THE UNIQUE EFFECTS OF THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR: THE FEMALE PERSPECTIVE

By

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Significant rates of psychological distress occur in implantable cardioverter defibrillator (ICD) patients. Research has demonstrated that women are a particularly at-risk group for developing psychological distress secondary to cardiac disease. The aim of the study was to examine the intersex differences between women and men, and the intragroup differences among women, with implantable cardioverter defibrillators.

One hundred thirty-two ICD patients were recruited at three medical centers: Shands Hospital at the University of Florida, Brigham and Women's Hospital in Boston, and Royal North Shore Hospital in Sydney, Australia. Seventy-one women and 61 men completed individual psychological assessment batteries, measuring the constructs of shock anxiety, death anxiety, body area satisfaction, and body image concerns. Medical record review was conducted for all patients regarding cardiac illnesses and ICD specific data.

Results revealed significant differences between males and females in their reported levels of shock anxiety, such that women in the study reported higher rates of shock anxiety (F (2,128) = 3.552, p = 0.03, η_p^2 = 0.053). The investigation of intrasex differences among females revealed that younger women (≤ 50 years of age) reported significantly higher rates of death anxiety than women over the age of 65 (F (2,68) = 3.681, p = 0.03, η_p^2 = 0.098) and significantly lower body area satisfaction and greater body image concerns than women aged 51 to 64 (*Pillai's trace* = 0.133, p = 0.05, η_p^2 = 0.067).

The present study identifies a subgroup of female ICD patients at risk for the development of distress subsequent to device implantation. Young women appear to be highly at risk for the development of psychosocial maladjustments across the domains of shock anxiety, death anxiety, and body image. Results suggest that more rigorous assessment and research are indicated in female ICD recipients under the age of 50. Collectively, findings from this study suggest that ICD patients who report elevated feelings of death and shock anxiety, as well as body image dissatisfaction or concerns, warrant considerable attention by healthcare professionals in an effort to minimize adjustment difficulties and possible declines in quality of life after ICD implantation.

CHAPTER 1
INTRODUCTION

Sudden cardiac death (SCD) accounts for over 450,000 deaths per year in the United States and is currently the highest ranked cause of mortality, claiming more lives annually than stroke, lung cancer, breast cancer, and AIDS combined. Sudden cardiac death is precipitated by the onset of life-threatening ventricular tachyarrhythmias, resulting in death if not promptly defibrillated (e.g., within 10 minutes) (American Heart Association, 2004). The implantable cardioverter defibrillator (ICD) is a biomedical device designed to contravene potentially lethal arrhythmias by automatic delivery of an electrical cardioverting shock to defibrillate the heart and restore normal sinus rhythm. The ICD is now implanted in approximately 150,000 Americans each year and randomized trials have demonstrated its superiority to pharmacological interventions in reducing mortality in patients at-risk for SCD (Antiarrhythmics Versus Implantable Defibrillators Trial Investigators, 1997; Bardy et al., 2005; Buxton, Lee, & Fisher, 1999; Moss et al., 1996). The implant rate of the ICD is likely to continue to rise dramatically, as its indications are broadened.

Despite the success of the ICD in preventing SCD, research indicates that the psychological impact of living with a defibrillator can be significantly distressing for recipients. Symptoms of fear and anxiety are considered the most common psychological response of device recipients, with 24-87% of patients reporting symptoms of anxiety (Sears & Conti, 2003), and 24-38% reporting elevated levels of depression (Sears et al., 1999). Collectively, these rates are significantly higher than the general population and

have prompted current researchers to examine how symptoms of psychological distress may affect the etiology of cardiac illness.

In patients with cardiac disease, the evidence that psychological distress can affect both quality of life (QOL) and health outcomes has been described as "clear and convincing" (Rozanski, Blumenthal, & Kaplan, 1999, p. 2192). Moreover, the impact of psychological distress is thought to "strongly influence the course of cardiac disease" (Rozanski et al., 2005, p. 637). Implantable cardioverter defibrillator patients are vulnerable to the development of psychological distress due to many factors, including ICD shock, the recognition of their potential mortality by cardiac disease, and the perceived lack of control over their medical condition (Sears et al., 1999). As such, ICD patients have been recognized as an appropriate population for the study of the development of distress (Godeman et al., 2001).

