ABSTRACT

Mary H. Wilson. THE RELATIONSHIP BETWEEN RELIGIOSITY AND QUALITY OF LIFE IN PATIENTS WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS. (Under the direction of Dr. Martha Engelke) College of Nursing, October, 2010.

The implantable cardioverter defibrillator (ICD) is often used in treatment and prevention of lethal cardiac arrhythmias in at-risk patients. Despite its established effectiveness, ICD therapy is associated with ongoing physical, emotional, and psychosocial distress that can impact patients' quality of life (QoL). For many patients living with chronic illness, religiosity may be central to dealing with the physical and psychosocial challenges they encounter. It is hypothesized that ICD patients who are more religious will demonstrate improved QoL. To date, there are no studies that have examined the influence of religiosity on general and disease-specific QoL in the ICD population.

The purpose of this study was to investigate the relationship between religiosity and QoL in ICD patients. Select variables (demographic, clinical, ICD specific, psychosocial, and religiosity) of the ICD population were explored to determine predictors of general (physical and mental health) and disease-specific QoL (patient acceptance of the device). Frankl's Motivational Theory of Meaning (1962) and Wilson and Cleary's Quality of Life Model (1995) provided the conceptual framework for this study.

Using a descriptive correlational design with purposive sampling, data were collected from 101 ICD recipients who were patients at a cardiology clinic in a southeastern state. Hierarchical regression analyses were conducted to assess relationships between study variables and identify the best predictors of QoL.

Study measures of religiosity did not relate to general QoL. However, there were significant correlations between religiosity and disease-specific QoL. Physical health (PH) was

significantly correlated with number of comorbidities, age, and depression scores, with depression the strongest predictor of PH. Both anxiety and depression scores were identified as significant predictors of mental health (MH). Regarding disease-specific QoL, study findings indicated sixty-seven percent of the variability in patient acceptance was predicted by race, age, number of comorbidities, shock anxiety, depression, knowledge of device, and importance of religion.

Overall, ICD patients in this study who were more religious reported a greater acceptance of their implantable device. Religiosity, as well as other psychosocial variables in the ICD population, could prove effective coping strategies to adjustment with this life-saving device and provide a model for interventions. Further studies are warranted to validate these findings in a larger sample.

THE RELATIONSHIP BETWEEN RELIGIOSITY AND QUALITY OF LIFE IN PATIENTS

WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

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THE RELATIONSHIP BETWEEN RELIGIOSITY AND QUALITY OF LIFE IN PATIENTS

WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

by

Mary H. Wilson

APPROVED BY:

DIRECTOR OF DISSERTATION:_____

Martha Engelke

COMMITTEE MEMBER:_____

Melvin Swanson

COMMITTEE MEMBER:_____

Janice Neil

COMMITTEE MEMBER:_____

Samuel Sears

DEAN OF THE COLLEGE OF NURSING:

_____

Sylvia Brown

DEAN OF THE GRADUATE SCHOOL:

_____

Paul Gemperline

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DEDICATION

With sincere gratitude, this dissertation is dedicated to my husband, Greg, for his enduring love and unwavering support; to my two beautiful daughters, Anna and Elizabeth for their hugs and kisses especially when I needed them the most; for my parents, Dorothy and James Hughes who instilled in me the faith and courage to never stop learning; to my seven brothers and sisters for their endless words of encouragement; and to my dear friend Sarah McPherson who began this journey with me and whose spirit remained throughout the peaks and valleys of my doctoral study.

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CHAPTER 1: INTRODUCTION

The implantable cardioverter defibrillator (ICD) can prevent lethal arrhythmias in at-risk patients. However, despite its established effectiveness in preventing sudden cardiac death, ICD therapy is associated with psychosocial distress which can affect patients' health related quality of life (Sears, Matchett, & Conti, 2009). A brush with death from life-threatening arrhythmias may trigger interest in religious activities to provide patients with comfort and a means of coping (Contrada, Goyal, Cather, & et al., 2004; Pargament, 1997). There is mounting evidence that religiosity and spirituality are related to health outcomes. For many individuals living with chronic illness, religiosity may be central to dealing with physical and psychosocial challenges they encounter. However, there are no studies that have examined the relationship between religiosity and quality of life in ICD patients.

Background and Significance

Each year, cardiovascular disease claims as many lives as cancer, lung disease, AIDS, and diabetes combined. In the United States alone, Sudden Cardiac Death (SCD) accounts for more than 450,000 of these deaths (American Heart Association Statistics Committee and Stroke Statistics Subcommittee [AHA], 2009). Defined as death resulting from an abrupt loss of cardiac function, SCD occurs when the electrical impulses in the heart become rapid (ventricular tachycardia) or chaotic (ventricular fibrillation) or both (AHA, 2009). Coronary heart disease and heart failure are major risk factors contributing to sudden cardiac death. Individuals who have sustained a myocardial infarction have a four to six times increase in the incidence of SCD and those with heart failure are 6 to 9 times more likely to have SCD than the general population. Often, sudden cardiac death is the first manifestation of heart disease in more than 50% of men and 64% of women (AHA, 2009).

To date, the standard of care for the primary and/or secondary prevention of Sudden Cardiac Death is the Implantable Cardioverter Defibrillator (ICD) (ACC/AHA/NASPE, 2002; Greenburg, Case, Moss, & et al., 2004; Moss, Hall, Cannom, & et al., 1996). Clinical trials have demonstrated that ICDs reduce mortality for cardiac patients with abnormal ventricular rhythms and patients with heart failure, nonischemic cardiomyopathies, and familial cardiac problems who are at risk of developing life-threatening ventricular dysrhythmias (Dunbar, 2005; Goldberger & Lampert, 2006). Developed in 1980, the ICD has continued to evolve from a large, nonprogrammable device surgically implanted through either a thoracotomy or sternotomy to small pocket-size devices implanted with minimally invasive procedures that are capable of sophisticated monitoring and tiered therapy for pacing and defibrillation (Carroll & Hamilton, 2008). Consistent positive findings from clinical trial results and improvements in technology and insertion techniques have led to an increase in the use of these devices (Zhan, Baine, Sedrakyan, & Steiner, 2008).

Despite the survival benefits of the Implantable Cardioverter Defibrillator (ICD), the impact of the device on patients' quality of life (QoL) is significant (Thomas, Friedman, Kao, & et al., 2006). Challenged by the psychosocial adjustment and physiological concerns of living with the device, ICD patients face the on-going threat of spontaneous, lethal arrhythmias and a reliance on their device to detect and terminate these rhythms (Sears, Matchett, & Conti, 2009). Current literature has revealed that ICD patients report feelings of fear, anxiety, depression, helplessness, and anger about their dependency on their device and the potential for technological failure (Dunbar, 2005; Neel, 2000; Sears, Todaro, Lewis, Sotile, & Conti, 1999; Thomas et al., 2006). Anxiety and depression in ICD patients has been associated with poor quality of life (Wheeler, Pretzer-Aboff, Hardie, & et al., 2009; Thomas et al., 2006; Wallace,

Sears, Lewis, & et al., 2002). Additionally, Dunbar (2005) notes that ICD patients who received device shocks or experience multiple consecutive shocks, and those with more severe heart failure have higher levels of anxiety than ICD patients with less severe disease. The increased levels of stress the ICD patient experiences may also impact their health status by increasing the risk for cardiac arrhythmias (Dunbar, 2006; Lampert, Diwaker, Matthew, Batsford, & McPherson, 2000). One study of ICD patients reported that those with higher depression scores were more likely to experience ventricular arrhythmias than patients with less depression (Whang, Mittleman, Rich, & et al., 2004).

For the patient living with an ICD there are physiological and psychosocial components that may affect the individual's quality of life. Psychological distress and poor QoL experienced by ICD patients can impact pathological processes which may increase the risk of sudden cardiac death. Nursing interventions to improve psychological health and QoL may decrease morbidity and mortality in this population (Bostwick & Sola, 2007; Thomas et al., 2006).

Because the heart is often viewed as central to the maintenance of life, any injury or treatment intervention involving the heart is recognized as bringing "one's spiritual side into greater focus" (Camp, 1991, p. 13). Previous research suggests that QoL and health are enhanced in people with chronic illness who have a strong sense of spirituality (Adegbola, 2006; Coyle, 2002). Despite studies indicating that one's religious beliefs can positively impact health, longevity, and recovery from physical illness, it is not known if this is true for individuals living with an ICD. As a response to the increasingly technological approach to health care, it is important to examine the mind-body connection and recognize the bio-psycho-social-spiritual model of care (Villagomeza, 2006). Health care providers are often uninformed about the

significance and potential impact of religiosity and how to incorporate the concept into a comprehensive plan of care (Walton, 1999).

Statement of the Problem

As the number of cardiac patients with Implantable Cardioverter Defibrillators (ICDs) continues to grow, there is added interest in understanding factors that promote a more positive quality of life (QoL) for those challenged with the physical and psychosocial implications of this life-saving technology. Religiosity is often noted as a central issue for patients dealing with a chronic illness, providing a way to cope and bringing forth a sense of meaning and purpose in the face of a challenging situation (Cotton, Puchalski, Sherman, & et al., 2006). Despite the current empirical evidence that spirituality and religion have a positive impact on health outcomes in people with chronic conditions, there is limited knowledge of the influence of religiosity in the lives of ICD patients and how religiosity is related to other factors known to affect adaptation to the device. Furthermore, most research has been done on Caucasian males and studies including females and minorities are needed. Determining which aspects of religiosity are positively associated with the QoL in ICD patients is important for clinical considerations and would provide additional insight into mechanisms that may affect acceptance of the device, effective coping, and positive mental health.

Purpose

The purpose of this study is to examine religiosity in a diverse sample of ICD patients and to determine if religiosity is related to general quality of life and disease-specific quality of life in these patients. The following research questions guided this study:

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1. Does religiosity in ICD patients vary by demographic factors (age, race, gender), clinical factors (ejection fraction, previous shock, co morbidities, time with device) or psychosocial factors (social support, depression, anxiety, shock anxiety)?

2. Is general quality of life or disease-specific quality of life in ICD patients related to demographic factors (age, race, gender), clinical factors (ejection fraction, previous shock, co morbidities, time with device) or psychosocial factors (social support, depression, anxiety, shock anxiety)?

3. Which factors (religiosity, demographic factors, clinical factors, and psychosocial factors) are the best predictors of general quality of life or disease-specific quality of life in ICD patients?

Specific Aims:

1. To describe the relationship between religiosity and quality of life (QoL) in Implantable Cardioverter Defibrillator (ICD) patients.

2. Explore variations in these relationships based on selected individual characteristics (demographics, clinical, ICD specific, and psychosocial characteristics) in ICD patients.

Conceptual Framework

The conceptual framework guiding this study is based on the Motivational Theory of Meaning by Frankl (1962) and Wilson and Cleary's (1995) Quality of Life Model.

Frankl's Motivational Theory of Meaning

Frequently noted in the social sciences, an established theory that would be appropriate to address the concept of religiosity and quality of life in ICD population is Victor Frankl's Theory of Meaning (Frankl, 1962; 1992; 1997). Frankl, a survivor of the Nazi concentration camps, believed that every individual has an innate desire to develop a purpose in life. He also

believed that spiritual health led to psychological hardiness. Frankl proposes that all human beings are driven to find purpose and meaning in life and that purpose is specific to the individual and is derived from the situations of that person's immediate life. Finally, his theory suggests that individuals find purpose even when confronted with a hopeless situation in life and that what matters most is how such experience transforms tragedy into achievement (Frankl, 1992).

Frankl's theory has been used in research regarding spirituality, hope, and quality of life in populations with cancer (Albaugh, 2003; Meraviglia, 2004) and HIV positive individuals (Litwinczuk & Groh, 2007). To support research involving religiosity and quality of life in ICD patients, Frankl's theory would be most fitting as the individual living with this device may be searching to find meaning and purpose in life while dealing with the physical, emotional, and psychological challenges of this chronic condition and a life that is now dependent on ever-changing technology.

Wilson & Cleary's Health Related Quality of Life Model (HRQOL)

Improving outcomes such as mortality and rehospitalizations for individuals with Implantable Cardioverter Defibrillators (ICDs) is clearly an essential task for health care providers today. However, improving the quality of life (QoL) for this population is equally important. Current studies involving heart failure patients and the variables that may impact their quality of life have incorporated the conceptual framework of Wilson and Cleary's HRQOL model (Heo, Moser, Riegel, Hall, & Christman, 2005; Heo, Moser, Lennie, Zabroski, & Chung, 2007; Krethong, Jirapet, Jitpanya, & Sloan, 2008). Wilson and Cleary (1995) proposed their model based on theory and practice as well as previous research findings. The model was designed to test potential causal relationships in an effort to enhance patients' HRQOL (Wilson

& Cleary, 1995). By combining both the clinical and psychological concepts of QoL, the Wilson and Cleary Model (WCM) proposes six categories of variables that are directly or indirectly related to HRQOL: health perception, symptom status, functional status, biological/physiologic status, individual and environmental characteristics. The terms HRQOL and quality of life (QoL) are used interchangeably in the WCM. Within the model, the relationships between variables may be direct and indirect and some relationships may be bidirectional (Heo et al., 2005).

These two theoretical frameworks will guide this study and lead to the following assumptions: The person living with the situations and implications of the Implantable Cardioverter Defibrillator (ICD) is best suited to determine their individual quality of life and a relationship with religiosity may impact that quality of life and provide a sense of life purpose.

Conceptual Model

In the proposed conceptual model (see Figure 1), relationships observed may be explained by conceptual pathways, both direct and indirect, involving religiosity, patient demographics, clinical and ICD specific, and psychosocial characteristics as they may influence quality of life (QoL) in the ICD patient. For the purpose of this study, there is one outcome variable (QoL) with three dimensions of physical and mental health (SF-12) and acceptance of the device (FPAS), two categories of independent variables (demographics and clinical characteristics), with religiosity and psychosocial characteristics noted as potential moderator variables. The proposed model suggests QoL in ICD patients may be influenced by demographic and clinical characteristics with religiosity and psychosocial variables moderating this effect.

