part in this study.

On the next screen you will see a detailed consent which tells you more about the survey and ensures your total confidentiality.

Please read the consent on the next page and select the "I Agree" at the bottom if you'd like to continue.

/* NEW PAGE */

/* QCONSENT */ CONSENT DOCUMENT

Title of Research Study: Shock 2010: The United States National Survey of Attitudes and Experiences of Shocks in the ICD Patients

Principal Investigator: Samuel F. Sears, PhD

Institution: East Carolina University

Address: 115 Rawl Building, Greenville, NC 27858-4353

Telephone #: (252) 328-6118

PURPOSE AND PROCEDURES

The purpose of this study is to examine the patient experience of implantable cardioverter defibrillator shock from multiple vantage points. This study is designed to tap an existing database of over 75,000 ICD patients who have "opted-in" to participation in an annual survey. This survey will provide a brief, descriptive assessment of the shock experience for many ICD recipients. For shocked patients, we want to understand their experience of ICD shock. For non-shocked patients, we want to know more about the perception of the potential for an ICD shock from a patient perspective. All participants will be asked to complete questions concerning physical health, mental health, quality of life, and personal beliefs. This process will take approximately 30 minutes.

POTENTIAL RISKS AND DISCOMFORTS

There are no foreseeable legal or social risks to you for answering the questionnaires truthfully, as your responses will remain confidential. However, it is possible that answering some of the

items may produce mild discomfort. Some minor psychological risks may be involved if you experience any personal emotional discomfort due to your responses to the questions. If you experience distress or have concerns about the study, please contact Dr. Samuel Sears of East Carolina University at 252-328-6118.

POTENTIAL BENEFITS

All participants will have the opportunity to complete the questionnaires, which may have the benefit of increasing self-awareness in terms of living with an implantable cardioverter defibrillator. On a group level, this project has the potential to help us better understand the patient experience of shock. There may be no other personal benefits from your participation, but the knowledge received may be of value to humanity.

SUBJECT PRIVACY AND CONFIDENTIALITY OF RECORDS

Your privacy and confidentiality will be maintained as the researchers will go to extensive lengths to fully protect your confidentiality. A cardiac device manufacturer, Medtronic, is funding this project. Information received during the study will not be used to market to you; your information will not be placed on any mailing lists or sold to anyone for marketing purposes. Again, the results will not be accessible to anyone outside the research team and responses to questionnaires will not be linked to your name. The results of this project may be presented at conferences or published and would not contain identifying information about you or any other participant. Your participation is voluntary and you may leave the study at any time without penalty.

COSTS OF PARTICIPATION & COMPENSATION

There are not costs to participating in this research other than the time to fill out the questionnaires.

VOLUNTARY PARTICIPATION

Participating in this study is voluntary. If you decide not to be in this study after it has already started, you may stop at any time without losing benefits that you should normally receive. Again, you may stop at any time you choose without penalty.

PERSONS TO CONTACT WITH QUESTIONS

The investigators will be available to answer any questions concerning this research, now or in the future. You may contact the investigators, Dr. Sam Sears at 328-6118 at any time. If you have questions about your rights as a research subject, you may call the Chair of the University and Medical Center Institutional Review Board at phone number (252)744-2914 (days). If you would like to report objections to this research study, you may call the ECU Director of Research Compliance at phone number (252)328-9473.

CONSENT TO PARTICIPATE

Title of research study: Shock 2010: The United States National Survey of Attitudes and Experiences of Shocks in the ICD Patients

I have read all of the above information

Please Check "I agree" if you would like to participate in this research. By checking this box you are agreeing that you have read and understand the information above:

- 1) I Agree
- 2) I DO NOT Agree /* TERMINATE */

Screeners

/* DISPLAY */ Before taking this survey, please keep in mind that all answers will be anonymous and will not be traced back to you individually.