Research has recognized females with cardiac illness as a particularly at-risk group for the development of psychological distress secondary to their disease (Chin & Goldman, 1998; Con et al., 1999; Frasure-Smith et al., 1999; Holahan et al., 1995; Mendes de Leon et al., 2001; Vaccarino, Lin, & Kasl, 2003; Ziegelstein, 2001). Among populations of patients with congestive heart failure (CHF), females have consistently exhibited worse quality of life than males as well as increased rates of depression (Gottlieb et al., 2004). Since CHF patients frequently require ICD implantation congruent with their cardiac disease progression, this population of females is explicitly at risk for adjustment difficulties (Holahan et al., 1995; Ziegelstein, 2001). Female recipients face unique challenges with the ICD by its impact on their femininity, sexuality, and body image satisfaction (Walker et al., 2004). Traditional ICD placement

often produces visible scarring and bulging around the implant site, presenting a particularly sensitive problem for women, whose clothing often leaves this part of the upper body exposed. Previous research examined quality of life among young ICD patients (Dubin et al., 1996), the majority of which were female, revealing significant patient concerns about the impact of the device on clothing fit (63%), socialization (75%), and sexual activity (50%). Despite these data, there is a paucity of literature in the examination of female-specific adjustment to living with an ICD. In epidemiological studies examining sex differences in depression and anxiety among the general population, women report clinical levels of depressive and anxious symptomatology with nearly twice the frequency of men (APA, 1996; Kessler et al., 1994; Regier, 1994). Therefore, the investigation of sex differences in psychological sequelae among ICD recipients is largely warranted.

CHAPTER 2
LITERATURE REVIEW

The following sections review literature as it applies to patient adjustment to the ICD. The female-specific adjustment issues for ICD patients are addressed across the domains of shock anxiety, death anxiety, and body image.

Shock Anxiety

To prevent SCD in the event of an arrhythmia, the ICD delivers an electrical shock to terminate the potentially lethal arrhythmia and restore normal heart rhythm. Within the first year of implantation, approximately 40 to 42% of ICD patients will experience a shock, 22% will receive 2 or more shocks, and 17% will sustain 3 or more shocks (Credner et al., 1998). In short, shock is a common experience for many ICD patients.

Sears and Conti (2002) state that patients who have a history of ICD firings are at particular risk for psychosocial difficulties. Recent research indicates that ICD patients who receive shocks experience more depression and anxiety, and have poorer adjustment to the device than patients who receive no shocks (Godeman et al., 2004; Kohn et al., 2000). Even in the minority of ICD patients who do not experience shocks, shock anxiety may result in increased avoidance behaviors and a perceived limitation in performing everyday activities (Sears & Conti, 2003). As such, the examination of shock anxiety in ICD populations is warranted.

Death Anxiety

Death anxiety is a multidimensional construct that is characterized by cognitive and affective changes, physical alterations, stress, and even pain (Lonetto & Templer, 1986).

Death anxiety has been described as a dynamic factor that changes with an individual's age, experiences, and health. Tomer and Eliason (2000) define death anxiety as the anticipation of a state in which the self does not exist, which is variable in intensity over time.

In the existing literature, gender is considered a moderating factor in the occurrence of death anxiety. Research has established that women report higher levels of death anxiety, on average (Iammarino, 1975; Schulz, 1979; Templer, Ruff, & Franks, 1971). Death anxiety research to date has traditionally used Templer's (1970) Death Anxiety Scale (DAS), to reveal that female participants display higher levels of death anxiety than do males, regardless of the sample population. However, more recently Neimeyer (1993) found that even when controlling for emotional expressiveness among gender, female participants endorsed greater death anxiety on the DAS compared to their male counterparts. The differences in the incidence of death anxiety among gender have been established in a variety of populations of men and women, including students, parents, psychiatric patients, and hospital staff (Templer et al., 1971). Unfortunately, no studies to date have examined this potential relationship in the context of cardiac disease.

The experience of death anxiety can be particularly salient in the presence of a life threatening illness. As an individual is faced with a life-changing event such as diagnosis of cardiac disease or the survival from sudden cardiac arrest, the frequency and intensity of death anxiety is likely to increase. Despite the heuristic value of this phenomenon, there is a notable absence of research devoted to examining death anxiety among cardiac populations.

Body Image

Implantation of an ICD produces noticeable scarring that can affect body image in recipients. Body image satisfaction is a prevalent issue in women's health research and poses particular relevance for female ICD recipients. Socially visible scars, similar to those created by implantation of an ICD, have been associated with poor self-ratings of appearance, appearance satisfaction, and appearance-related anxiety (Dubin et al., 1996; Lawrence et al., 2004). Several comparisons can be made between women who receive ICDs and women who undergo surgical treatment for breast cancer. In a recent study by Hoeller et al. (2003), women who had undergone breast conservation treatment rated the presence of highly visible scars as the single most important determinant of their perception of the cosmetic outcome of the surgery. Similarly, women have reported significant displeasure with the cosmetic outcome of their surgery and the accompanying sexual and body image sequelae, and continued to overestimate their risk of developing future cancer (Payne et al., 2000). This scenario is strikingly similar to those women who receive ICDs for primary prevention of future cardiac events. Despite their protection from premature sudden cardiac death by the device, patients have a tendency to overestimate their potential mortality by their heart condition (Sears, Shea, & Conti, 2005). Congruous with the breast cancer literature, the changes in physical appearance that female ICD recipients experience may constitute difficulties in their perception of body image. Research indicates that women in general are more concerned with body image, possibly due to societal expectations that pressure women to strive for attractiveness. This pressure regarding their physical appearance may affect a woman's social experiences, mood, and overall quality of life (Wolszon, 1998).