Summary

Despite the many clinical benefits of the device, the Implantable Cardioverter Defibrillator (ICD) may impact the physical, emotional, and psychosocial aspects of life for
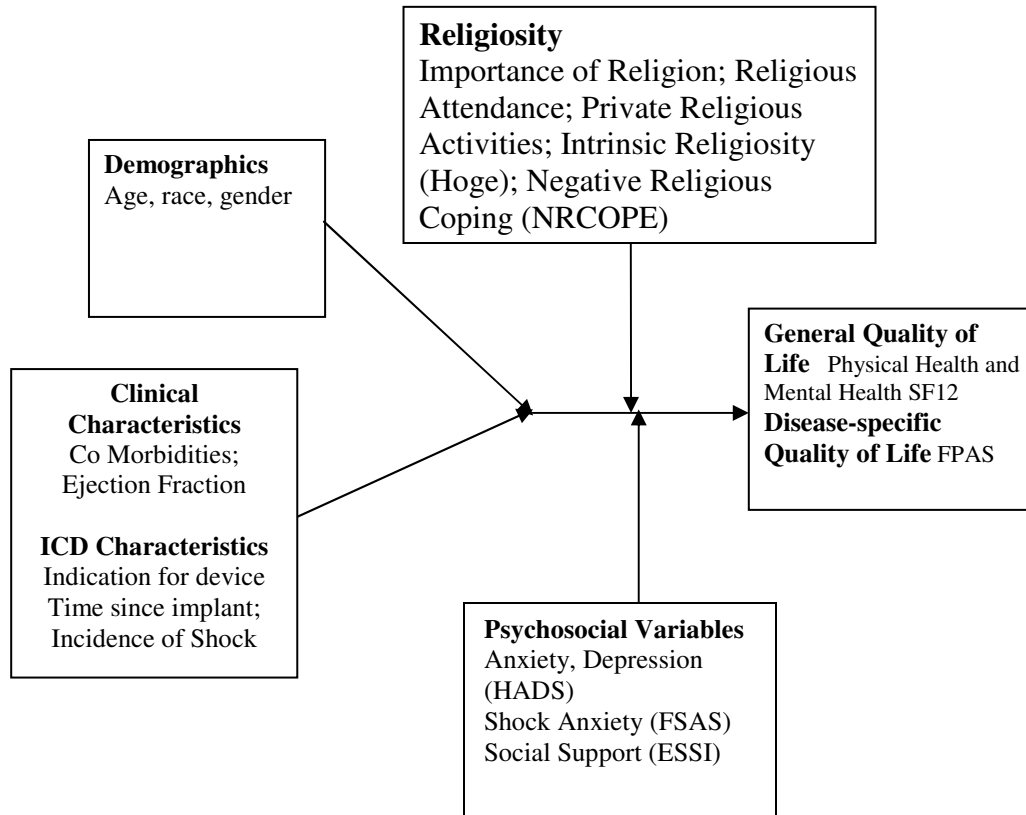
Figure 1. Proposed Model of Quality of Life in ICD patients.

patients and families. For the health care provider, it is essential to identify such ramifications and provide support for the ICD patients and their caregivers in an effort to promote positive coping and overall quality of life (QoL). Religious beliefs and participation in religious activities may provide these individuals with comfort and a means of coping (Pargament, 1997). Assessment of religiosity in ICD patients may provide useful information leading to strategies that maintain or improve QoL for those living with this life-saving device. The results of this study will not only add to the current body of knowledge of religiosity and conceptualization of the term, they will build support for the influence of religiosity on QoL for individuals living with a chronic illness. While this study will have relevance for health care providers of many disciplines, it is particularly relevant for nursing because the general paradigm of nursing science is based on a holistic approach to patient care. The nurse, whether at the staff or advanced practice level, is in a unique position to provide support for the physical, psychosocial, and spiritual needs of the ICD patient.

CHAPTER 2: REVIEW OF THE LITERATURE

For the person living with an Implantable Cardioverter Defibrillator (ICD), the physical and psychosocial effects can significantly impact their overall quality of life (QoL). The constant threat of unpredictable shocks and the physical and psychological impact of experiencing them, may contribute to the ICD patient's mental health and general satisfaction with life. Recent studies have examined the influence of religiosity on health outcomes and QoL in various populations (Ai, Peterson, Bolling, & Rodgers, 2006; Contrada et al., 2004; Gall, 2004; Koenig, 2007b; Koenig, Cohen, Blazer, & et al., 1992; Rippentrop, Altmaier, Chen, Found, & Keffala, 2005; Smith et al., 2003). However, to date, there is a lack of research investigating the relationship among religiosity and QoL in ICD patients using a model which includes other factors (demographic, clinical, psychosocial) known to be related to acceptance of living with an ICD. This chapter will begin with an overview of the ICD, indications and ICD demographics, and the experiences of patients following implantation of an ICD, including the influence on physical and psychosocial functioning. The literature related to QoL in the ICD population, including the influence of various physical and psychosocial factors, will be discussed. Finally, a review will be presented on the influence of religiosity on general health outcomes, coping with cardiovascular conditions, and living with an ICD.

Implantable Cardioverter Defibrillators (ICDs)

The Implantable Cardioverter Defibrillator (ICD) is a small implanted device that is connected to the heart via electronic leads designed to monitor and detect life-threatening dysrhythmias. The device is designed to deliver cardioversion, pacing, and/or defibrillation depending on the type of intervention needed to abort the abnormal cardiac rhythm (Edelman, Lemon, & Kidman, 2003; Kim, 2007). Motivated by the sudden death of a colleague, two

physicians in the 1970s, Drs. Michel Morowski and Morton Mower developed the concept of an implantable device that would automatically monitor, detect, and treat lethal ventricular fibrillation. After several years of testing and research, the first implanted device was placed in 1980 in a young woman who suffered from recurrent ventricular fibrillation (DiMarco, 2003; Morowski, Mower, & Reid, 1980). Since then, the Implantable Cardioverter Defibrillator (ICD) has evolved from the final option for patients with life-threatening ventricular arrhythmias to the current standard treatment for primary (first-time prevention of lethal event) and/or secondary prevention (prevention of recurrence of potentially lethal cardiac arrhythmias) in patients with cardiac disease (DiMarco, 2003; Goldberg & Lampert, 2006).

To date, ICDs are effective in reducing mortality in both patients at risk for Sudden Cardiac Death (SCD) and those patients living with heart failure (Thomas et al., 2006). Clinical trials have demonstrated that the use of ICDs with conventional pharmacological therapy is the preferred treatment option. The Multicenter Automatic Defibrillator Implantation Trial (MADIT) and the Antiarrythmics Versus Defibrillator (AVID) trial both demonstrated the efficacy of ICDs in decreasing patient mortality (AVID, 1997; Moss et al., 1996; Sears et al., 1999). A subsequent investigation, MADIT-II, examined the prophylactic use of ICDs in 1,232 patients following myocardial infarction who had poor left ventricular function but no arrhythmias. They demonstrated a 31% decrease in mortality, based on reduction of SCD (Greenburg et al., 2004). Due to the overall improved survival rates in the ICD groups, all three of these clinical trials were stopped prematurely by their data safety and monitoring boards (AVID, 1997; Greenburg et al., 2004; Moss et al., 1996; Thomas et al., 2006). Further investigative trials have revealed the efficacy of ICDs in reducing mortality for heart failure patients. In the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), researchers compared the use of ICDs with conventional

therapy plus amiodarone, and conventional therapy plus placebo in 2521 heart failure patients

with increase risk of SCD, but no documented ventricular arrhythmias. In the patients who

received the ICD, there was a 25% reduction in mortality when compared to those patients who

received conventional therapy plus placebo and those who received conventional therapy plus

amiodarone (Bardy, Lee, Mark, & et al., 2005; Thomas et al., 2006).

Since its introduction, there have been numerous advances in ICD technology which have

expanded its use to include treatment for both lethal and potentially lethal cardiac rhythms in

addition to cardiac resynchronization therapy (CRT) for chronic heart failure (Goldberg &

Lampert, 2006). The ICD device is comprised of a pulse generator and cardiac pacing and

defibrillator lead wires. The pulse generator contains a battery, intricate circuitry,

microprocessors, and a telemetry monitor (DiMarco, 2003). Insertion of the ICD has changed

dramatically in the past few decades. Initial insertion of the device was performed through a

thoracotomy approach with pacing and defibrillation leads attached to epicardial patches. Early

devices were large and bulky and placed in the lower abdominal area. Current technological

advances have now afforded the patient the option of a smaller device. Typically, the ICD is

implanted under the subcutaneous pocket of the pectoral region of the patient's upper chest. A

transvenous lead is placed into the patient's right ventricle that contains a defibrillator shock coil

and additional leads may be placed for pacing in the right ventricle and/or the left ventricle

(DiMarco, 2003). The ICD is programmed to monitor, detect, and treat abnormal cardiac

rhythms through several technological mechanisms. The electrophysiologist (a cardiologist with

specialized training in electrophysiology), who implants the ICD, is trained to program the

device based on the patient's underlying cardiac disease and presenting symptoms.

Subsequently, following implantation, the ICD is tested and the patient receives a device shock

while sedated to insure proper functioning. Follow-up for the patient usually involves scheduled clinic visits to assess the patient's response to the ICD, in addition to interrogating the implanted device to assess the battery, lead impedance, and examine the presence and treatment of past arrhythmia episodes.

Based on guidelines from the American College of Cardiology and the American Heart Association, patients can be treated with an ICD for both primary and secondary prevention of Sudden Cardiac Death (SCD). Primary prevention of SCD is commonly defined as a decrease in mortality in patients at risk for cardiac arrest due to pre-existing disease but without clinical evidence of lethal arrhythmias. Secondary prevention of SCD is noted as reduction in the mortality for patients who have experienced and survived a cardiac arrest due to ventricular arrhythmias (Myerburg, Reddy, & Castellanos, 2009). In addition, there are less common cardiac conditions that may be indications for treatment with an ICD. For example, the ICD may be indicated for either acquired or inherited conditions such as viral myocarditis, cardiac sarcoidosis, hypertrophic cardiomyopathy, or Long QT syndrome (ACC/AHA/NASPE, 2002). With the positive results from numerous clinical trials in preventing SCD, implantation of the ICD has steadily increased nationally and internationally (Goldberg & Lampert, 2006; Myerburg et al., 2009; Thomas et al., 2006). Despite the established benefits of the ICD, the effects of living with this device on quality of life (QoL) and psychosocial status are equivocal (Thomas et al., 2006). To achieve the full benefits from the ICD, the patient's QoL and psychosocial status must be addressed and maintained (Freidman, Thomas, Inguito, & et al., 2006).

With the advances in ICD technology and enhanced approved indications, the population living with these devices is expanding. Consequently, an understanding of the impact of living

with an ICD is necessary for health care providers to be able to improve outcomes for these individuals and their families beyond the mortality benefit (Dunbar, 2005).

Quality of Life in ICD Patients

To date, there is a large body of literature addressing the psychological and health related quality of life (QoL) in the ICD population. A multidimensional construct, patient perceived QoL encompasses three core domains: physical, emotional, and social functioning (Kamphuis, Verhoeven, de Leeuw, & et al., 2004; Sears et al., 2009). Meta analysis of QoL studies in ICD populations has reported QoL following implant as unchanged or improved in a majority of ICD patients, unrelated to whether the device is indicated for primary or secondary prevention (Dunbar, 2005; Kamphuis et al., 2003; Sears et al., 2009).

In the SCD-HeFT trial, the largest single QoL study in ICD patients, heart failure patients treated with an ICD had significantly improved psychological QoL at 3 and 12 months post implant compared to heart failure patients treated with amniodarone alone. At 30 months, however, there were no differences between the groups in patient reported QoL (Bardy et al., 2005; Sears et al., 2009).

Sears et al. (1999), examined global QoL and psychosocial issues in a national survey of 450 ICD patients and spouses. More than 90% of ICD patients reported QoL either improved (45%) or unchanged (46%) after implantation. A significant difficulty in emotional adjustment was reported in approximately 15% of ICD patients. Study patients that were 50 years of age and younger, noted better general health, but worse QoL and emotional functioning than the other age groups (Sears et al., 1999; Sears & Conti, 2002).

Age and Quality of Life in ICD Patients

Even though the ICD is noted as a life-saving technology, adjusting to life after ICD implantation may vary based on the age of the patient. In a qualitative study, McDonough (2009) investigated the experiences and concerns of young adults (18-40 years) living with an ICD. The study data revealed these individuals expressed concerns unique to this age group, including body image, physical activity, childbearing, child rearing, and worries regarding financial security. All participants experienced anxiety and depression, however, for many, these mood disturbances dissipated months following ICD implantation. The findings suggested the importance of age-appropriate interventions to address the many psychosocial concerns of this ICD subset of patients (McDonough, 2009). Sola and Bostwick (2005) reported that ICD patients less than 50 years of age were at risk for increased anxiety, reduced QoL, and compromised adjustment to the device. In a more recent literature review, Bostwick and Sola (2007) noted six additional studies that demonstrate conflicting results. DeMaso, Lauretti, Spieth, & et al. (2004) in a study involving 20 ICD patients ages 9-19 found despite declines in physical functioning, participants did not reveal increased anxiety or depression. The sample of young ICD patients however, did express an increase need for social acceptance (DeMaso et al., 2004). In a study of 91 ICD patients, Bilge, Ozben, Demircan, and et al. (2006) determined there were no significant differences between age and depression or anxiety scores. In a separate study, Yarnoz and Curtis (2006) revealed that elderly patients reported more anxiety and less satisfaction with physical activity when compared to younger ICD patients.

Further studies investigating age and QoL in ICD patients have noted differing results (Bostwick & Sola, 2007). Hamilton and Carroll (2004) examined 70 ICD patients ages 21-84 years and reported anxiety scores in younger subjects were significantly higher than older

patients. Despite the finding that older patients experience less anxiety than the younger group, older ICD patients perceived minimal improvements in physical health and functioning after receiving their ICD. The study suggested a reciprocal relationship between QoL and anxiety levels (Bostwick & Sola, 2007). Overall, despite minor limitations in their functional status, younger ICD patients are thought to experience worse QoL and more psychological distress when compared to older adults (Friedmann et al., 2006; Thomas et al., 2006).

In a recent study, Sears et al. (2009) examined quantitative studies regarding ICD psychosocial outcomes for children and young adults. Their literature review indicated that anxiety may be the most problematic psychosocial reaction for young ICD patients and since young ICD patients may also be more likely to experience shocks, shock anxiety is especially common. In one study, young adults with hypertrophic cardiomyopathy (N=22), 71.4% of secondary prevention patients experienced an ICD shock compared to 11% in an adult sample (Kaski, Tomè Esteban, Lowe, & et al., 2007). In separate studies it was suggested that young ICD patients experience up to 38% of inappropriate shocks and approximately 50% of young ICD patients over a 4-year period also experienced inappropriate device shocks (Gradaus et al., 2004; Korte, Köditz, Niehaus, Paul, & Tebbgenjohanns, 2004).