1. Are you...?
 - 3) Male
 - 4) Female

2. Which of the following age groups do you fall into?
 - 1) Less than 18 years old
 - 2) 18-20
 - 3) 21-29
 - 4) 30-39
 - 5) 40-49
 - 6) 50-54
 - 7) 55-64
 - 8) 65 or older

3. What is your level of education?
 - 1) Grade school
 - 2) Some high school
 - 3) High school graduate
 - 4) Some college
 - 5) College graduate
 - 6) Graduate school
 - 7) Technical school
 - 8) Don't know / refused

4. For demographic purposes only, can you please tell me your race?
 - 1) White
 - 2) Black / African-American / Caribbean-American
 - 3) Hispanic / Latino
 - 4) Asian
 - 5) Arab
 - 6) Other

- 7) Don't know / refused
5. Which category best describes your yearly household income? Include all sources of income, and all people living in your home.
- 1) \$0 to \$9,999
 - 2) \$10,000 to \$19,999
 - 3) \$20,000 to \$29,999
 - 4) \$30,000 to \$39,999
 - 5) \$40,000 to \$49,999
 - 6) \$50,000 to \$74,999
 - 7) \$75,000 to \$99,999
 - 8) \$100,000 to \$149,999
 - 9) \$150,000 and above
 - 10) Don't know / refused

Activity Avoidance

/* METRIC A */ Can you do this activity today?

- 1) Yes
- 2) No

/* METRIC B */ Do you avoid doing this activity?

- 1) All the time
- 2) Most of the time
- 3) Some of the time
- 4) Rarely
- 5) Never

/* METRIC C */ ## IF C1, 2, 3, 4 TO PREVIOUS METRIC B ## Why do you avoid this activity? **/* RANDOM ROTATE CHOICES */** **/* MULTIPLE RESPONSES PERMITTED */**

- 1) Fear of shock
- 2) Increase heart rate
- 3) Doctor instruction
- 4) No desire
- 5) Other **/* SPECIFY */** **/* DO NOT ROTATE */**

/* REPEAT CODES */ **/* RANDOM ROTATE SERIES */**

6. Take care of yourself (eating, dressing, bathing, or using the toilet)
7. Walk indoors such as around your house

8. Walk a block or two on level ground
9. Climb a flight of stairs or walk up a hill
10. Run a short distance
11. Do light work around the house like dusting or washing dishes
12. Do moderate work around the house like vacuuming sweeping floors or carrying in groceries
13. Do heavy work around the house like scrubbing floors or lifting and moving heavy furniture
14. Do yard work like raking leaves weeding or pushing a power mower
15. Have sexual relations
16. Participate in moderate recreational activities like golf bowling dancing doubles tennis or throwing a baseball or football
17. Participate in strenuous sports like swimming singles tennis football basketball or skiing

/* END SERIES */

Impact of ICD on Quality of Life

18. Today, how would you describe your **general health**?
 - 1) Excellent
 - 2) Very good
 - 3) Good
 - 4) Fair
 - 5) Poor

19. Overall, how much has the ICD affected your **general health**? Is your general health now...
 - 1) Much better
 - 2) Somewhat better
 - 3) About the same
 - 4) Somewhat worse
 - 5) Much worse

20. Today, how would you describe your **quality of life**?
 - 1) Excellent
 - 2) Very good
 - 3) Good
 - 4) Fair
 - 5) Poor

21. Overall, how much has the ICD affected your **quality of life**? Your quality of life is now...
 - 1) Much better
 - 2) Somewhat better
 - 3) About the same
 - 4) Somewhat worse
 - 5) Much worse

22. Today, how would you describe your **general emotional health**?
- 1) Excellent
 - 2) Very good
 - 3) Good
 - 4) Fair
 - 5) Poor
23. Overall, how much has the ICD affected your **emotional well-being**? Is your emotional well-being now...
- 1) Much better
 - 2) Somewhat better
 - 3) About the same
 - 4) Somewhat worse
 - 5) Much worse
24. Overall, how much has the ICD affected your **relationship with your family**? Is your relationship now...
- 1) Much better
 - 2) Somewhat better
 - 3) About the same
 - 4) Somewhat worse
 - 5) Much worse
25. How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means "very secure" and 1 means "not at all secure"?
- 1) 1 – Not at all Secure
 - 2) 2
 - 3) 3
 - 4) 4
 - 5) 5
 - 6) 6
 - 7) 7 – Very Secure
26. Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?
- 1) More secure
 - 2) The same
 - 3) Less secure

The ICD Experience

/* DISPLAY */ Now we're going to ask you a few questions about your personal experiences with your ICD.