Unfortunately, there has been little examination of the impact of cardiac surgery on female body satisfaction (Allen & Wellard, 2001). Although several studies have examined cardiac disease and body image in the context of perceived physical functioning, there has been virtually no examination of the impact of defibrillators on body image (Lichtenberger et al., 2003). The potential dissatisfaction of cosmetic outcome of device placement and consequent body image sequelae may act as a catalyst for psychological distress in female ICD patients.

Hypotheses

Question 1: Intersex Differences

Do female or male ICD patients experience different levels of shock anxiety, body area satisfaction, and body image concerns?

Hypothesis. Female ICD patients will report more shock anxiety and body image concerns, and less body area satisfaction than male patients.

Participants. All female and male ICD patients.

Analysis. An ANCOVA and a MANCOVA will be performed to determine if sex affects shock anxiety, body area satisfaction, and body image concerns reported by ICD patients.

Table 2-1 Hypothesis 1, Analysis 1

Variables	Statistical analysis	Participants
DV = Shock anxiety	ANCOVA	Females Males
IV = Sex		

Table 2-2 Hypothesis 1, Analysis 2

Variables	Statistical analysis	Participants
DV = Body satisfaction Body image concerns	MANCOVA	Females Males
IV = Sex		

Question 2: Intrasex Differences

Do young, middle-aged, or older female ICD patients experience different levels of shock anxiety, death anxiety, body area satisfaction, and body image concerns?

Hypothesis. Younger women will report higher rates of shock anxiety, death anxiety, and body image concerns, and less body area satisfaction.

Participants. Female ICD patients

Analysis. MANOVAs will be performed to determine if age affects shock anxiety, death anxiety, body area satisfaction, and body image concerns reported by female ICD patients.

Table 2-3 Hypothesis 2, Analysis 1

Variables	Statistical analysis	Participants
DV = Shock anxiety Death anxiety IV = Age	MANOVA	Females

Table 2-4 Hypothesis 2, Analysis 2

Variables	Statistical analysis	Participants
DV = Body satisfaction Body image concerns IV = Age	MANOVA	Females

CHAPTER 3
METHODS

Procedure

Female and male ICD patients were recruited during outpatient cardiac clinic appointments at one of three enrollment sites: Shands Hospital at the University of Florida, Brigham and Women's Hospital in Boston, or Royal North Shore Hospital in Sydney, Australia. After an introduction of the study and gathering of informed consent, patients were provided with individual psychological assessment batteries, and asked to complete the questionnaires and return them to the researcher prior to leaving the clinic. The assessment battery took approximately 15-25 minutes to complete. Upon completion and submission of the assessment questionnaires, patients completed their participation in the study. Medical record review was conducted for information regarding cardiac illnesses and ICD specific data.

Sample

The mean age of the sample was 61.30 years (SD = 14.28) with a range of 23 to 92 years of age. Of the 132 individuals who participated in the study, 61 were male (46%) and 71 were female (54%). Ethnically, 91% of participants self-rated as Caucasian, 6% rated as African American, 2% rated as Asian/Pacific Islander, and 1% rated as Hispanic/Latino. The majority of participants were married (73%), 8% reported being separated or divorced, 8% reported being single, and 7% and 3% reported being widowed and living with a partner, respectively. Of the total sample, 42% had earned a high school diploma or less, 38% had earned a college degree, and 21% had completed a

graduate degree. Table 3-1 provides demographic information for the total sample of ICD patients. Table 3-2 provides complete demographic information categorized by gender.

Table 3-1 Demographic variables of total sample (N = 132)

Demographic	n / %
Gender	
Males	61 (46.2%)
Females	71 (53.8%)
Mean age	61.30 (SD = 14.28)
Ethnicity	
Caucasian	90.9%
African American	6.1%
Asian/Pacific Islander	2.3%
Hispanic/Latino	0.8%
Marital status	
Married, remarried	73.4%
Separated, divorced	8.1%
Single, never married	8.1%
Widowed	7.3%
Living with partner	3.2%
Education	
High school degree or less	41.6%
College degree or less	37.5%
Graduate	20.9%
Employment	
Retired	50%
Disability/ government	17.7%
Full time	16.2%
Part time	9.2%
Homemaker	6.2%
Unemployed	0.8%

Table 3-2 Demographic variables by gender

Demographic	Males	Females	Test statistic	*p*-value
Mean age*	67.36	56.08	F (1,130) = 24.07	p = 0.01
Ethnicity			χ^2 = 5.14, df = 3	p = 0.16
Caucasian	96.7%	85.9%		
African American	1.6%	9.9%		
Asian/Pacific Islander	1.6%	2.8%		
Hispanic/Latino	0.0%	1.4%		
Marital status			χ^2 = 5.62, df = 3	p = 0.23
Married, remarried	80.7%	67.2%		
Separated, divorced	8.8%	7.5%		
Single, never married	3.5%	11.9%		
Widowed	3.5%	10.4%		
Living with partner	3.5%	3.0%		
Education*			χ^2 = 7.15, df = 2	p = 0.03
High school or less	38.9%	43.9%		
College degree or less	29.7%	43.9%		
Graduate	31.5%	12.1%		
Employment*			χ^2 = 21.11, df = 5	p = 0.01
Retired	68.3%	34.3%		
Disability	10.0%	24.3%		
Full time	16.7%	15.7%		
Part time	5.0%	12.9%		
Homemaker	0.0%	11.4%		
Unemployed	0.0%	1.4%		