Gender and Quality of Life in ICD Patients

Although the majority of patients who receive an ICD are male, there are a few studies that compare QoL for men and women with ICDs. Female gender may be an independent risk factor related to QoL. Thomas and colleagues (2006) noted that female patients of an ICD reported lower scores on the emotional subscale of the SF-36 when compared to male ICD patients. Women who receive an ICD device often face additional concerns related to childbearing, nursing, parenting, body image, and mammograms (Dunbar, 2005; Sowell, Kuhl,

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Sears, Klodell, & Conti, 2006; Walker, Campbell, Sears, & et al., 2004). Female ICD patients may experience more pain during implantation due to the sensitivity of the breast tissue and frequency of use of the upper extremities with daily activities (Dunbar, 2005).Compared to men, women ICD patients are younger, less functional, and less likely to have spousal support (Bostwick & Sola, 2007; Vasquez, Kuhl, Shea, & et al., 2008). In an international multi-center study including 88 female ICD patients, Vasquez et al. (2008) revealed younger women (under 50 years of age) reported higher rates of death and shock anxiety when compared to the older female ICD patients. Two separate groups of researchers (Sowell et al., 2006; Walker et al., 2004) noted that female ICD patients revealed significantly more depression and anxiety than male ICD patients with the common links to this distress being body image and loss of social roles. However, consensus regarding the effects of gender on QoL in ICD patients continues to be an issue. In another study, Smith, Dubar, Valderrama, and Viswanathan (2006) found women experienced more pain and less sleep than their male counterparts, but reported no increase in depression and anxiety. Overall, female ICD patients can be considered a vulnerable subpopulation and future research is warranted to support interventions that are designed to meet their unique needs and enhance their quality of life.

Race and Quality of Life in ICD Patients

Similar to the literature to date on women and utilization of Implantable Cardioverter Defibrillators (ICDs), there is a scarcity of studies that include African American (AA) ICD patients. Despite the fact that age-adjusted sudden cardiac death (SCD) rates are highest for this population compared to other racial groups, black patients are less likely to receive an ICD for primary prevention of SCD (Thomas, Al-Khatib, Kelsey, & et al., 2007). Using data from the National Registry to Advance Heart Health (ADVANCENT) of more than 7,170 patients eligible

for ICD implant, Thomas et al. (2007) determined that black patients (n=660) were more often women, younger, had more co-morbidities, and lower mean ejection fraction. Their results noted that blacks were significantly less likely to have ICD implantation (30% vs. 41%, p<0.001) when compared to white patients (Thomas et al., 2007). These findings have been supported in another study examining the influence of race and gender on the use of ICDs in eligible patient populations. In an observational analysis of more than 13,000 patients with heart failure and an ejection fraction of 30% or less, Hernandez, Fonarow, Liang, and et al. (2007) found that among 4615 eligible patients 35.4% received ICD therapy at discharge. Of those patients, 28.2% were Black women, 29.8% white women, 33.4% black men, and 43.6% white men. Overall, the study results showed that less than 40% of potentially eligible cardiac patients received ICD therapy, with rates lowest for women and black men (Hernandez et al., 2007). Despite inclusion of both white and black ICD patients in QoL research, there were no studies found that specifically identified racial differences in QoL. To effectively address the apparent gap in knowledge related to gender and racial issues in ICD patients, more research is needed to promote an understanding of the perceptions held by these challenged populations. Through further study, pertinent racial and ethnic perspectives may be revealed and incorporated into culturally relativistic interventions in an effort to eliminate health care disparities.

Co-Morbidities and Quality of Life in ICD Patients

In their literature review on the QoL and psychological status of ICD patients, Thomas et al. (2006) examined longitudinal studies to address relationships of patients' severity of cardiac illness and changes in QoL over time. They reported a single study involving 81 heart failure patients treated with ICDs by Kühlkamp (2002). The study found that ICD patients with NYHA class III/IV reported significant improvement in QoL at 1 month and 3 months following

implantation, while patients with NYHA class II heart failure revealed no changes in QoL at the same identified time intervals. Overall, Thomas and colleagues noted that the QoL in ICD patients is frequently poorer than that in the general population and that QoL in ICD patients in past studies did not differ from QoL in heart failure patients treated with pharmacological therapy or pacemakers (Thomas et al., 2006). However, there are other studies that note that the QoL in ICD patients may be better when compared to patients treated with drug therapy alone. Herbst et al. (1999) in a cross-sectional study of 157 patients with lethal ventricular arrhythmias sought to determine whether differences in treatment were associated with changes in psychological distress and QoL The study sample consisted of four groups: ICD only (n=24); ICD plus anti-arrhythmic drug (n=25); anti-arrhythmic drug only (n=35); and a general cardiac group (n=73). Using the SF-36 and three supplementary scales that measured sleep, marital and family functioning, and sexual issues, groups were then compared. They found no significant differences in reported QoL and psychological distress between patients with or without ICD, even after controlling for age, gender, disease severity, and duration of treatment. However, the drug treatment patients reported more impaired QoL in physical functioning, vitality, emotional role limitations, and sleep in addition to greater psychological distress in comparison to the ICD groups. These results suggest that for the ICD patient, QoL may be higher in comparison to patients treated only with pharmacological therapy for their life-threatening arrhythmias (Herbst et al., 1999; Sears & Conti, 2002).

In yet another study using three groups, there was no significant difference in QoL or psychological distress between ICD patients (n=45) and those treated with Anti-arrhythmic drugs (n=30) or the cardiac sample group (n=29). Study results indicated that younger patients and those with more severe cardiac dysfunction reported reduced QoL (Arteaga & Windle, 1995;

Sears & Conti, 2002). Patients living with an ICD may also be challenged with multiple chronic health conditions that impact their overall QoL and psychosocial well-being. Future research focused on understanding the relationships between QoL and religious coping in ICD patients may provide knowledge that would benefit this population facing multiple cardiac related health conditions.

Time Since Implantation and Quality of Life in ICD Patients

As a separate factor that may impact QoL, time since implant has been studied in the ICD population. Studies reveal that most ICD patients adjust after the first year following device implantation (May, Smith, Murdock, & Davis, 1995; Schron, Exner, Yao, & et al., 2002). However, other research findings indicate that despite initial improvement in QoL, some ICD patients experience a trend toward reduced functioning following implantation. With a prospective, longitudinal design, Carroll and Hamilton (2008) investigated changes in health and psychological status and QoL in ICD patients from implantation to 4 years later. They measured QoL using the SF-36 and the Quality of Life Index- Cardiac III as well as the Profile of Mood States at implantation, 6 months, and 1, 2, 3, and 4 years in a sample of 41 men and women (Carroll & Hamilton, 2008). After 6 months, ICD patients indicated an improved mental state and less psychological distress, suggesting adjustment does occur over time. However, the ICD patients in this study did note significant reductions in physical functioning at 3 and 4 years after device implant. Despite their findings, the authors noted that a major study limitation was related to inadequate power to detect differences with the small convenience sample.

In a cross-sectional study of 58 ICD patients who had their device from 1 to 4 years, the time since implant was predictive of general QoL despite patient's age. QoL was assessed using the AVID checklist and was noted to be lower the longer the ICD was in place (Thomas et al.,

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2006; Wallace et al., 2002). Flemme et al. (2005) in a longitudinal study examined long-term (defined as 6.9 years) QoL in 35 Swedish ICD patients who received the device for secondary prevention of lethal ventricular arrhythmias. Using the Quality of Life Index Cardiac version (QLI-C) and the Mishel Uncertainty in Illness Scale, the researchers determined that the overall QoL and health/ functioning for the ICD participants were unchanged over time and uncertainty of illness decreased. Their results indicated that uncertainty was a predictor of low QoL (Flemme et al., 2005).

Freidmann et al. (2006), in a cross-sectional assessment of QoL and psychological responses of 48 patients who received ICDs within the past 10 years, noted different findings related to QoL and time since implant. Using the Beck Depression Inventory and the Sickness Impact Profile as measurement tools with a final sample of 48 ICD patients, study results indicated that ICD patients who had the device for longer time periods experienced worse depression and QoL. Time since implant significantly predicted overall QoL, as the researchers reported the psychosocial and physical dimensions of QoL explained 55.5, 54, and 34.9% of the variance, respectively (Freidmann et al., 2006). To truly understand and address the unique needs of the ICD population related to physical, emotional, and psychosocial functioning and adjustment to living with their device, researchers need to include the key factor of time since implantation with larger samples.

Incidence of Shocks and Quality of Life in ICD Patients

It is reasonable to include the incidence of ICD shocks as a factor in the QoL of patients living with this device. Experiencing shocks is physically painful and emotionally disturbing for ICD patients and many individuals experience fear, anxiety, hyper vigilance, and uncertainty (Dougherty & Hunziker, 2009; Dunbar, 2005). Schron et al. (2002), in the AVID trial, reported

that among the sample of 416 ICD participants enrolled, sporadic shocks were associated with reduced QoL. The researchers found that patients who experienced device shocks had decreased mental and physical functioning and an increased number of concerns compared to ICD patients who had not received any shocks (Dunbar, 2005; Schron et al., 2002). Similar findings were noted in a study of 167 ICD patients by Kamphuis et al. (2003). They concluded that patients who have experienced an ICD shock adapt poorly to living with the device and reveal more anxiety and depression than patients who received no device shock (Kamphuis et al., 2003). In a multi-site randomized study involving 412 ICD patients, investigators of the OPTIC trial noted that despite use of advanced device technology and pharmacological treatment, ICD shocks occur commonly in the first year after implant, decreasing QoL and increasing health care utilization (Connolly, Dorian, Roberts, & et al., 2006). Inappropriate device shocks continue to be problematic for many patients with the possibility of experiencing multiple shocks or "ICD storm" defined as more than 3 shocks in 24 hours (Sears & Conti, 2002; Sears et al., 2009). Passman, Subacius, Rue et al. (2007) noted in the DEFINITE trial (Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation Study) that ICD shock was associated with a reduction in some measures of QoL, but effects were not likely to result in clinically significant alterations until the patient had received 5 or more device shocks (Passman et al., 2007). Researchers from the MADIT-II study noted that inappropriate shocks occurred commonly; constituting 31.2% of the total shock episodes and were associated with increased risks of mortality (Daubert, Zareba, Cannom, & et al., 2008). Whether ICD shocks received are appropriate or inappropriate, the incidence of even an isolated shock event can be a distinguishing factor in the life of the ICD patient and is important to ICD patients and families (Dunbar, 2005; Sears et al., 2009). Future

studies involving ICD patients must address the physical, psychosocial, and emotional impact of device shocks in an effort to improve the QoL for these individuals.

Psychosocial Factors and Quality of Life in ICD Patients

Despite overall positive acceptance following device implantation, ICD patients experience psychological problems such as anxiety, depression, anger, and fear (Bostwick & Sola, 2007; Dunbar, 2005; Heller, Ormont, Lidagoster, Sciacca, & Steinberg, 1998; Kamphuis et al., 2003; Sears et al., 1999; Sears & Conti, 2002). Many ICD patients often fear that the device will shock them, that the device will fail to work, or that physical activity will cause the device to fire. Additional concerns include changes in the ICD patient's role and mental status, sexual and recreational activities, physical limitations, and driving restrictions (Dunbar, 2005). In a review of literature, Sears et al. (1999), noted 24-84% of ICD patients experienced increased symptoms of anxiety following implantation with 13-38% being clinically diagnosed with significant anxiety disorders. Depression symptoms have been reported in 24-33% of ICD patients, which is consistent with other cardiac populations (Sears & Conti, 2002).

For many ICD patients, the level of psychological distress may decline over time. However, for others, mood disturbances such as anxiety, fear, depression, and hyper- vigilance can persist (Dunbar, 2005). As a result, some ICD patients may experience worsened QoL and a substantial proportion of them will develop significant psychological disturbances (Bostwick & Sola, 2007). A number of factors have been associated with increased psychological distress and decreased functioning including age, gender, multiple co-morbidities, negative interpretation of treatment with the ICD, reduced physical functioning and incidence of device shocks or ICD storm (Dunbar, 2005; Hamilton & Carroll, 2004; Sears et al., 2005). Furthermore, Sears and Conti (2002) in their review of literature on QoL and psychological distress, revealed similar risk

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factors for experiencing psychological difficulties including previous psychiatric problems, younger age (<50 years), female gender, increase rate of device shock, multiple comorbidities, poor social support, and decreased understanding of cardiac condition. Thomas et al. (2006) supported these findings by stating that low anxiety and high social support were predictive of better QoL. Documented in the literature, social support is noted as a coping resource linked to decreased morbidity and mortality in cardiac patients and may provide a buffer for stressful situations (Ahern, Gorkin, Anderson, & et al., 1990; Dunbar, 2005; Gorkin, Schron, Brooks, & et al., 1993; Vaglio, Conard, Poston, & et al., 2004). In noting predictors of QoL in ICD patients, Sears et al. (2005) found that social support accounted for a significant amount of the variance in predicting QoL outcomes. The use of social supports and organized support groups has been shown to improve ICD patients' ability to cope, facilitate information-sharing, and enhance their psychosocial adjustment to living with the device (Dickerson, Posluszny & Kennedy, 2000; DeBasio & Rodenhausen, 1984; Ocampo, 2000; Thomas et al., 2006). However, in a study to assess the influence of social support on self-management behaviors, Luyster et al. (2009) noted that social support did not significantly predict adherence to dietary guidelines in a sample of eighty-eight heart failure patients treated with an ICD. Thus, additional research is warranted to understand the role of social support in self-care behaviors of the ICD population.

In addition to social support, education to promote the patients' understanding of their cardiac condition and the functions and implications of the ICD are essential. Despite findings that ICD knowledge was not related to QoL in the study sample of 70 patients, Sossong (2007) noted that emphasis is needed for patient education that addresses issues of living with the device, grieving the loss of a stable heart rhythm, and celebrating life returned by implantation of the device. To date, few studies have addressed the impact of ICD knowledge on the outcome of

QoL in patients with ICDs. As the number of individuals eligible for ICDs continues to increase, health care providers must be prepared through education and research to address the many psychosocial issues that challenge this patient population and their families to assist them in successful transition to living with an ICD.

Religiosity and Religious Coping

While some might consider religiosity and religious coping as psychosocial variables, Frankl and others would support these separately. For many individuals, religion is essential to their identity and sense of self and is frequently used to cope with difficult life situations. A national Gallup poll survey indicates that nearly 93% of Americans believe in God or a higher power; 89% report a religious affiliation; and 80% report that religion is fairly or very important, noting " I receive a great deal of comfort and support from my beliefs" (Gallup, 2008). In a meta-analysis representing nearly 126,000 total study participants, McCullough, Howt, Larson, Koenig, and Thoresen (2000) concluded that religious involvement has a favorable association with all-cause mortality and that highly religious people were 29% more likely to be alive at any given follow-up time. They noted that given the large numbers of religiously active individuals, this positive association is a health phenomenon with relevance and future research in the area of religion and health outcomes is important to health care professionals (McCullough et al., 2000).

Many people when faced with medical illness likewise, seek religion and religious practices as a way to cope with physical illness. Over 40% of individuals indicate that religion is the most important factor that keeps them going (Koenig, 2007a). Religious coping is defined by Koenig (2007a) as:

> …the use of religious beliefs or practices to reduce the emotional distress caused by loss or change. Religious beliefs and practices, then, are used to regulate emotion during times

of illness, change, and circumstances that are out of the patient's perceived control (p. 20).