SHOCK QUESTIONS

27. Have you even been shocked by your device?
- 1) Yes
 - 2) No
28. **## IF YES TO PREVIOUS ##** On how many occasions have you been shocked?
- 1) 1-4 times
 - 2) 5-10 times
 - 3) More than 10 times
29. **## IF YES TO Q27 ##** Did you feel adequately prepared to handle the post-shock experience?
- 1) I felt well prepared and knew just what to do
 - 2) I felt moderately prepared
 - 3) I could have been more prepared
 - 4) I was not prepared at all
30. **## IF YES TO Q27 ##** If you have experienced a shock, which of the following actions did you take after you received your shock? Please select all that apply. **/* MULTIPLE RESPONSES PERMITTED */**
- 1) Went to the emergency room
 - 2) Called my physician/nurse/ hospital/clinic
 - 3) Sent my device information to the doctor via my Medtronic CareLink Network
 - 4) Lost ability to make rational decisions/actions
31. **## IF YES TO Q27 ##** How disruptive was the overall shock event to your life? Please rate the disruption on a scale of 1 to 7, where 1 means "extremely disruptive" and 7 means "not at all disruptive".
- 1) 1 – Extremely Disruptive
 - 2) 2
 - 3) 3
 - 4) 4
 - 5) 5
 - 6) 6
 - 7) 7 – Not at all Disruptive

Frequency of ICD Shock Fears and Emotions

/* METRIC A */ Now we want to understand your feelings about ICD shocks. Please select the frequency with which you feel the following ways about your ICD.

- 1) Not at all

- 2) Rarely
- 3) Some of the time
- 4) Most of the time
- 5) All the time

/* REPEAT CODES */ /* RANDOM ROTATE SERIES */

- 32. I am scared to exercise because it may increase my heart rate and cause my device to shock me.
- 33. I am afraid of being alone when the ICD shocks me and I need help.
- 34. I do not get angry or upset because it may cause my ICD to shock me.
- 35. It bothers me that I do not know when the ICD will shock me.
- 36. I worry about the ICD not shocking me sometime when it should.
- 37. I am afraid to touch others for fear I'll shock them if the ICD shocks me.
- 38. I worry about the ICD shocking me and creating a scene.
- 39. When I notice my heart beating rapidly, I worry that the ICD will shock me.
- 40. I have unwanted thoughts of my ICD shocking me.
- 41. I do not engage in sexual activities because it may cause my ICD to shock me.

/* END SERIES */

- 42. Are there any feelings or comments that you have related to ICD therapy that were not adequately addressed in the questions you just answered? If so, please share them here: **/* OPEN END */**

APPENDIX C: SUPPLEMENTAL TABLE

Table C1

FSAS Levels

	<i>n</i>	Percent
10.00	134	30.2
11.00	42	9.5
12.00	45	10.2
13.00	31	7.0
14.00	26	5.9
15.00	19	4.3
16.00	16	3.6
17.00	10	2.3
18.00	12	2.7
19.00	18	4.1
20.00	8	1.8
21.00	14	3.2
22.00	13	2.9
23.00	6	1.4
24.00	4	.9
25.00	3	.7
26.00	3	.7
27.00	9	2.0
28.00	4	.9
29.00	2	.5
30.00	3	.7
31.00	3	.7
32.00	5	1.1
33.00	2	.5
34.00	3	.7
35.00	2	.5
36.00	3	.7
38.00	1	.2
39.00	1	.2
40.00	1	.2
Total	443	100.0