*indicates significant difference

Patients' medical records were reviewed to obtain the following information. Mean time since ICD implantation was 3.47 years (SD = 2.77). Fifty-one percent of patients were diagnosed with an Ischemic Cardiomyopathy, while 49% were diagnosed

with a Nonischemic Cardiomyopathy. Of the entire sample, 33% had Coronary Artery Disease and 29% met criteria for Congestive Heart Failure. This sample of ICD patients had a mean ejection fraction of approximately 36% (SD = 17.32). Approximately 19% of patients had experienced sudden cardiac arrest and received the ICD for secondary prevention of any future cardiac events. Forty-two percent of patients had received shock therapies prior to enrollment in the study; the mean number of shocks of the entire sample was 3.44 (SD = 11.96). Table 3-3 provides information regarding medical variables for patients. Table 3-4 provides medical variable information categorized by gender.

Table 3-3 Medical variables of total sample (N = 132)

Medical Variable	**n / %**
Mean length of time since implantation	3.47 years (SD = 2.77)
Cardiac Diagnoses	
Ischemic Cardiomyopathy	51.3%
Nonischemic Cardiomyopathy	48.7%
Coronary Artery Disease	32.6%
Congestive Heart Failure	28.8%
Mean ejection fraction	35.79% (SD = 17.32)
History of sudden cardiac arrest	18.9%
History of shocks	
Yes	42.4%
No	57.6%
Mean number of shocks	3.44 (SD = 11.96)

Table 3-4 Demographic variables by gender

Medical Variable	Males (n = 61)	Females (n = 71)	Test statistic	*p*-value
Mean length of time since implantation	3.83 (SD = 2.69)	3.14 (SD = 2.83)	F (1,128) = 2.04	p = 0.16
Cardiac diagnoses				
Ischemic Cardiomyopathy	77.4%	29.0%		
Nonischemic Cardiomyopathy	22.6%	71.0%		
CAD	49.2%	18.3%		
CHF	27.9%	29.6%		
Mean ejection fraction*	32.3% (SD = 15.75)	38.8% (SD = 18.10)	F (1,109) = 4.04	p = 0.05
History of sudden cardiac arrest			χ^2 = 1.22, df = 1	p = 0.27
Yes	16.7%	25.0%		
No	83.3%	75.0%		
History of shocks*			χ^2 = 4.68, df = 1	p = 0.03
Yes	52.5%	33.8%		
No	47.5%	66.2%		
Mean number of shocks	3.78 (SD = 14.30)	3.15 (SD = 9.65)	F (1,129) = 0.09	p = 0.77

*indicates significant difference

Recruitment was conducted at three locations: 63 patients were recruited from Shands Hospital at the University of Florida, 46 from Brigham and Women's Hospital, and 23 from Royal North Shore Hospital in Australia. Table 3-5 presents relative percentages of the total sample by recruitment site.

Table 3-5 Recruitment locations of total sample (N = 132)

Recruitment Site	n
Shands Hospital at the University of Florida	47.7%
Brigham and Women's Hospital	34.8%
Royal North Shore Hospital	17.4%

Chi-square analyses and ANOVAs were conducted for all demographic and medical variables to assess for any significant differences. Among the demographics, significant differences were found in level of education attained and current work situation; among the medical variables, a significant difference was found in mean ejection fraction between the three sites, such that Brigham and Women's had a mean of 41%, followed by Shands with a mean of 34%, and lastly, Royal North Shore with the lowest mean ejection fraction, at 20%. Table 3-6 provides information related to significant demographic differences between recruitment sites. Table 3-7 provides information related to cardiac diagnoses and mean ejection fraction by site.

Table 3-6 Demographic variables by recruitment site

Demographic	**Shands UF**	**Brigham & Women's**	**Royal North Shore**	**Test statistic**	***p*-value**
Education*				$\chi^2 = 16.19$, df = 4	$p = 0.01$
High school or less	50.8%	20.0%	57.1%		
College degree or less	33.9%	42.5%	38.1%		
Graduate	15.3%	37.5%	4.8%		
Employment*				$\chi^2 = 20.28$, df = 10	$p = 0.03$
Retired	45.2%	52.2%	59.1%		
Disability	29.0%	8.7%	4.5%		
Full time	16.1%	21.7%	4.5%		
Part time	6.5%	8.7%	18.2%		
Homemaker	1.6%	8.7%	13.6%		
Unemployed	1.6%	0.0%	0.0%		

*indicates significant difference

Table 3-7 Medical variables by recruitment site

Medical Variable	Shands UF	Brigham & Women's	Royal North Shore	Test statistic	*p*-value
Cardiac diagnoses					
Ischemic Cardiomyopathy	49.2%	51.1%	63.6%		
Nonischemic Cardiomyopathy	50.8%	48.9%	36.4%		
Ejection fraction*				F (2,108) = 6.26	p = 0.01
Mean	33.9%	41.1%	20.1%		
Standard Deviation	2.17	2.47	5.85		

*indicates significant difference

Measures

Demographics. This measure is a brief self-report tool to facilitate collection of demographic information. It includes information such as age, gender, education, work status, income, marital status, religion, and use of past and/or present psychological treatment.