Studies dating as far back as the 1880s have indicated religion as a possible influence on depression (Koenig, 2001). The first study to highlight that religiosity was related to recovery from a depressive disorder was conducted by Koenig et al. (1992). Through structured interviews of 850 older men with medical or neurological illness hospitalized at the Veterans Administration hospital, the investigators found that the degree to which religion was used to cope (religious coping) was inversely correlated to both self-rated and observer-rated depression. The relationship was stronger in those facing more severe disability. In the prospective phase of the study, following more than 200 men an average of 6 months after discharge, the investigators noted religious coping as the only characteristic that predicted lower future depression scores (Koenig et al., 1992). In over 100 investigations examining the association between religiousness and depression during the twentieth century, nearly two-thirds (65%) of the observational studies noted significantly lower rates of depression or depressive symptoms in those who were more religious and 68% of prospective studies revealed greater religiousness predicted less depression (Koenig, 2007a).

Similar results were noted in a meta-analysis of 147 studies by Smith et al. (2003). They reported that in all studies greater religiousness is reliably associated with fewer depressive symptoms. Further examination also revealed that the association was stronger in studies of individuals who were undergoing stressful recent life events and the effect was moderated by the type of measure of religiousness used in the study, with negative religious coping associated with higher depressive symptoms (Smith et al., 2003).

Despite the notable protective effects of positive religious coping, it is important to mention that religious methods of coping are neither always positive nor negative and health care professionals should be sensitive to the potential helpful and detrimental sides to religious coping (Pargament, Smith, Koenig, & Perez, 1998). Negative religious coping is commonly associated with poorer health (Ai et al., 2006). In a longitudinal study of 596 medical inpatients, Pargament et al. (2001) examined the impact of religious struggle on mortality. Their study results suggest that elderly men and women who experience religious struggle during their medical illness may be at an increased risk of death, even after controlling for demographics and baseline mental and physical health (Pargament et al., 2001). For the health care professional providing patient care, such study findings emphasize the significance of differentiating potential adaptive and maladaptive religious coping methods (Ai et al., 2006).To more accurately assess relationships between religiosity and health outcomes and develop appropriate interventions for individuals, it is essential to include measurement of both positive and negative religious coping.

Influence of Religiosity on General Health Outcomes

General well being, better coping, less depression, and positive emotions appear to be more prevalent in people who are religious. Levin (1994) following an extensive review of literature concluded that religiosity appears to have a salutary influence on health. One can surmise that religiousness may also lead to improved physical health and greater longevity (Koenig, 2007a). Research involving religiousness and the immune system is currently in its infancy, yet there are published studies that note clinically significant findings suggesting a relationship (Koenig, Cohen, George, & et al., 1997; Lutgendorf, Russell, Ullrich, Harris, & Wallace, 2004). In their study of more than 1,700 community-dwelling adults, Koenig et al. (1997) found high levels of the inflammatory marker, cytokine interleukin 6 (IL-6) more

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common in those individuals who did not attend religious services when compared to those who did (Koenig, 2007a; Koenig et al., 1997). More recently, Lutgendorf et al. (2004) replicated this study in a population from another area of the country and again noted similar results, with frequent church attendees had lower IL-6 levels and greater longevity.

The influence of religion and religious coping may extend to populations faced with chronic health issues. Religious involvement has been shown to be associated with better health outcomes, coping skills, and QoL, even during terminal illness (Mueller, Plevak, & Rummans, 2001). Gall (2004) investigated religious and general coping in relation to physical, social, and emotional functioning in a group of 34 prostate cancer patients using the Religious Coping Scale, the Brief COPE survey, and the SF-36. Study findings revealed religious coping was related to positive aspects of cognitive appraisal and both active and avoidance forms of general coping. Despite the limitations of self-reporting measures and small sample size, results suggest that religious coping may be a strong predictor of general functioning in prostate cancer survivors and may be used to help "block out" the experiences and challenges of living with cancer (Gall, 2004).

In a population sample of 122 patients dealing with chronic pain, researchers found that religion/spiritual practices (prayer, meditation) were inversely related to physical health outcomes such that those with worse physical health were more likely to engage in private religious activities possibly as a way to cope (Rippentrop et al., 2005). Using the Brief Multidimensional Measure of Religion and Spirituality (BMMRS), the McGill Pain Questionnaire, and the Multidimensional Pain Inventory, the investigators found significant relationships between components of religion/spirituality and health outcomes. They noted that those patients dealing with the worst physical pain may be more likely to turn to private religious

activities as a means to cope and that negative religious coping may be an obstacle to healthy

emotional functioning (Rippentrop et al., 2005). Their research findings emphasize the need for

future research to examine the role of religious coping in caring for patients with chronic health

problems.

Influence of Religiosity and Coping with Cardiac Disease

Coronary artery disease (CAD), a leading cause of disability and death, is one of the most

common health problems challenging our world today. Epidemiological research involving

various religious groups has provided evidence that religious involvement is associated with

lower risk of myocardial infarction and CAD (Koenig, 2007a; Koenig, McCullough, & Larson,

2001). Further research has suggested that religious practices may have a positive effect on

cardiac rhythm. In an Italian study of 23 healthy adults, Bernardi, Sleight, Bandinelli, and et al.

(2001) examined the autonomic and cardiovascular effects of saying the rosary in Latin and

repeating a yoga mantra in Hindu. When recited six times per minute, the researchers noted a

significant improvement in the cardiovascular rhythms and baroreflex sensitivity, a finding

associated with a positive cardiac outcome of greater heart rate variability (Bernardi et al., 2001).

Studies have also examined the relationship between religiosity and cardiac surgery outcomes in

an attempt to note if religion has an effect on post-operative healing and functioning. A

prospective study at Dartmouth Medical Center, conducted by Oxman and colleagues (1995),

followed 232 post- operative patients ages of 55 and older for one and six months after elective

cardiac surgery. Religious variables including affiliation, religious attendance, strength and

comfort from religion, and self-rated religiousness were examined. After adjusting for other

predictors, analysis revealed that patients with lack of religious strength or comfort from religion

were more than three times more likely to die. Of the patients who had high religious strength

and comfort, only 2.5 % died, as compared to over 21% of the 49 patients who reported no strength or comfort from religion (Oxman, Freeman, & Manheimer, 1995).

A second study, examining the impact of religiousness and psychosocial outcomes in cardiac surgery patients was conducted by Contrada et al. (2004). In a prospective study, the researchers assessed 142 cardiac surgery patients one week prior to surgery using instruments to measure religious attendance, intrinsic religiosity (religiousness) using items from the Hoge Scale, psychosocial factors using the Beck Depression Scale, the Life Orientation Test, and the Multidimensional Scale of Perceived Social Support. Two dependent variables were then assessed following surgery, post-operative complications and hospital length of stay determined by medical chart review. Frequency of religious attendance was unrelated to complications and frequency of prayer had no predictive effect. The study's most noteworthy finding was evidence that patients with stronger religious beliefs had fewer complications and reduced hospital length of stay (Contrada et al., 2004). Despite the limitations of less comprehensive assessment of biomedical risk factors and the use of a convenience sample, the study suggests that religious involvement may influence adaptation to cardiac procedures and further supports previous findings linking religion to health outcomes (Koenig, 2007a).

In a more recent study involving cardiac surgery patients, Ai and colleagues (2006), examined 335 patients, ages 35-89, using a prospective longitudinal investigation to determine the effect of depression and religious coping on post-operative global functioning. Multiple regression analysis revealed that preoperative positive religious coping contributed to better postoperative global functioning, even after controlling for preoperative depression and other patient characteristics (age, illness impact, non-cardiac conditions). Despite the methodological merit of a larger sample size, the study patients were white, of an affluent socioeconomic status,

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and of the same faith background, therefore limiting generalizability of results. Future research is needed to examine religiosity in other cardiac populations with various racial, socioeconomic, and faith backgrounds.

Summary

The presented review of literature supports the idea that patients living with an ICD are challenged with physical, emotional, and psychosocial issues that may impact their QoL. Religious coping may be an important component for dealing with these stressors. Despite growing evidence of the beneficial effects of religiosity on patients with chronic illness, there are no studies to date that address the influence of religiosity on the QoL in the ICD population. Additionally, it is important to note the need for future research involving female and non-white ICD patients. Therefore, the proposed study was designed to examine the relationship among religiosity and QoL in ICD patients, with the intent to include men and women from various racial and ethnic backgrounds. In addition, this study will explore relationships among religiosity, QoL, and various demographic, clinical, ICD specific, and psychosocial characteristics.

CHAPTER 3: METHODOLOGY

The purpose of this chapter is to describe the research methodology used to address the study questions:

1. Does religiosity in ICD patients vary by demographic factors (age, race, gender), clinical factors (ejection fraction, previous shock, co morbidities, time with device) or psychosocial factors (social support, depression, anxiety, shock anxiety)?

2. Is general quality of life (QoL) or disease-specific QoL in ICD patients related to religiosity factors, demographic factors (age, race, gender), clinical factors (ejection fraction, co morbidities, time since implant, incidence of shock) or psychosocial factors (social support, general anxiety and depression and shock anxiety)?

3. Which factors (religiosity, demographic factors, clinical factors, and psychosocial factors) are the best predictors of general quality of life or disease-specific quality of life in ICD patients?

Research Design

A descriptive correlational design was used to examine the relationships between religiosity and QoL in Implantable Cardioverter Defibrillator (ICD) patients. In addition, the influence of demographics, clinical characteristics, and psychosocial factors on these relationships was explored. Based on Polit and Beck (2008), this design allows for the examination of associations between variables and the potential for the discovery of variables that can be manipulated for future research.

Setting and Sample

The study sample consisted of patients recruited from an outpatient cardiology clinic associated at an academic-affiliated hospital located in southeastern North Carolina. The patients

seen in the clinic are from a variety of socioeconomic backgrounds. A purposive convenience sample was used; every patient seen in the clinic between January and August 2010, who met inclusion criteria, was asked to participate. Benefits of using this type of sampling include: (1) an increase likelihood of a more diverse sample reflecting the ethnicity of the population served, (2) an increase sample size that can increase the power to detect statistically significant responses and (3) an opportunity to capture or improve heterogeneity of the sample (DeJong, 2007).

The sample size goal for this study was 100 subjects. This sample size was based on two aspects of sample size estimation for multiple regression analyses. The first consideration was identifying a sample size for detecting a minimum R2 of 12 to 15% at the 0.05 level with a power of .80 with 5 – 10 predictor variables. Using a table from Hair, Blauch, and Babin (2006, p. 195), a sample size of 100 subjects would be needed that satisfied those assumptions. The second consideration was to estimate a sample size that would provide a basis for generalizing the study results to other samples. According to Hair, the ratio of subjects to predictor variables should never fall below 5:1, and a desired level is between 15 to 20 subjects for each predictor variable. This rule suggests that for 8 predictor variables, a minimum sample size could be as low as 40 to a desired sample size of 120 – 160 subjects. Tabachnick and Fidell (2007, p. 123) give a rule that the sample size should be at least 50 + 8m (where m = number of predictor variables). For 6 predictor variables, a sample of 98 subjects is desirable, while for 9 predictors, 122 subjects would be needed. The final sample size of 101 was adequate for generalizing results regarding predicting physical health (3 predictors), but may not be as generalizable for predicting mental health (7 predictors) or disease specific quality of life (9 predictors).

All patients who met the following inclusion criteria were invited to participate in the study: (a) Alert, oriented, and able to read and write in the English language.

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(b) Are of legal age (18 years or older), able to understand and provide consent.

(c) Currently treated with an ICD for either primary or secondary prevention of lethal cardiac

dysrhythmias; (d) Diagnosed with heart failure and classified using the NYHA functional class I,

II, III, or IV (as documented in the medical record by the cardiologist). Any ICD patient in the

clinic who met the following exclusion criteria were not asked to participate in the study: (a)

Incapacitating dementia or cognitive impairment due to multiple co-morbidities (i.e. recent

cerebrovascular accident and /or significant hypotension); (b) Impaired hearing as documented in

the medical record or by observation, such that neither an interview nor completing written

questionnaires is possible; (c) Documented history of chronic mental illness that includes serious

impairment of thought processes.

Instrumentation

Demographic and Clinical Characteristics Tools

Demographic, clinical, and ICD-specific data for each study participant was obtained

from medical record review and patient self-report using a tool designed to gather the following

information: age, race, gender, and educational level. For the proposed research, the following

clinical characteristics were also assessed from the medical record: Ejection Fraction (EF);

presence and number of co-morbidities; NYHA classification; and previous cardiac event

(myocardial infarction, cardiac surgery, sudden cardiac arrest). The following ICD specific data

was included for this study: indications for ICD implant; time since implantation, history of ICD

shocks since implant and history of ICD shocks in the past 30 days.

Psychosocial Measures

The extraneous variables of social support, general anxiety and depression, and device-

related shock anxiety were measured using the ENRICHD Social Support Instrument (ESSI), the

Hospital Anxiety and Depression Scale (HADS), and the ICD specific instrument, the Florida

Shock Anxiety Scale (FSAS).

Initially developed for the ENRICHD trial to evaluate perceived social support among

recovering myocardial infarction patients, the ENRICHD Social Support Inventory (ESSI) is a 7-

item scale that measures the availability of someone to provide social support. Individuals rate

the first six items using a Likert scale from 1 ("none of the time") to 5 ("all of the time"). The

last item asked the respondent to note if they were married or living with a partner, indicated by

a score of 4 for 'yes' and a score of 2 for 'no'. A total score of social support is obtained by

summing the responses for all 7 items. The scores range from 8-34 with higher scores indicative

of more social support (Luyster, Hughes, & Gunstad, 2009). Reliability and validity have been

established for the ESSI with use in cardiac patients. Acceptable internal consistency has been

demonstrated with reported Chronbach alpha = .86 (Luyster et al., 2009; Mitchell, Powell,

Blumenthal, & et al., 2003; Vaglio et al., 2004).

The measure for anxiety and depression used for this study was the Hospital Anxiety and

Depression Scale (HADS). The instrument is a 14-item scale evenly divided into 2 subscales that

measure anxiety and depressive symptoms. Each item is scored from 0 to 3, with higher scores

indicative of more anxiety and/or depression. Scores equal to or higher than 11 on the anxiety

subscale and 9 on the depression subscale indicate a potential for clinically significant anxiety or

depressive symptoms (Herrmann, Brand-Driehorst, Buss, & Ruger, 2000; Kim, Pressler, Welch,

& et al., 2009). Acceptable reliability and validity have been reported (Bjelland, Dahl, Haug, &

Neckelmann, 2002). Chronbach alpha's for the subscales have been established with the

subscales for anxiety and depression, .86 and .83 respectively (Bjelland et al., 2002; Kim et al.,

2009).

Disease-specific anxiety was measured in this study using the Florida Shock Anxiety Scale (FSAS). The FSAS is a 10-item survey designed to assess patient fears and concerns regarding experiencing an ICD shock, including cognitive, behavioral, emotional, and social implications. Respondents score each item using a 5-point Likert scale ranging from 1 to 5 with higher scores indicative of greater anxiety related to being shocked by their device. Reliability for the FSAS has been demonstrated with Chronbach's alpha = 0.91 (Kuhl, Dixit, Walker, Conti, & Sears, 2006; Vasquez et al., 2008).