Shock anxiety. The Florida Shock Anxiety Survey (FSAS) is a 10-item measure used to assess ICD-specific anxiety including the cognitive, behavioral, emotional and social impacts of shock; alpha coefficients suggest good reliability (Cronbach's = .91, split-half = .92) and moderate correlation (r = -.65) with death anxiety. Higher scores on the FSAS indicate higher shock anxiety. Full psychometric information has been established (Kuhl et al., in press).

Death anxiety. The Multidimensional Fear of Death Scale (MFODS) is a 42-item assessment device with 5-point Likert response formatting (Neimeyer & Moore, 1994). This scale is composed of eight factors: (1) Fear of the dying process, (2) Fear of the dead, (3) Fear of being destroyed, (4) Fear for significant others, (5) Fear of the

Unknown, (6) Fear of conscious death, (7) Fear of the body after death, and (8) Fear of premature death (Neimeyer & Moore, 1994). For this study only the Fear of the Dying Process (6 items) and Fear of Premature Death (4 items) Scales will be used. The range of scores for the whole measure is from 42 to 210, with lower scores indicating higher death anxiety. Previous research has calculated the Cronbach's alpha of reliability at .85 (Neimeyer & Moore, 1994).

Body area satisfaction. The Body-Self Relations Questionnaire (BSRQ) is a widely used, self-report measure of body image (Brown, Cash, & Mikulka, 1990). It has 10 subscales assessing patient satisfaction of appearance, fitness, health and illness, and weight; Appearance Evaluation, Appearance Orientation, Fitness Evaluation, Fitness Orientation, Health Evaluation, Health Orientation, Illness Orientation, Body Area Satisfaction, Overweight Preoccupation, and Self-classified Weight. Participants respond to questions on a scale of 1 ("definitely disagree") to 5 ("definitely agree"). Higher scores reflect greater investment or satisfaction. The BSRQ has acceptable validity and reliability; normal values are based on a large, national sample (Brown et al., 1990). For the purposes of this study, we will only be using the Body Area Satisfaction subscale, on which patients rate the extent to which they are satisfied with particular areas of their body.

Body image concern. The Florida Patient Acceptance Survey (FPAS) is a valid and reliable 18-item measure used to assess patient acceptance of cardiac device treatment (Burns et al., 2005). Patient acceptance refers to achieving maximal benefit from a biomedical device such as an ICD. The FPAS is composed of four factors: 1) Return to Function, 2) Device-Related Distress, 3) Positive Appraisal, and 4) Body Image

Concerns. The FPAS total score and subscale scores demonstrated both convergent and divergent validity with the SF-36, Atrial Fibrillation Symptom Severity Scale, CES-D, STAI, and the Illness Intrusiveness Rating Scale (Burns et al., 2005). For this study, only the Body Image Concerns scale will be used. Higher scores on the Body Image Concerns subscale indicate higher levels of distress or concerns.

Medical variables. Data on the following medical variables was collected through medical record review: left ventricular ejection fraction, cardiac diagnosis, ICD placement duration, history of mental health problems or treatment, current medications, cardiac risk factors, and shock history. Stored intracardiac electrograms allowed for definitive identification of arrhythmias leading to the delivery of shock.

CHAPTER 4
RESULTS

The following statistical analyses were performed to evaluate the proposed hypotheses for this research project. The Statistical Package for the Social Sciences (SPSS) was utilized to perform all the analyses. In order to correct for violations of the Box-M test and the Levene's test for the assumption of homogeneity of variance, the relatively conservative *Pillai's trace* was used for the estimation of F-statistics in the analyses that follow. Variables were examined on a list wise basis; therefore, participants who did not complete all measures were not included in analyses. When appropriate, Bonferroni corrections were applied to rectify the possibility of Type I error. Family wise error rates are noted for each analysis. This method of correction was utilized in order to provide a conservative and methodical analysis of the data.

Intersex Differences

Hypothesis 1: Female ICD patients will report more shock anxiety and body image concerns, and less body area satisfaction than male patients.

Findings: The following analyses controlled for ejection fraction and shock history as significant differences were found among men and women at study onset. Data from all ICD patients were utilized in the following analyses. In all analyses, Bonferroni corrections were applied. The first analysis was conducted to evaluate the effects of participant group (male and female) on the amount of reported shock anxiety. An ANCOVA was performed to evaluate the differences between male patients and females. Results revealed a significant difference between males and females in reported

shock anxiety (F (2,128) = 3.552, p = 0.03, η_p^2 = 0.053), such that female patients reported higher rates of shock anxiety than their male counterparts. Despite using shock history as a covariate, differences still remained between men and women enrolled in the study in reported shock anxiety.