Religiosity

The terms religiosity and religion, for the purposes of this study, will be used interchangeably. A definition of religion is presented by Koenig (2009):

> Involves beliefs, practices, and rituals related to the 'transcendent,' where the transcendent relates to the mystical, supernatural, or God (Western religious tradition) or the Ultimate Truth, Enlightenment (Eastern traditions). Religion is often organized and practiced within a community, but can be practiced alone or in private, outside of an institution.

Both religion and spirituality are complex and multi-dimensional constructs and capturing their essence with any psychometric measurement can be challenging (Rippentrop et al., 2005). However, it is essential that research that examines religion and health related outcomes be thoughtfully designed and carefully executed using high-quality measures of religiosity. If religious and health measurement tools are not sensitive, reliable, and valid, a strong correlation between the variables may not be found, even if such a relationship exists. Measurement error will add variability to the association and weaken correlation results (Koenig et al., 2001).

Religiosity Measures

The following three instruments were chosen to measure various aspects of religiosity in an effort to obtain accurate and valid data. The first survey, the Duke Religion Index (DUREL) is a measure of religious involvement, including frequency of religious attendance and private prayer. The Hoge Intrinsic Religiosity Scale was incorporated in the study to examine religious commitment and positive religious coping. Finally, in an attempt to identify any correlation between negative religious coping and health outcomes, a brief 7-item Negative Religious Coping Scale (Negative RCOPE) was used.

The Duke Religion Index (DUREL) is a reliable, brief 5-item instrument designed to measure organized religious activity (frequency of attending religious services); non-organized religious activities (frequency of praying, meditating, or studying religious text); and intrinsic religiosity (internalization of one's religious practices and beliefs). The items are scored on a 5-point (Items 3-5) and 6 point (Items 1&2) Likert scale. The first 2 items are reversed scored to determine frequency of religious attendance and activities; the second subscale, items 3-5 are also reversed scored to determine sum of intrinsic religiosity score. Authors recommend noting subscale scores separately as using a total of the 2 subscales may cancel out the effects of each other. Total scores range from a low of 5 to a high of 27. Chronbach's alpha for the intrinsic religiosity subscale has been noted ranging from 0.75 to 0.88 (Koenig, George, & Peterson, 1998). In the current study, to avoid duplication of questions, only the first two items of the DUREL will be used a single item measures to assess the frequency of religious attendance and activities. Intrinsic religiosity will be measured with the following instrument (Hoge Intrinsic Religiosity Scale), which contains the identical items 3-5 from the DUREL.

Religious coping is conceptually defined as the extent to which an individual incorporates their beliefs and practices to enable them to cope with difficult and stressful life situations. In the present study, in an effort to examine the potential impact of both positive and negative religious coping, religious coping was operationally defined using the Hoge Intrinsic Religiosity Scale and the 7-item Negative Religious Coping Scale (Pargament et al., 1998).

The Hoge Intrinsic Religiosity Scale (Hoge, 1972) measures the individual's internal religious commitment and reflects the influence of religious beliefs and teachings on a person's lifestyle and decisions. The Hoge survey is a 10-item instrument designed to measure an individual's intrinsic religiosity. Individuals are asked to rate on a 1 to 5 scale the extent to which they feel the statement is true for them. The scale consists of seven intrinsic items and three extrinsic items (reverse scored). Scoring is based on a 5-point Likert scale with 1, being "definitely not true" and 5, being "definitely true". Total scores range from 1 to 50 with higher scores indicating greater religiosity. The Hoge Scale has both high internal reliability (Chronbach's alpha = 0.87) and high test-retest reliability (91.3% agreement after 6-week interval. Validity has been demonstrated by Hoge (1972) with a high correlation between scale scores and ministers judgment (r = 0.59).

Adopted from the Religious Coping Scale (RCOPE), the Negative Religious Coping Scale (Negative RCOPE) is a measure developed to assess negative religious coping strategies (spiritual discomfort, punishing God reappraisal, interpersonal religious discontent, demonic reappraisal, and reappraisal of God's power). The instrument is scored using a 4-point Likert scale with response options including "not at all", "somewhat", "quite a bit", and "a great deal". Total scores range from 7 (low) to 21 (high), with higher scores reflective of greater negative

coping. Internal consistency for the survey has been high (Coefficient alpha = 0.81 to 0.90) in addition to good discriminate validity (Pargament et al., 1998; Phelps et al., 2009).

Quality of Life

Quality of life (QoL) is defined as the subjective individual experiences including physical, psychological, social and spiritual realms of health (Rummans, Bostwick, Clark, & Mayo Clinic Cancer Center Quality of Life Working, Group, 2000). Quality of life is influenced by perception, expectations, beliefs, and experiences. A person's location on the illness continuum can affect their individual QoL. Individuals living with a chronic illness often face the challenges of leading restrictive lives, feelings of social isolation and burdening others (Steele, Bartlett, Moore, & Gantt, 2006). For the patient living with a chronic disease, QoL can range from the suffering associated with the disease process and sense of decline, to the experience of redefining a sense of purpose and meaning and transitioning through the dying process (Byock & Merriman, 1998). In this study, QoL is conceptually defined as the ICD patient's perception of well-being including functional (physical) and psychosocial (emotional) aspects. Additionally, patient acceptance is considered a device-specific construct of QoL for the ICD patient (Burns, Serber, Keim, & Sears, 2005). Therefore, measuring patient acceptance in ICD patients is essential to understanding their unique experiences and establishing an awareness of the device's impact on their lives.

General Quality of Life Measure

An abbreviated instrument, the SF-12 is one of the most extensively used health status inventories and is considered a general measure to assess health domains relevant to an individual's functional status and well-being (Rippentrop et al., 2005; Ware, Kosinski, & Keller, 1996). Based on the SF-36, the SF-12 includes measures of physical, emotional and social

functioning in addition to general mental health and vitality. The instrument can be administered either by self-report using pen and paper or by interview with respondent. The SF-12 is composed of various items that are scored either using a Likert scale or by a dichotomous scale. Physical Component Summary (PCS) items are scored on a Likert scale of 1 to 3, 1 to 5 for the bodily pain, social function, and general health perception items, 1 to 6 for vitality and Mental Component Summary (MCS); and a yes/no dichotomous scale for the presence of role function limitations. The results are expressed in terms of the Physical Component Summary (PCS) and the Mental Component Summary (MCS). The SF-12 is scored such that a high score is reflective of better physical and mental health (Ware et al., 1996). Ware et al. (1996) reported test-retest (2-week) correlations of 0.89 and 0.76 for the PCS and the MCS respectively, in the general US population (n = 232). When related to the SF-36, they noted relative validity for the PCS ranged from 0.43 to 0.93 with a median of 0.67 and relative validity for the MCS ranged from 0.60 to 1.07, with a median of 0.97 (Resnick & Parker, 2001; Ware et al., 1996).

Disease-Specific Quality of Life Measure

In an effort to evaluate the quality of life (QoL) for the patient with an Implantable Cardioverter Defibrillator (ICD), additional measurements were used to examine the individual's acceptance of the device and the psychological response to shocks from the ICD. The Florida Patient Acceptance Scale (FPAS) operationally defined the ICD patient's QoL for the purpose of the current study (Burns et al., 2004; Kuhl et al., 2006).

The Florida Patient Acceptance Survey (FPAS) is an 18-item measure to assess patient acceptance of a cardiac implantable device. All items are scored using a 5-point Likert scale from 1 to 5 with higher total scores indicating more acceptance of the cardiac device. The scale is composed of four factors: Return to Function (four items; e.g., 'I have returned to a full life.'),

Device-Related Distress (five items; e.g., 'Thinking about the device makes me depressed.'), Positive Appraisal (four items; e.g., 'I am safer from harm because of my device.'), and Body Image Concerns (two items; e.g., 'I feel less attractive because of my device.'). In the four subscales of the instrument, a high score on Return to Function and Positive Appraisal means more acceptance, whereas a high score on Device-Related Distress and Body Image Concerns represents less acceptance. Additionally, there are 3 single items that are not included in the subscales or total scale scoring, related to knowledge of the device and continuing normal sexual activities. For the current study, a total scale score based on the 15 items, from the four factor subscales, was used for simplicity. The three remaining single items were examined separately due to their clinical and research utility for the ICD patient population.

Reliability has been demonstrated with Chronbach's alpha on each of the four factors of the FPAS ranging from 0.74 (Body image concerns) to 0.89 (Return to function). Total FPAS score also exhibited good internal consistency with Chronbach's alpha of 0.83 (Burns et al., 2004; Vasquez et al., 2008).

Data Collection Plan

Following approval from the Institutional Review Board, the study was conducted at the outpatient cardiology ICD clinic located in southeastern North Carolina. The investigator approached potential participants, identified by staff through medical record review, as they waited for their scheduled clinic appointment. Once an interest in the study was expressed, each potential participant was provided an explanation of the study purpose in lay terms, allowing time for questions and review of the written materials. After indicating an understanding and willingness to participate in the study, the informed consent was signed by both the participant and the investigator, and a copy given to the participant. For ICD participants who were unable

to read the consent and/or questionnaires, the investigator was available to read the consent and questionnaires to the participant using a directed script. Consented study participants were then allowed 15-20 minutes to complete the study interview in a designated room apart from the clinic exam area to provide a private and quiet area.

Once the questionnaires were completed, the participant returned them to the investigator. If the participant requested to have the survey questions read by the researcher, the completed questionnaires were checked with the participant to assure accuracy of their responses. Each questionnaire was then numbered consecutively for study purposes and to maintain confidentiality of participants. Demographic data (age, race, gender, and educational level) in addition to disease severity and ICD specific data (Co-morbidities, Ejection fraction, ICD information) was obtained from individual medical records.

Data Analysis Plan

Data were entered and analyzed using SPSS-PC for Windows (version 18.0). Prior to analysis, all data was screened for completeness and missing data was identified. Descriptive analysis for each variable was conducted including mean, standard deviation, and actual range. Estimates of internal consistency reliabilities using Cronbach's coefficient alpha were completed for all multi-item measures, including the SF-12, the FPAS, the ESSI, the HADS, the FSAS, the HOGE, and the NRCOPE. Diagnostic tests for violations of assumptions for statistical analyses, such as normality, linearity, homoscedasticity, and multicollinearity were completed and no violations were noted. Significance level was set at a p value of $< .05$.

Hierarchical multiple regression was used to determine if there were any psychosocial and religiosity measures that improved the prediction of general and disease specific quality of life after controlling for any demographic and clinical variables that were statistically

significantly associated with the quality of life measures. Preliminary analyses were conducted to ensure no violations of the assumptions of normality, linearity, multicollinearity and homoscedasticity. Inspection of the scatterplot of the regression standardized residuals and standardized predicted value for each outcome measures revealed no outliers or violations of the normality, linearity, and homoscedasticity assumptions. Demographic, clinical, psychosocial, and religiosity variables that had a statistically significant correlation with each of the quality of life outcome measures were selected as possible predictor variables for each hierarchical regression model. If none of the intercorrelations among the potential predictor variables were greater than 0.70, then all the potential predictors were retained for analysis.

Summary

The presented chapter described the methodology that guided the current study. Understanding how religiosity relates to QoL in ICD patients may promote a more effective approach in providing care to this population; fostering adherence to a therapeutic plan of care, enhancing acceptance of their device, reducing anxiety related to ICD shocks, and providing a buffer to the physical and emotional stressors associated with living with an ICD. The results of this study will add to the knowledge base for health care providers and build support for the influence of religiosity on QoL for patients of an ICD.

CHAPTER 4: RESULTS

Sample Characteristics

From January through June of 2010, a total of one hundred and seventy-one ICD patients were approached to participate in the study. Seventy patients declined enrollment due to verbalized lack of time or no interest in participation. The final sample consisted of one hundred and one ICD patients participated in the study. Study participants' demographic, clinical, and ICD characteristics are summarized in Table 1. The ages of participants ranged from 29 to 88 years *(M = 65, SD=*12.8 years). The study sample was predominately male (66%), Caucasian (58%), married (57%), and high school graduates (74%). Forty-five percent of the participants stated their religious affiliation was Baptist. The majority of the study participants had NYHA Class II or Class III heart failure (57% and 17% respectively) and the mean ejection fraction was 31.5% (range 10 - 60%). A large portion of the study sample reported multiple comorbidities (see Table 2), with the most frequent being coronary artery disease (54%), hypertension (44%), and diabetes (33%).

The sample characteristics related to the ICD are listed in Table 3. The majority of participants had received their ICD device for primary prevention (91%) and had been living with their ICD for more than 2-5 years (45%). In the study sample, most ICD patients had either a dual chamber (66%) or biventricular (24%) device. The experience of ICD shock was evenly split with 49% of the ICD patients having no shock and 51% experiencing one or more ICD shocks since implant.

Characteristics of the Instruments

Descriptive statistics, including means, standard deviations, estimates of internal consistency and indices for normality for all study measures are presented in Table 4. Due to

Table 1

Demographic Characteristics of the Study Participants (N = 101)

Variables		*f*	*%*
Gender	Male	66	66
	Female	35	34
Race	Caucasian	59	58
	African American	42	42
Marital Status	Married	57	57
	Single	18	18
	Widowed	16	16
	Divorced	9	9
	Separated	1	1
Education Level	< 12 years	21	21
	High School completed	36	35
	Some college	17	17
	College Graduate	11	11
	Post-Graduate Education	11	11
	Not Reported	5	5
Religious Affiliation	Baptist	45	45
	Protestant	20	20
	Non-Denominational	8	8
	Catholic	3	3
	Not Reported	25	24

Table 2

Clinical Characteristics (N = 101)

Comorbidities Variables	f	%
Heart Failure Classification – New York Heart Association (NYHA)		
NYHA I	5	5
NYHA II	58	57
NYHA III	17	17
NYHA IV	2	2
Not Reported	19	19
Coronary Artery Disease (CAD)	54	54
Hypertension	44	44
Myocardial Infarction	34	34
Diabetes	33	33
Atrial Fibrillation	34	33
Paroxysmal	4	4
Chronic	30	29
Coronary Artery Bypass Graft (CABG)	30	30
Pulmonary Disease	24	24
Stroke	20	20
Obesity	15	15
Percutaneous Coronary Intervention	13	13
Valve Surgery	12	12
Renal Failure	11	11
Sudden Cardiac Death	8	8
Cancer	7	7
Substance Abuse	6	6
Clinical Depression	3	3

Table 3

ICD Characteristics (N = 101)

Variables		f	%
ICD Indication	Primary	92	91
	Secondary	9	9
ICD Type	Dual Chamber	66	65
	BiVentricular	24	24
	Single Chamber	11	11
ICD Shocks	≥ one shocks	51	51
	No Shocks	50	49
ICD Shocks in Past 30 days	None	98	97
	More than one	2	2
Time since Implant	< 1 year	12	12
	1-2 years	9	9
	2-5 years	45	45
	> 5 years	35	34

Table 4

Psychometric Properties of the Multi-Item Measures

Multi-Item Measures	# Items	Score Range	*a*	Skewness	Kurtosis
SF-12	12	0-100	.85		
PH				0.14	-0.66
MH				-1.06	0.26
FPAS	15	18-100	.85	-0.98	0.35
RTF	4		.77		
DRD	5		.77		
PA	4		.88		
BIC	2		.82		
ESSI	7	8-34	.88	-1.87	3.50
HADS Anxiety	7	0-21	.85	0.84	0.07
HADS Depression	7	0-21	.81	1.48	3.44
FSAS	10	10-50	.89	2.26	4.96
Hoge	10	10-40	.86	-1.08	1.19
NRCOPE	7	0-21	.23	-1.55	1.37

Note. PH = Physical Health; MH = Mental Health; FPAS = Patient Acceptance Scale; Subscales: RTF=Return to Function; DRD=Device-Related Distress; PA=Positive Appraisal; BIC=Body Image Concerns; ESSI = ENRICHD Social Support Instrument; HADS = Hospital Anxiety and Depression Scale; FSAS = Florida Shock Anxiety Scale; Hoge = Intrinsic Religiosity Scale; NRCOPE=Negative Religious Coping Scale.

the low reliability (Chronbach's alpha = .23) of the Negative Religious Coping Scale
(NRCOPE), it was decided to delete this instrument from the analysis.

Psychosocial Measures

The ENRICHD Social Support Index (ESSI) is a measure to evaluate perceived social
support, in particular emotional support. In this instrument, higher scores indicate a higher level
of social support. For this study sample, scores ranged from 10-34 (*M*= 29.92, *SD* = 5.19)
revealing that most participants had strong social support. Chronbach's alpha for this sample was
.88 and is consistent with reported levels in the literature (Luyster, Hughes, & Gunstad, 2009;
Vaglio et al., 2004).

General anxiety and depression were measured using the Hospital Anxiety and
Depression Scale (HADS). The 14-item instrument is evenly divided into two separate subscales
to evaluate anxiety and depression. Response scores for individual items range from 0-3, with
higher scores indicating more anxiety or more depressive symptoms. Mean general anxiety and
depression scores for the study sample were 4.38 (*SD* = 4.04) and 3.64 (*SD* = 3.32) respectively.
Women reported higher scores for general anxiety compared to the male ICD patients. African
American (AA) women scored the highest overall in both HADS depression and anxiety (*M* =
5.0 and *M* = 5.8 respectively). In the study sample, acceptable reliability was found with
Chronbach's alpha for each of the subscales of anxiety and depression .85 and .81 respectively
(see Table 4).

To assess ICD specific anxiety, the Florida Shock Anxiety Scale (FSAS) was used. Total
scores range from 10-50 with higher scores indicative of higher levels of anxiety related to living
with an ICD. The 10-item instrument demonstrated high reliability in the study sample with the

Chronbach's alpha of .90. Total FSAS scores for the study sample ranged from 10-42, with a mean score of 14.51($SD = 7.28$).

Religiosity Measures

The Hoge religiosity scale measures intrinsic religiosity and how individuals use religion in their lives. In the study sample, this instrument demonstrated a Chronbach's alpha of .86. The study sample total scores for the HOGE ranged from 8-40, with a mean score of 32.19 ($SD = 6.45$). These scores are similar to those reported by Hoge (1992). In addition to the Hoge scale, there were two questions taken from the Duke Religiosity Scale (DUREL) that assessed participation in religious activities and individual religious practices. To further evaluate religiosity, a single item question was included for participants to rank the importance of religion on a Likert scale from 1('Not Important') to 4 ('Very Important'). These results are listed in Table 5. Most participants noted that religion was either important or very important to them (91%). The majority of the study sample reported they attended religious services once a week or more (52.5%) and participated in private prayer daily (40.6%) or more than once a day (27.7%). Summary scores for the measures of religiosity are presented in Table 6.

Quality of Life Measures

General quality of life (QoL) was measured using the SF-12 scale, which is comprised of two subscales, Physical Health (PH) and Mental Health (MH). Chronbach's alpha for this sample was .85. Higher scores on each subscale indicate better quality of life. Total scores on the SF-12 can range from 0-100. In the study sample, mean scores for Mental Health ($M =53.57$, $SD= 11.09$) were higher compared to the scores for Physical Health ($M = 37.78$, $SD = 11.08$). These results indicate that adult participants in this study reported better mental health than physical

Table 5

Descriptive Statistics of Study Measures (N= 101)

Measures	Actual Range	*M*	*SD*
SF-12 PH	13-58	37.78	11.08
SF-12 MH	19-68	53.57	11.09
FPAS	32-100	80.92	16.54
RTF		63.00	28.56
DRD		15.59	20.30
PA		90.28	18.49
BIC		10.64	22.25
Knowledge of Device	1-5	4.23	1.08
ESSI	10-34	29.92	5.19
HADS Anxiety	0-16	4.38	4.05
HADS Depression	0-19	3.64	3.32
FSAS	10-42	14.51	7.28
Hoge	8-40	32.19	6.46
NRCOPE	0-4	.65	1.06
Importance of Religion	1-4	3.63	0.76
Religious Attendance	1-6	2.63	1.58
Private Religious Activities	1-6	2.45	1.48

Note. PH = Physical Health; MH = Mental Health; FPAS = Patient Acceptance Scale; Subscales: RTF=Return to Function; DRD=Device-Related Distress; PA=Positive Appraisal; BIC=Body Image Concerns; ESSI = ENRICHD Social Support Instrument; HADS = Hospital Anxiety and Depression Scale; FSAS = Florida Shock Anxiety Scale; Hoge = Intrinsic Religiosity Scale; NRCOPE=Negative Religious Coping Scale.

Table 6

Single Item Religiosity Questions (N = 101)

Variables	*f*	*%*
Importance of Religion		
Not Important	4	4.0
Somewhat Important	5	5.0
Important	15	14.9
Very Important	77	76.2
Religious Attendance		
More than once a week	33	32.7
Once a week	20	19.8
A few times a week	22	21.8
A few times a year	11	10.9
Once a year or less	7	6.9
Never	8	7.9
Private Religious Activities		
More than once a day	28	27.7
Daily	41	40.6
Two or more times a week	12	11.9
Once a week	6	5.9
A few times a month	7	6.9
Rarely or never	7	6.9

well-being. Males and African American women reported the lowest scores for physical health ($M = 38$ and $M = 36$ respectively).

Disease-specific QoL was assessed using the 18-item Florida Patient Acceptance Scale (FPAS). In the study sample, the measure demonstrated a Chronbach's alpha of .85. Total scores for the FPAS can range from 0-100 with higher scores indicative of better patient acceptance of their ICD device. The study sample of ICD patients rated their acceptance with scores that ranged from 32-100 ($M = 80.92$, $SD=16.54$). The four subscales of the FPAS: Return to Function; Device-Related Distress; Positive Appraisal; and Body Image Concerns all revealed adequate reliability with Chronbach's alpha for each noted in Table 4. Three single items that assessed knowledge of the ICD and sexual activity, that are not included in the subscale or total FPAS scoring, were also assessed separately for correlations with other study variables. Since two of the items related to the ICD patient's understanding of the device were closely related, only Knowledge of Device was included in the final analysis based on displaying the highest correlation with the other study variables. The remaining single item, related to continuing sexual activities, was not included in the analysis as most participants chose not to respond.

There was little correlation between the SF12 mental and physical health QOL scores ($r = 0.04$, p=.72). FPAS scores had a large correlation with SF12 mental health ($r = 0.53$, $p < .001$, 28% shared variance) and a moderate correlation with SF12 physical health ($r = 0.36$, $p < .001$, 13% shared variance). Since the largest amount of shared variance among the three measures was only 28%, the three QOL measures were assessing different aspects of QOL.

Research Question #1

Does religiosity in ICD patients vary by demographic factors (age, race, gender), clinical factors (ejection fraction, co morbidities, time since implant, incidence of shock) or psychosocial factors (social support, general anxiety and depression and shock anxiety)?

Correlational analyses were conducted to determine if the demographic, clinical, or psychological variables were related to measures of religiosity (see Table 7). Of the demographic variables, there was no relationship with age, but a significant relationship with race and gender. African Americans and women reported higher scores on religious importance, religious attendance, and private religious activities. None of the clinical factors (ejection fraction, comorbidities, time since implant or incidence of shock) were correlated with indicators of religiosity. Of the psychosocial variables, only social support had a significant relationship with some measures of religiosity. Participants with higher social support reported higher scores on importance of religion and private religious activities. General anxiety, depression, and shock anxiety, were not correlated with any measure of religiosity (see Table 7).

Research Question #2

Is general quality of life (QoL) or disease specific QoL in ICD patients related to religiosity factors (importance of religion, religious attendance, private religious activities, and intrinsic religiosity), demographic factors (age, race, gender), clinical factors (ejection fraction, co morbidities, time since implant, incidence of shock) or psychosocial factors (social support, general anxiety and depression and shock anxiety)? In particular, are there any gender and racial differences in the level of patient acceptance of the ICD (disease-specific quality of life)?

Table 7

Correlations of Select Variables and Religiosity

Variable	Importance of Religion	Religious Attendance	Private Religious Activities	Hoge
Age	.09	.03	.10	.10
Race[1]	.20*	.25*	.21*	.22*
Gender[2]	-.24*	-.29**	-.21*	-.29**
ESSI	.24*	.07	.21*	.18
FPAS	.26**	.11	.24*	.06

Note. [1]0 =Caucasian; 1 = African American; [2]0=Female; 1= Male;
Hoge = Intrinsic Religiosity Scale; ESSI = ENRICHD Social Support Instrument;
FPAS = Patient Acceptance Scale.
*p < .05
** p < .01

To determine which variables were related to both general and disease-specific quality of life (QoL), bivariate correlations were performed. Results from each of the factors (demographic, clinical, psychosocial and religiosity) are presented in Tables 8 – 11. General QoL Physical Health (PH) in the study sample was significantly correlated with age ($r = -.20$; $p < .05$), the number of comorbidities ($r = -.26$; $p < .01$), and depression ($r = -.36$; $p < .01$). Participants who reported lower PH scores were older, had more comorbidities, and tended to be depressed. General QoL Mental Health (MH) in the study sample was highly correlated with age, race, depression, anxiety (both general and shock related), and social support. Participants in the sample who were younger and African American reported higher levels of depression, anxiety, and shock anxiety and lower scores for mental health. Additionally, those participants with poor social support also rated their mental health as poor.

In the current study sample, disease-specific QoL as measured by the total FPAS score, indicated participants were generally accepting of their ICD. Significant correlations with patient acceptance were noted in the study results (see Tables 8 - 11). Specifically, participants who reported higher scores on the total FPAS were Caucasian, older, had less shock anxiety, less depressive symptoms, were knowledgeable about their device, had strong social support, and reported that religion was important to them.

Despite the overall acceptance of the ICD, subgroups in the study sample, particularly African Americans, indicated less acceptance of their device overall, more device-related distress, concerns of body image and lacking knowledge of how their ICD functions. The next section focuses on the level of acceptance of the ICD among study subjects stratified by gender and race. Table 12 presents the means and standard deviations of the Total FPAS, the four sub-scales of the FPAS, and the total scores for the device shock anxiety scale (FSAS). Of

Table 8

Correlation Matrix of Demographic Variables with Quality of Life Measures

Variable	1	2	3	4	5	6
1 Age	1.00					
2 Race[1]	.29**	1.00				
3 Gender[2]	-.12	-.40**	1.00			
4 SF-12 PH	-.20*	-.09	.01	1.00		
5 SF-12 MH	.31**	-.23*	.06	.03	1.00	
6 FPAS	.31**	-.25*	.04	.36**	.52**	1.00

Note. [1]0 =Caucasian; 1 = African American; [2] 0=Female; 1=Male; PH = Physical Health; MH = Mental Health; FPAS = Patient Acceptance Scale.
*p < .05
** p < .01

Table 9

Correlation Matrix of Clinical Variables with Quality of Life Measures

Variable	1	2	3	4	5	6	7
1 EF	1.00						
2 Shock[1]	-.08	1.00					
3 Comorbidities	-.18	.04	1.00				
4 Time since Implant	-.19	.44**	-.02	1.00			
5 SF-12 PH	-.07	-.15	-.26**	-.12	1.00		
6 SF-12 MH	-.04	.05	.03	.19	.03	1.00	
7 FPAS	-.17	-.18	-.21*	.19	.36**	.52**	1.00

Note. [1]0= No shock, 1= Shock; EF = Ejection Fraction; PH = Physical Health;
MH = Mental Health; FPAS = Patient Acceptance Scale.
*p < .05
** p < .01

Table 10

Correlation Matrix of Psychosocial Variables with Quality of Life Measures

Variable	1	2	3	4	5	6	7	8
1 ESSI	1.00							
2 FSAS	-.31**	1.00						
3 HADS Anxiety	-.43**	.48**	1.00					
4 HADS Depression	-.54**	.43**	.68**	1.00				
5 Knowledge of Device	.23**	-.29**	-.33**	-.39**	1.00			
6 SF-12 PH	.02	-.15	-.19	-.37**	.05	1.00		
7 SF-12 MH	.47**	-.42**	-.66**	.03	.33**	.49**	1.00	
8 FPAS	.47**	-.61**	-.53**	-.64**	.36**	.33**	.49**	1.00

Note. ESSI = ENRICHD Social Support Instrument; FSAS = Florida Shock Anxiety Scale; HADS = Hospital Anxiety and Depression Scale; PH = Physical Health; MH = Mental Health; FPAS = Patient Acceptance Scale.
*p < .05
** p < .01

Table 11

Correlation Matrix of Religiosity Variables with Quality of Life Measures

Variable	1	2	3	4	5	6	7
1 Importance of Religion	1.00						
2 Religious Attendance	.56**	1.00					
3 Private Religious Activities	.69**	.61**	1.00				
4 Hoge	.77**	.57**	.60**	1.00			
5 SF-12 PH	.10	-.03	.11	-.13	1.00		
6 SF-12 MH	.16	.03	.16	.06	.03	1.00	
7 FPAS	.26**	.11	.24*	.06	.36**	.52**	1.00

Note. Hoge = Intrinsic Religiosity Scale; PH = Physical Health; MH = Mental Health;
FPAS = Patient Acceptance Scale.
*p < .05
 ** p < .01

Table 12

Racial and Gender Differences for Quality of Life and Disease-specific Measures

Scale	Caucasian		African American	
	Male (N=48) Mean (SD)	Female (N=11) Mean (SD)	Male (N=18) Mean (SD)	Female (N=24) Mean (SD)
SF-12 PH	37.86 (11.03)	41.81 (13.01)	37.83 (11.10)	35.74 (10.42)
SF-12 MH	55.49 (10.61)	56.80 (8.85)	50.20 (10.54)	50.81 (12.64)
FPAS	83.78 (16.30)	86.97 (11.92)	75.19 (14.55)	76.74 (18.70)
RTF	67.45 (28.63)	72.73 (22.06)	49.31 (29.54)	59.90 (27.76)
DRD	9.69 (15.31)	12.27 (19.41)	25.83 (24.69)	21.25 (22.47)
PA	87.37 (20.57)	98.30 (4.04)	94.10 (7.87)	89.58 (22.55)
BIC	7.03 (15.01)	9.09 (20.98)	8.33 (20.56)	20.31 (32.51)
Knowledge of Device	4.35 (1.00)	4.73 (0.47)	3.89 (1.32)	4.00 (1.14)
FSAS	12.29 (4.68)	14.45 (5.32)	18.06 (9.12)	16.33 (9.41)

Note. PH = Physical Health; MH = Mental Health; FPAS = Patient Acceptance Scale; Subscales: RTF=Return to Function; DRD=Device-Related Distress; PA=Positive Appraisal; BIC=Body Image Concerns; FSAS = Florida Shock Anxiety Scale.

interest, racial and gender differences were noted in the mean scores for the general QoL and disease-specific measures, including the single item for knowledge of device and ICD shock anxiety (FSAS). Selected results are presented in Table 12. African American (AA) ICD patients in this sample overall reported lower mean scores for general QoL (physical and mental health), patient acceptance (FPAS total score), and the single item measure for knowledge of the device. On the subscales of the FPAS (Return to Function and Device Related Distress) the AAs in this study reported the lowest scores for return to life and the most device related distress. Additionally, African American ICD patients, compared to Caucasians in this sample, reported the highest score on the shock anxiety scale. Gender differences were found in the subscales of the FPAS with white males reporting the lowest scores for the Positive Appraisal and AA women revealing the highest concern related to body image.