The second analysis was conducted to evaluate the effects of participant group on reported body image concerns and body area satisfaction. A MANCOVA determined that males and females did not significantly differ overall in their reported body area satisfaction and body image concerns (*Pillai's trace* = 0.042, p = 0.10, η_p^2 = 0.042). This suggests that male and female ICD patients report similar levels of body area satisfaction and body image concerns. Inspection of the mean values indicated that females did report lower body area satisfaction and more body image concerns, on average, than did men in the study, although these differences did not reach significance with this sample. Table 4-1 provides means on psychosocial measures by the total sample.

Table 4-1 Psychosocial means of total sample

	Male M	Female M	Male n	Female n
FSAS*: Shock anxiety	15.53* (SD = 6.77)	16.33* (SD = 7.12)	60	71
MBSRQ: Body area satisfaction	36.43 (SD = 21.96)	29.95 (SD = 6.87)	61	70
FPAS: Body image concerns	9.63 (SD = 21.33)	16.72 (SD = 25.52)	61	71

*indicates significant difference

Intrasex Differences

Hypothesis 2: Younger women will report higher rates of shock anxiety, death anxiety, and body image concerns, and less body area satisfaction.

Findings: Data from all female ICD patients were utilized in the following analyses. In all analyses, Bonferroni corrections were applied. The first analysis was conducted to evaluate the effects of participant group (young, middle-aged, or older females) on the amount of reported shock anxiety and death anxiety. A MANOVA determined that participant groups did not significantly differ overall in their reported shock anxiety and death anxiety (*Pillai's trace* = 0.127, $p = 0.06$, $\eta_p^2 = 0.064$). However, upon examination of the univariate death anxiety ANOVA, it was evident that there was a significant group difference in reported death anxiety (F (2,68) = 3.681, $p = 0.03$, $\eta_p^2 = 0.098$) such that younger women reported significantly higher death anxiety than older women ($p = 0.025$). This analysis suggests that young women may experience more death anxiety than women over the age of 65.

The second analysis was conducted to evaluate the effects of age on reported body area satisfaction and body image concerns. A MANOVA revealed that participant groups did significantly differ overall in their reported body area satisfaction and body image concerns (*Pillai's trace* = 0.133, $p = 0.05$, $\eta_p^2 = 0.067$). Multiple comparisons determined that younger women reported significantly higher body image concerns than their middle-aged cohorts ($p = 0.03$). Results suggest that female ICD recipients under the age of 50 may experience more body image concerns than women between 51 and 64 years of age. Table 4-2 provides means on psychosocial measures by the three groups of females.

Table 4-2 Psychosocial means of females by age group

	Young (n = 28)	Middle-Aged (n = 21)	Older (n = 22)
FSAS: Shock anxiety	18.72 (SD = 8.23)	15.12 (SD = 7.10)	14.45 (SD = 4.60)
MFODS*: Death anxiety	30.10* (SD = 10.83)	33.20 (SD = 9.17)	37.83* (SD = 9.70)
MBSRQ: Body area satisfaction	30.32 (SD = 7.24)	28.95 (SD = 5.59)	30.44 (SD = 7.70)
FPAS*: Body image concerns	26.78* (SD = 29.01)	8.33* (SD = 19.49)	12.50 (SD = 22.70)

*indicates significant difference

CHAPTER 5
DISCUSSION

Summary of Results

The major objectives of the current study were to investigate the intersex and intrasex differences among patients with ICDs. Specifically, this study investigated through analyses of variance, the strength of the associations between sex, age, shock anxiety, death anxiety, and body image, while controlling for left ventricular ejection fraction, at a single time point.

Results from this study suggest that males and females exhibit significantly different levels of shock anxiety. Recent literature has suggested that female ICD patients may be at increased risk for psychological distress, although specific avenues for distress have yet to be established (Walker et al., 2004). Fear of future shock may persist as a particular area of concern for female patients. In the current study, women reported higher rates of shock anxiety than did males. Based on our results, shock anxiety is an area of highlighted concern for female patients and should be fully explored in future research and acknowledged by clinicians.

Although rates of body area satisfaction and body image concerns were not significantly different among males and females, an obvious trend was identified. On average, women reported lower body area satisfaction and more body image concerns than men in the study. There are several explanations why this trend may exist. Previous research has established that women tend to report more body image disturbances after physical scarring than men, on average (Lawrence et al., 2004). Therefore, it would seem

logical than this trend would persist even among cardiac populations. However, an even more likely explanation of this phenomenon is the obvious imposition of the device on the physiognomy of the female body. Standard placement can be challenging for women due to their anatomy; the weight of the breast itself may pull and tear on incisions making the scar larger still. The practical limitations of bra straps, purse straps, and seat belts (Giudici, 2001) are side effects of standard device placement that have been acknowledged. Davis and colleagues (2004) examined the body satisfaction of women implanted with cardiac pacemakers. They reported that the visibility of their scar, how their clothing fit with the device, and the impact their device had on wearing swimsuits, were significant concerns of women, compared to their male cohorts. As an ICD is significantly larger than a pacemaker, it is reasonable to assume that women who receive ICDs may also experience considerable concerns related to the impact of the device on body image.