Research Question #3

Which factors (demographic factors, clinical factors, psychosocial factors, and religiosity) are most strongly related to (1) general physical health quality of life; (2) general mental health quality of life; and (3) disease-specific quality of life in ICD patients? More specifically:

> After controlling for the possible effects of demographic and clinical predictors, are there any psychosocial and religiosity variables still able to predict a significant amount of the variance in the general (physical and mental health) and disease-specific quality of life?

> To determine the best predictors of general and disease-specific QoL in ICD patients, regression models were developed to test multivariate relationships among the study variables. All study variables; including religiosity, demographic, clinical, psychosocial, and the dependent variables for QoL were examined. Since there were no significant correlations found with the

religiosity variables, these were not included in the regression model for general QoL (Physical Health and Mental Health). However, the religiosity variable, Importance of Religion, was significantly correlated with disease specific QoL (FPAS-patient acceptance) and therefore included in the regression analysis. In addition, the single item from the FPAS (Knowledge of Device) that was not included in the subscale or total scoring, was incorporated into select regression analyses based on the high correlation with measures of QoL. Race was recoded into African-American and Caucasian categories to produce dichotomous variables for the regression analysis. The following present the results of the hierarchical regression analyses for identifying the best predictors of general quality of life (physical and mental) and disease-specific quality of life (FPAS-patient acceptance).

General Quality of Life

Physical Health (PH)

To identify predictors of self-reported physical health, the variables with the strongest correlation: age, number of comorbidities, and depression were incorporated into the model (see Tables 9, 10, and 11). None of the intercorrelations among these variables exceeded 0.70. Age and number of comorbidities were entered into Step 1, explaining 9.3% ($p < .01$) of the variance in physical health. After entry of depression at Step 2, the total variance explained by the model as a whole was 25% ($p < .001$). The one variable entered at Step 2 explained an additional 15.7% of the variance in physical health ($p < .001$). In the final model, three of the variables made a unique statistically significant contribution to the prediction of physical health. In order of importance, they are: depression ($\beta = -.40$), age ($\beta = -.23$), and, comorbidities ($\beta = -.21$). A summary of the model is presented in Table 13.

Table 13

Hierarchical Regression Model of Physical Health (SF-12 PH)

| | Unstandardized Coefficients | | | | |
Model Predictors	*B*	Std. Error	Standardized *ß*	*t*	*p*
Step 1					
Age	-.14	.08	-.16	-1.62	.11
Comorbidities	-1.32	.54	-.24	-2.44	.03
$R^2 = .093$; Adjusted $R^2 = .075$, F (2, 98) = 5.03, p < .01			$R^2\Delta = .093, p < .01$		
Step 2					
Age	-.20	.08	-.23	-2.58	.01
Comorbidities	-1.19	.49	-.21	-2.40	.02
HADS	-1.34	.30	-.40	-4.50	<.001
Depression					
$R^2 = .250$; Adjusted $R^2 = .227$, F (3, 97) = 10.77, p < .001			$R^2\Delta = .157, p < .001$		

Note. HADS = Hospital Anxiety and Depression Scale.

Mental Health (MH)

To ascertain how much variance in mental health (MH) could be explained by the study variables, a hierarchical regression analysis was performed. Age, race, anxiety, depression, shock anxiety, social support, and knowledge of device were all significantly related to mental health (see Tables 9, 10, and 11). None of the intercorrelations among these variables exceeded 0.70. Age and race were entered at Step 1, explaining 11.9% ($p < 0.01$) of the variance in mental health. After entry of anxiety, depression, shock anxiety, social support, and knowledge of device at Step 2, the total variance explained by the model as a whole was 55.3% ($p < 0.001$). The five variables entered at Step 2 explained an additional 43.5% of the variance in mental health ($p < .001$). In the final model, two of the variables made a unique statistically significant contribution to the prediction of mental health. In order of importance, they are: anxiety ($\beta = -.34$) and depression ($\beta = -.32$). A summary of the model is presented in Table 14.

Disease-Specific Quality of Life

A hierarchical regression on the study variable of disease-specific QoL, FPAS (patient acceptance), was examined to determine predictor variables. Race, age, comorbidities, shock anxiety, anxiety and depression, knowledge of device, social support, and importance of religion were all significantly related to disease specific QoL, patient acceptance. None of the intercorrelations among the six variables exceeded 0.70. Race, age, and comorbidities were entered into Step 1, explaining 19.8 % ($p < .001$) of the variance in patient acceptance of the device. After entry of shock anxiety, anxiety and depression, knowledge of device, social support, and importance of religion at Step 2, the total variance explained by the model as a whole was 67% ($p < .001$). The six variables entered at Step 2 explained an additional 46.8 % of the variance in patient acceptance of the device ($p < .001$). In the final model, five of the

Table 14

Hierarchical Regression Model of Mental Health (SF-12 MH)

| | Unstandardized Coefficients | | | | |
Model Predictors	*B*	Std. Error	Standardized *β*	*t*	*p*
Step 1					
Age	.23	.09	.27	2.69	.01
Race[1]	-3.46	2.22	-.15	-1.56	.12
R² = .119; Adjusted R² = .101, F (2, 98) = 6.59, p= .002			*R²Δ = .119, p = .002*		
Step 2					
Age	.07	.07	.08	1.00	.32
Race[1]	-1.90	1.67	-.08	-1.14	.26
ESSI	.24	.18	.11	1.35	.18
HADS Anxiety	-.93	.28	-.34	-3.36	.001
HADS Depression	-1.09	.36	-.32	-3.02	.003
FSAS	-.02	.14	-.01	.33	.74
Knowledge of Device	.26	.80	.03	.33	.74
R² = .553; Adjusted R² = .519, F (7, 93) = 16.44, p < .001			*R²Δ = .435, p < .001*		

Note. [1]0 =Caucasian; 1 = African American. ESSI = ENRICHD Social Support Instrument; HADS = Hospital Anxiety and Depression Scale; FSAS = Florida Shock Anxiety Scale

variables made a significant contribution to the prediction of patient acceptance of their device. In order of importance they are: shock anxiety (β = -.31), depression (β = -.25), knowledge of device (β = .23), comorbidities (β = -.19), and importance of religion (β = .17). A summary of the model is presented in Table 15.

Table 15

Hierarchical Regression Model of Patient Acceptance (FPAS)

	Unstandardized Coefficients				
Model Predictors	*B*	Std. Error	Standardized *ß*	*t*	*p*
Step 1					
Race[1]	-6.47	3.18	-.19	-2.03	.04
Age	.38	.12	.30	3.10	.003
Comorbidities	-2.28	.76	-.28	-2.99	.004

$R^2 = .198$; *Adjusted* $R^2 = .173$, $F (3, 97) = 7.98$, $p < .001$ $R^2\Delta = .198$, $p < .001$

Step 2					
Race[1]	-3.27	2.27	-.10	-1.44	.15
Comorbidities	-.01	.10	-.01	-.13	.89
Importance of Religion	3.80	1.47	.17	2.59	.01
ESSI	.43	.24	.13	1.76	.008
HADS Anxiety	-.25	.37	-.06	-.67	.50
HADS Depression	-1.26	.48	-.25	-2.64	.01
FSAS	-.70	.18	-.31	-3.85	<.001
Knowledge of Device	3.60	1.04	.23	3.46	.001

$R^2 = .670$; *Adjusted* $R^2 = .633$, $F (9, 91) = 21.26$, $p < .001$ $R^2\Delta = .468$, $p < .001$

Note. [1]0 =Caucasian; 1 = African American. ESSI = ENRICHD Social Support Instrument;
FSAS = Florida Shock Anxiety Scale; HADS = Hospital Anxiety and Depression Scale.

CHAPTER 5: DISCUSSION

The primary goal of this study was to evaluate religiosity in ICD patients and examine the relationship between religiosity and general and disease specific quality of life (QoL) in this sample. A secondary goal was to determine which variables (demographic, clinical, psychosocial, and religiosity) are most predictive of QoL in ICD patients. This chapter presents the major findings of the study, a discussion of the research questions, review of the study strengths and limitations, recommendations for future research, and implications for professional practice.

The majority of the participants were older *(M* = 65 years), male (66%), married (57%) and Caucasian (58%). However, the current sample included a larger number of African American participants (42%) when compared to previous research involving ICD patients (Carroll & Hamilton, 2008; Groeneveld, Matta, Suh, Yang, & Shea , 2007; Passman et al., 2007). Most participants reported they were Baptist, attended church, and prayed or read religious scripture regularly. Similar to studies inclusive of ICD patients (Groeneveld et al., 2007; Passman et al., 2007), most of the sample had multiple comorbidities, a low ejection fraction (*M* = 31.5%), received their device for primary prevention (91%), and experienced a device shock (51%). Only 2 study participants had experienced a recent device shock (within past 30 days).

Religiosity in ICD Patients

The current study found associations between religiousness and race and gender. African American females in the sample population reported the highest scores on importance of religion, religious attendance, private religious activities, and intrinsic religiosity (Hoge Scale). Prior research involving cardiac patients (Contrada et al., 2004) and patients who are chronically ill (Koenig, 2007b; Koenig et al., 1997), noted that religiosity may buffer against the stressors of

disease and illness. This study found that while measures of religiosity were not related to physical or mental health (general QoL), they were related to social support and disease-specific QoL. Social support, in the current sample, correlated with importance of religion and private religious practices ($p < .05$). Study findings indicated a significant association between the importance of religion and patient acceptance of their ICD. These results add to earlier research and potentially lend support to the idea that religiosity may be positively associated with health related quality of life (Gall, 2004; Koenig, 2007b; Koenig et al., 1998; Koenig et al., 2004; Mueller et al., 2001; Rippentrop et al., 2005).

In the study sample, religiosity levels were high and the variability of religiosity scores was low. The resulting restriction of range of scores may have limited the number of statistically significant associations between religiosity measures and QoL to one statistically significant association between disease-specific QoL (patient acceptance of the device) and the single item measure of religious importance.

General Quality of Life

In the current study of ICD patients, the mean scores for general QoL Physical Health (PH) and Mental Health (MH) were 37.78 and 53.57 respectively. The SF-12 measure for this study indicated lower physical health scores and slightly higher mental health scores than the general SF-12 scores for the national population $M = 50$ (Ware et al., 1996). However, study participants indicated poorer physical functioning compared to mental health. The results related to physical health were similar to those findings from Passman et al. (2007) in their study of QoL and ICD patients who reported mean scores for physical health as 38 and mental health as 45. However, ICD patients in this study had somewhat higher mental health scores.

Significant correlations were observed between physical health (PH), and number of comorbidities, age, and HADS depression scores. Together, 25% of the variance in physical health scores was predicted by age, number of co-morbidities, and HADS depression. The size and direction of the relationships suggest that ICD patients with lower physical functioning tend to have more depressive symptoms, more co-morbidities, and are younger. However, of these three predictors, depression scores were the most significant. These results were consistent with previous research (Hamilton & Carroll, 2004; Kim et al., 2009), indicating that the number of comorbidities and older age might explain low levels of physical functioning. Older ICD patients with more comorbid conditions may experience poor physical health, which, in turn, could be related to a greater potential for depression.

Mean scores for Mental Health (MH) in the current study were higher than the PH scores. Both age and race were significant demographic factors in the reported mental health scores. Younger ICD patients and African American ICD patients both reported significantly lower mental health scores than older Caucasian ICD patients. In the literature, the most frequently cited risk factor for psychological distress is younger age, most likely due to these patients dealing with an "age inappropriate illness" and the chronic disease is even more intrusive to developmental phases in the lifespan (Sears et al., 2009). The current results support this previous finding.

Many of the study variables were correlated with mental health, including age, race, HADS anxiety and depression, shock anxiety, knowledge of the ICD, and social support. Fifty-five percent of the variability in mental health scores was predicted by these variables. Multiple regression identified only HADS anxiety and HADS depression as independent, statistically significant predictors of mental health. It appears that the mental health of the ICD patients in

this study, who are on average above the national norm, is not directly related to the device itself, but to the patient's general anxiety and depressive symptoms.

Disease-Specific Quality of Life (Patient Acceptance of ICD)

The mean FPAS summary score of 81 was similar to those reported in the literature (Groeneveld et al., 2007; Passman et al., 2007). Caucasian ICD participants in the current study were more accepting of their device compared to the African American (AA) ICD patients. In addition, AAs in this study sample reported more concern about returning to a full life and higher levels of device-related distress as compared to the Caucasian ICD patients. Of particular interest, AA females reported the greatest concern related to body image. The present study results add to the limited research regarding racial and gender differences in the ICD population.

Patient acceptance is a unique construct of QoL for the ICD patient. Statistically significant correlations were observed between the FPAS summary scores and race, age, number of co-morbidities, shock anxiety, knowledge of the device, social support, HADS anxiety and depression, and importance of religion. Sixty-seven percent of the variability in the FPAS scores was predicted by these variables. Multiple regression identified number of co-morbidities, shock anxiety, depressive symptoms, knowledge of the device, and importance of religion as unique, statistically significant predictors of patient acceptance of the ICD. The size and direction of the relationships indicated that shock anxiety, depressive symptoms, and knowledge of the device were the most important predictors of device acceptance. Lower shock anxiety, fewer depressive symptoms, and more knowledge of the device were strongly associated with patient acceptance.