Although intrasex differences in shock anxiety were not found, highly significant differences in death anxiety were reported among female patients enrolled in the current study. Results suggest that women under the age of 50 experience clinically significant levels of death anxiety, largely in excess of their older-aged cohorts. Many of these women have experienced sudden cardiac death and have been faced with the prospect of dying. Younger women often experience a rapid onset of cardiac disease, such as non-ischemic cardiomyopathy, giving them little time to adjust with the life-altering events they have recently experienced. While the ICD has been widely established as a life-saving device, some patients appear to have significant anxiety related to the device and fears of death (Pauli et al., 1999). Death anxiety appears to be a particularly relevant

construct to this population of young female patients, which may be due to the rapid onset of their cardiac disease coupled with the implantation of an ICD as a constant reminder of their potential mortality.

In the current study, results revealed highly significant differences in reported body image issues between women under the age of 50 and women between the ages of 51 and 64. This suggests that middle- and older-aged women who have undergone implantation of an ICD experience similar rates of body area satisfaction and body image concerns, while younger women experience highly clinically significant symptoms of distress associated with body image. The visibility of a defibrillator and the accompanying socially visible scar may likely contribute to body dissatisfaction among younger women with ICDs. Martin, Leary, and Rejeski (2000) described a variety of psychological implications accompanying disease- and age-related changes that resulted in a perceived decrease in physical attractiveness. Notably, low self-esteem, depression, social isolation, and symptoms of hypochondriasis were associated with negative self-ratings of appearance. Previous research examined quality of life among younger ICD patients (Dubin et al., 1996) and revealed significant patient concerns about the impact of device placement on clothing fit (63%), socializing problems due to their device (75%), and worries about sexual activity with an implantable device (50%), suggesting body image and quality of life are highly related. As such, the imposition of the device on a woman's body in terms of visibility and scarring warrants increased attention to body image issues surrounding ICD implantation and subsequent adjustment in younger female recipients.

Strengths and Limitations

When interpreting results from this study, there are several strengths and limitations that should be taken into consideration. In an attempt to recruit an unbiased

sample, we enrolled participants from three distinct medical centers with a considerably wide geographical area. Analyses evaluating this sample found participants to be relatively equivalent to each other in regards to demographic and medical variables, with the exception of education and vocational status, and ejection fraction. Despite extending recruitment to multiple locations, our sample size may be considered relatively limited in the number of patients participating in data collection. This limitation may have resulted in reduced significant findings regarding the stated hypotheses. We attempted to minimize the effect of this limitation through the use of Bonferroni corrections to control for Type I errors. It should also be noted that this study examined data from a single time point, and may not accurately represent comprehensive psychosocial functioning over time. In order to rectify this methodological limitation, future research should include repeated measurement over time with a randomized controlled design.

For purposes of investigating intrasex differences among female participants in the study, women were stratified according to age. We divided the women into three age groups; ≤ 50, 51-64, and ≥ 65 years of age. Despite the potential limitations of grouping women by age, and thus splitting a continuous variable into a categorical variable, we felt we were justified in doing so for several reasons. First, previous cardiac research has utilized this methodology, categorizing females as young women (under 50), middle aged women (51 to 64), and older women (over the age of 65). Second, research within breast cancer has often organized women into similar groupings by age to examine differences between younger and older females in their experience with breast cancer and subsequent treatment. Third, the experience of heart disease may be very different across the lifespan. Younger women more typically have a rapid onset of a more non-ischemic

cardiac disease and often receive an ICD for secondary prevention after they have already experienced a sudden cardiac arrest. Older women more typically have experienced years of coronary risk factors, suffer from a more ischemic form of cardiac disease, and receive the device for primary prevention of future cardiac events. Therefore, women across the lifespan may experience different forms of cardiac disease and may also present with different indications for receiving an ICD, which makes clinical sense to separate them by age in research.

As with all research, consideration of self-report measures should be made; self-report measures may be influenced by patient demand characteristics, such as participant perception of how they should respond or would like themselves to be perceived. The measures used in assessing psychosocial functioning in patients were restricted to the use of standardized and validated measures that were chosen for their established reliability and validity in measuring the constructs of interest. We also attempted to minimize the influence of demand characteristics by allowing patients to complete the measures in privacy in outpatient clinics and by assuring confidentiality of responses and anonymity after data collection.

Clinical Implications

Collectively, results from this study highlight the growing need for comprehensive psychological care for women with ICDs. The lack of research in the female-specific adjustment to the ICD represents absence of innovation in the area of comprehensive care for women. Without such innovation, healthcare professionals fail to provide universal comprehensive care to the female ICD recipients. Only with appropriate facilitative care can female ICD patients return to previous levels of physical and psychosocial functioning. The study emphasizes the need for healthcare providers to

recognize and acknowledge symptoms of distress among female patients in an attempt to identify those women most at risk for the development of psychosocial maladjustments secondary to cardiac disease. Clinicians can utilize this information to improve outcomes in ICD recipients by providing patients with increased attention to their psychological needs and referrals for psycho-educational interventions when indicated.

Implantable cardioverter defibrillator patients may experience improved health outcomes through a combination of optimal medical treatment and tailored psychosocial care, including pre- and post-implant psychological consultation, support groups with other recipients, or individual psychotherapy. This process can be facilitated by the integration of cardiac psychologists as an essential component of the electrophysiology team.

The changes in physical appearance that female ICD recipients experience may constitute differences in their perception of body image. Traditional ICD placement involves creating an incision in the left chest wall wherein the device is implanted. This procedure produces both visible scarring and bulging around the implant site due to the placement of the device underneath the skin. This protocol presents a particularly sensitive problem for women, whose clothing often leaves this part of the upper body exposed. Female ICD recipients would likely benefit from well-developed treatment protocols that include a variety of implant options, pre-operative education, and plastic surgery consultation. As therapies continue to advance, female ICD patients, particularly those under the age of 50, may benefit from well-established guidelines that take into consideration the unique issues women face with the implantation of a cardiac device.

Research Implications

The review of the relevant literature to date suggests that the female-specific adjustment to the ICD has not been thoroughly assessed. The current study substantially adds to this body of literature, in the exploration of the unique experience female patients face in living with an ICD. Given that women with cardiac disease experience more psychological morbidity than men, it is reasonable to predict that female ICD patients demonstrate different patterns of adjustment relative to males; this hypothesis in part was supported by our results. The investigation of the unique issues women face in living with an ICD is noteworthy, as it could largely improve quality of life, adjustment, and psychological fitness of female ICD recipients.

Given the findings of the current study and other research documenting psychological maladjustment to the ICD, future research needs to next address the potential differences in psychological functioning among age groups of device recipients. Results from the current study revealed several intrasex differences among females, including the reported frequencies of clinically significant death anxiety and body image concerns; further exploration of these constructs is largely warranted.

Future research focused on tailored psychological care for female patients is also indicated, including the investigation of psychosocial interventions and their effects on health outcomes of ICD patients post-implant. To date, however, there have been very few studies that have examined the impact of such interventions on ICD patient adjustment and psychosocial functioning (Kohn et al., 2000). Additionally, given the paucity of research that has been conducted to date examining individual differences influencing the adjustment of females to the ICD, future studies would be beneficial in providing useful information to clinicians about the potential differences between male

and female ICD recipients. Finally, additional research identifying and further scrutinizing potential risk factors for psychological maladjustment to the ICD is indicated. While the current study provides useful information in this regard, future studies could more specifically address the independent value of each of the aforementioned variables by determining the differential risk associated with each of these factors. While this type of analysis was beyond the original scope of the current study, it is clearly an extension that is implicated from the findings and should be incorporated in future research endeavors. This data emphasizes the importance of a multidisciplinary approach in the investigation and treatment of ICD patients.

Conclusion

In summary, the ICD is a life-saving device whose use is increasing annually. Although the effectiveness of its life-saving utility is well established, quality of life and adjustment issues persist. Women in particular appear to be a vulnerable subpopulation for developing subsequent distress after implantation. Shock anxiety, death anxiety, and body image issues are possible avenues of distress for female recipients. Given these considerations, this study offers new information regarding the female-specific experience in living with an ICD.

In closing, the findings from this study suggest that ICD patients who report elevated feelings of death and shock anxiety, as well as body image dissatisfaction or concerns, should be evaluated for psychological intervention to minimize adjustment difficulties and possible declines in quality of life after ICD implantation. Subsequent to implant, young women appear to be highly at risk for the development of psychosocial distress associated with shock anxiety, death anxiety, and body image. More considerable attention is warranted in women under the age of 50 by researchers and

clinicians alike, as this population has been identified to be increasingly more likely to receive an ICD as the indications for implantation continue to grow exponentially (Wolbrette et al., 2002).

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BIOGRAPHICAL SKETCH

Lauren Vazquez Sowell was born in Farmington Hills, Michigan, on March 11th, 1982, to Dr. and Mrs. Paul and Teresa Vazquez. She has one younger sister, Andrea, and a younger brother, Paul Evan. Lauren graduated cum laude from the University of Florida in May 2004 with a Bachelor of Health Science degree in health science and a Bachelor of Science in psychology. She married David Sowell on May 6th, 2005. Lauren and her husband, David, currently reside in Gainesville, Florida, where she is pursuing her Ph.D. in clinical and health psychology at the University of Florida. Her clinical and research interests lie in medical and health psychology, with a focus on cardiovascular disease and cardiac device therapy.