Study Strengths and Limitations

A major strength of this study was the high representation of both females and African Americans, groups that have been underrepresented in previous studies of ICD patients but who

are receiving these devices with increased frequency. This diversity in the sample population led to a preliminary understanding of how adjustment to an ICD device can vary for different subgroups of the cardiac population. In addition, previous research has not examined the role of religiosity in the quality of life (QoL) of ICD patients. Both religiosity and QoL are multidimensional concepts. The use of various measures for both of these concepts in this study helps to expand our knowledge about the relationships between these concepts. Another strength of this research is the integration of religiosity and other specific variables into the study model as possible covariates. By incorporating various demographic, clinical, psychosocial, and religiosity factors in the study design, the existence of relationships among significant predictor variables and QoL were identified while considering the individual's physical and emotional characteristics, belief systems, social network, and context of chronic illness. In so doing, this research represents a more holistic and complete view of the experiences of ICD patients.

However, several limitations must be considered when reviewing these findings. The use of a cross-sectional convenience sample from one regional teaching medical center limits the generalizability of the findings because the sample may not be representative of the entire pool of ICD patients. Another limitation of this study is that no information was obtained regarding care the sample ICD patients received related to psychosocial issues (i.e. patient education, support groups, counseling).

In addition, there is some evidence that religiosity and QOL may change over time and circumstances (Rippentrop et al., 2005). Therefore, a longitudinal design would allow for a more thorough explanation of the impact (both positive and negative) that religiosity may have over the course of living with an ICD. A further study limitation is the use of self-reporting (such as the frequency of shock occurrence) that may present bias and less objective reporting of

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information. Self-report has been noted to be a valid and convenient method to assess physical and psychosocial functioning. However, the inclusion of biomedical and clinical data for reliability comparisons would add to the validity of study findings reported and should be a consideration for future research (Burns et al., 2004).

The sample for this study was relatively homogeneous with regard to religiosity, possibly due to the participants living in a rural southeastern region of the United States where the majority of the population is of the Christian faith. Due to the limitation of the pre-dominantly Christian study sample, the applicability of the findings to individuals with different religious backgrounds is uncertain. Future studies would benefit from a more diverse sample of ICD patients to more fully understand the relationship of religiosity with QoL. Also, a larger sample would afford the opportunity to expand the model and to include additional variables, which might be related to QOL in ICD patients.

Recommendations for Research

Future studies need to recruit more representative samples of ICD patients, particularly of varying ethnic and religious backgrounds to more completely assess the effect of religiosity and other pertinent variables on the QoL in this population. Future studies should also include other measures of QoL and religiosity that may be more predictive of pertinent relationships in this population and facilitate clarification of the concepts of religiosity and spirituality in health research. Variables that have been identified in the current study that are related to improved QoL should be incorporated into interventional studies in an effort to support translational research and evidence-based practice. For example, this study suggests that an intervention that includes a standard protocol for educational support of the ICD patient and family might be effective in promoting adjustment to living with the device. Tested interventions may inform

theory and assist nurses and other health care professionals in providing care that is evidence-based and relevant to the ICD population.

To address the issue of causality and improve the validity of relationships identified from this study, future research studies need to incorporate prospective designs. Such studies would further evaluate whether religiosity and other significant variables associated with QoL, such as disease severity and psychosocial factors, impact compliance with medical regimes, acute hospitalization length of stay, and end-of-life decisions. Of particular interest would be studies to examine the role of depression in predicting physical and psychosocial outcomes of ICD patients. Another step for research is to develop, implement, and evaluate both the content and process of psychosocial interventions.

Future research should also involve the use of qualitative studies to better understand the lived experience of ICD patients and their families. Viewing the life situation through the eyes of those most impacted would provide health care professionals with a more complete assessment of the unique needs of this challenged population and their caregivers. Another recommendation for further research would be to combine quantitative and qualitative methodologies to enable researchers to more clearly identify or confirm key constructs and themes that highlight the unique experiences and perceptions of the individual living with an ICD.

<div align="center">

Implications for Professional Practice

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There is a consensus in the literature on the importance of patient education and counseling (Bostwick, 2007; Groeneveld et al., 2007; Sears, 2009) and the current study findings support that belief. The hierarchical multiple regression models used to predict the three dimensions of QoL in this study found that after controlling for variables that are not amenable to intervention, other variables that are amenable to intervention are important predictors of

quality of life and patient acceptance of the ICD device. The strongest predictor of poor physical health, controlling for age and number of co-morbidities, was depressive symptoms. The strongest predictors of poor mental health, after controlling for age and race, were generalized anxiety and depressive symptoms. In the prediction of patient acceptance of the ICD, after controlling for race, age, and number of co-morbidities, the strongest predictors of poor patient acceptance were shock anxiety, depressive symptoms, and knowledge of the ICD. Interventions such as patient education and counseling by nurses, psychologists, physicians, and other health care professionals are essential in providing care for the ICD patient.

There are several factors that affect the ICD patient's overall QoL and adjustment to living with the implanted device. This research supports the need for health care professionals to recognize that the ICD patient is the most appropriate person to define their QoL and those factors that are most influential to that QoL, such as demographic, clinical, spiritual, and psychosocial factors. Study findings emphasize the importance of a religious/spiritual assessment in providing care for this population. Religiosity and spirituality may enable some ICD patients to deal with the challenges of their chronic illness and be more accepting of their device. Results from the current study indicate the need for nurses and other clinicians to attend to the poor physical and mental health of ICD patients and expand the scope of interventions such as support groups, cognitive behavioral therapy, and physical exercise training. In addition, the study results may suggest the use of faith-based interventions for some ICD patients. Effective coping may further help to decrease the psychological distress of living with an ICD, lessening the shock anxiety, and promoting a positive influence on QoL. As appropriate, health care providers can use these findings to encourage ICD patients who value religion to continue their religious

activities so as to maintain the benefits offered, such as psychosocial and emotional support, and finding a sense of meaning in their lives.

It is essential for health care professionals caring for the ICD population, to assess and identify individuals who may be at risk for poor QoL related to living with their device. The findings from this study emphasize the significant role of patient education in promoting acceptance of living with an implantable cardiac device. Nurses, in both the acute and outpatient setting, are in an ideal position to develop strategies and interventions for patient and family education. From pre-implant and the acute care experiences, and throughout ICD patient follow-up, nurses and clinicians should maintain on-going support for the educational and psychological needs of this population and their caregivers.

Providing information on the implantable device, how it functions, potential side-effects, and the benefits and limitations of everyday living with the device, is imperative for all ICD patients. However, this study suggests that for the ICD patient who is younger, female, or African American (AA), there may be concerns, fears, and issues that are especially pertinent to the quality of their life situation. Through identification of specific factors that impact understanding and acceptance of an ICD, health care providers can develop strategies that would empower these individuals to successfully adapt to living with their device.

Educational and psychological interventions should be implemented that address the unique needs of at risk individuals, such as lifestyle consequences, device-related distress, and concerns of body image. Supportive programs, designed specifically for these vulnerable sub-groups, may help to reduce anxiety, encourage effective problem-solving and coping skills, and instill confidence. A more positive and patient-focused approach may enhance communication

with nurses and other health care providers, promote compliance with medications and ICD follow-up, and improve QoL for patients.

Although participants in this sample had low levels of depressive symptoms on average, these were predictive of perceived physical and mental health in addition to patient acceptance of their device. Results from this study highlight the importance of assessment and treatment of psychological symptoms, especially depressive symptoms, in an effort to enhance overall and disease-specific QoL in ICD patients. Sears et al. (2009) has presented a clinically based strategy to facilitate effective management of the ICD patient: (1) assessment of demographic and clinical risk factors, such as age < 50 years, female gender, history of psychological distress; (2) clinical observation of ICD patient appearance, behaviors; verbal cues and (3) use of brief questions to assess for key symptoms of anxiety or depression that warrant medical or psychological referral (Sears et al., 2009). Once an assessment is completed, it would be important to have a mental health professional (i.e. medical psychologist) available to handle complex psychosocial issues that an ICD patient may present. Such an assessment strategy could be of benefit in both acute and outpatient settings. A nurse, for example, caring for the patient scheduled to receive an ICD, has an opportunity to use the assessment to identify and address educational and psychosocial needs prior to implant and avoid possible fears and misconceptions. Information can then be reinforced during scheduled ICD follow-up visits. If needed, the medical psychologist may be helpful for the ICD patient who is experiencing device-related distress, such as shock anxiety, hypervigilance, and avoidance behaviors. As noted in the literature, fears and concerns related to the ICD, even among those who do not experience a device shock, can still produce psychological distress (Kuhl et al., 2006). Thus, assessment of ICD patients, especially those most at risk for psychological distress, would allow for appropriate referrals and treatment.

The use of ICD support groups, facilitated by trained health care professionals, would afford individuals a chance to share their experiences and concerns and receive information and clarification about the device. Face-to-face, internet-based, and computer-facilitated support forums have demonstrated positive results (Dickerson et al., 2000; Serber et al., 2010). As noted in this study, the African American (AA) ICD patients who are religious may benefit from a support group designed within a community faith-based organization. Through information sharing and discussion of device-related issues in an environment that is culturally relevant, the AA ICD patient and their significant others may develop a better understanding of their device and a more positive acceptance of life with an ICD. Advanced practice nurses (e.g. Clinical Nurse Specialist; Nurse Practitioner), and mental health professionals working with lay health advisors in the community would be an appropriate team to guide group discussions, provide technical information, and promote positive coping with potential shock anxiety (Dickerson et al., 2000). Current findings indicate that a strong social network paired with knowledge of the ICD may support acceptance of the device and enhanced QoL in the ICD population.

In summary, this study provides a beginning understanding of the effect of religiosity and other factors on the QoL of ICD patients. Although most measures of religiosity in the present research did not reveal significant correlations with either general or disease-specific QoL, ICD patients who were more religious reported a greater acceptance of their implantable device. Religiosity, in some ICD patients, could prove an effective coping strategy to living with the device. This may be especially pertinent for the African American, younger, or female ICD patient who experiences psychological distress when faced with the challenges and life-changes that accompany implantation of this device. As the number of ICD patients increases, it is critical

that ICD related research continue and health care providers strive to transform study results into

clinical practice to benefit those most affected by this life-saving technology.

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APPENDIX A: DEMOGRAPHIC DATA

Demographic Data Form   ID Number: _____

                                                        Date: _____

Age: _____ yrs

Gender: ☐ Male   ☐ Female

Ethnicity: ☐ Hispanic   ☐ Non-Hispanic

Race: ☐ Caucasian   ☐ African-American ☐ Asian Native ☐ American ☐ Other

Marital Status: ☐ Single   ☐ Married ☐ Separated _____ (yrs)

                    ☐ Divorced _____ (yrs) ☐ Widowed _____ (yrs)

Currently living alone? ☐Yes   ☐ No

Highest Level of Education Achieved?

☐ Did not complete HS (enter last grade completed) _____

☐ HS (or equivalent) completed ☐Some college ☐ College graduate ☐ Post-graduate

        education

Medical Record #_____ ☐

Religious Affiliation: _____

APPENDIX B: CLINICAL AND ICD DATA FORM

Clinical and ICD Data Form   ID Number: _____

Date: _____

Implant date: _____
Implant type: ☐ Single chamber   ☐ Dual Chamber   ☐ BiVentricular
ICD Indications: ☐ Primary prevention   ☐ Secondary prevention
Time since Implantation: ☐ Less than 30 days
                        ☐ Less than 1 year
                        ☐ 1-2 years
                        ☐ 2-5 years
                        ☐ More than 5 years

Co-morbidities
☐ NYHA class
    ☐ I   ☐ II   ☐ III   ☐ IV
☐ LVEF _____%   Date _____
☐ Sudden Cardiac Death
☐ Atrial fibrillation
    ☐ Paroxysmal
    ☐ Chronic
☐ CAD
☐ Congenital heart disease
☐ CABG
☐ Valve surgery
☐ Ventricular reduction surgery
☐ Diabetes
☐ Hypertension
☐ Myocardial infarction (heart attack)
☐ PCI
☐ Stroke
☐ Renal failure
☐ Pulmonary disease (hx smoking, sleep apnea)
☐ Substance abuse (alcohol, drugs, etc)
☐ Obesity (BMI____)
☐ Cancer
☐ Clinical Depression

ICD
1. Shock Received: Yes_____ No _____

2. Incidence of ICD shocks (discharges) in past
30 days: None   One   More than one

APPENDIX C: INTERVIEW SCRIPT FOR POTENTIAL STUDY PARTICIPANTS

"I would like to talk to you today about participating in a small study I am doing here at the heart clinic. This study involves you completing some short surveys about your sense of religion and quality of life as a person with an implantable defibrillator. It should take about 15-20 minutes to complete the surveys in a quiet area away from the waiting room and your answers will remain private. If you are interested, you will be asked to sign a consent form. After you read the consent form, you can ask questions and then let me know if you would like to be a part of this study. I can also read the form to you if you wish and you can ask me questions along the way."

If the patient says no, the study recruiter will then say: "OK, if it's because you are in a hurry, would you agree to allow us to discuss the study again at your next visit to the clinic?"

APPENDIX D: INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

University and Medical Center Institutional Review Board
East Carolina University • Brody School of Medicine
600 Moye Boulevard • Old Health Sciences Library, Room 1L-09 • Greenville, NC 27834
Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Mary Wilson, RN, College of Nursing, ECU, 3152 LAHN Building

FROM: UMCIRB

DATE: December 31, 2009

RE: Expedited Category Research Study

TITLE: "The Relationship between Religiosity and Quality of Life in Patients with Implantable Cardioverter Defibrillators"

UMCIRB #09-0951

This research study has undergone review and approval using expedited review on 12/19/09. This research study is eligible for review under an expedited category because it is research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) The Chairperson (or designee) deemed this **unfunded** study no more than minimal risk requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **12/19/09** to **12/18/10**. The approval includes the following items:

- Internal Processing Form
- Informed Consent (dated 12/16/09)
- Protocol/Dissertation Draft
- Conflict of Interest Disclosure Form (dated 12/16/09)
- Interview Script
- Demographic Data Form
- Clinical and ICD Data Form
- SF-12 Health Survey
- Florida Patient Acceptance Scale (FPAS)
- Hospital Anxiety and Depression Scale
- Enrichd Social Support Instrument (ESSI)
- Duke University Religion Index
- Hoge Intrinsic Religiosity Scale

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

IRB0000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418
IRB00004973 East Carolina U IRB #4 (Behavioral/SS Summer) IORG0000418
Version 3-5-07

UMCIRB #09-0951
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