

INTERACTIVE EFFECTS OF FOCUSED FEARS AND AVOIDANT COPING ON
ANXIETY IN PATIENTS WITH IMPLANTABLE CARDIOVERTER
DEFIBRILLATORS

By

JULIA D. BETENSKY

A dissertation submitted to the
Graduate School-New Brunswick
Rutgers, The State University of New Jersey

In partial fulfillment of the requirements

For the degree of

Doctor of Philosophy

Graduate Program in Psychology

Written under the direction of

Richard J. Contrada, Ph.D.

and approved by

New Brunswick, New Jersey

October, 2012

ABSTRACT OF THE DISSERTATION

Interactive Effects of Focused Fears and Avoidant Coping on Anxiety in Patients with Implantable Cardioverter Defibrillators

By JULIA D. BETENSKY

Dissertation Director:

Richard J. Contrada

The implantable cardioverter defibrillator (ICD) has become the standard treatment for patients at risk for sudden cardiac death. When it detects a life-threatening arrhythmia the ICD delivers a shock to normalize cardiac activity. While medically effective, up to 88% of patients who receive an ICD experience some form of anxiety symptoms. Potentially relevant factors that have been implicated in the development and maintenance of anxiety include fear of anxiety (i.e., anxiety sensitivity; AS), fear of pain (FP), and fear of being shocked (i.e., shock anxiety; SA) as well as avoidant coping (i.e., attempts to regulate fear and prevent anxiety by reducing the probability of exposure). The purpose of this longitudinal study was to test a cognitive-behavioral model in which effects of specific fear on anxiety severity in ICD patients are magnified by avoidant coping behavior. Forty-two ICD recipients completed the Anxiety Sensitivity Index, the Florida Shock Anxiety Scale, the Pain

Anxiety Symptoms Scale, an Avoidant Coping Scale, and the Beck Anxiety Inventory, at the time of an electrophysiology visit and at a 12-week follow up. As hypothesized, there was a significant interaction between AS and avoidant coping, as well as between FP and avoidant coping, such that avoidant coping strengthened associations linking higher baseline AS and FP to increased 12-week anxiety severity. A significant interaction between SA and avoidant coping was not of the predicted form. Overall, these findings help to clarify the role of specific fears and avoidant coping in the maintenance of anxiety and may facilitate the tailoring of nonpharmacologic interventions designed to controvert the exacerbation of anxiety among ICD patients.

Acknowledgement

I am extremely grateful to my advisor Richard J. Contrada for his dedicated support and to the mentors who helped and supported me throughout this project, including Jan Mohlman, Danielle E. McCarthy, and Elaine Leventhal. I would also like to thank Archana Patel, KatanehMaleki, and Abel Moreyra for their indispensable contributions to this work. This project was supported by NIMH NRSA Predoctoral Fellowship F31 MH085457-01A2.

Table of Contents

Abstract	ii
Acknowledgement	iv
List of Figures	vii
List of Tables	vi
Table of Contents	v
Introduction	1
Arrhythmias	1
Anxiety in ICD Recipients	2
Guiding Theories	2
Anxiety Sensitivity as a Risk Factor for Anxiety Symptoms	4
Fear of Pain as a Risk Factor for Anxiety Symptoms	4
Shock Anxiety as a Risk Factor for Anxiety Symptoms	5
Linking Fear Acquisition and Avoidant Coping to Anxiety	6
Proposed Model	7
Aims and Hypotheses	10
Methods	11
Participants	11
Measures	11
Procedure	14
Results	15
Preliminary Analyses	15
Predictors of Change in Anxiety Severity	15

Discussion	18
Main Findings	18
Extension of ICD Literature	20
Theoretical Implications	21
Clinical Implications	22
Limitations	23
Summary and Conclusions	23
References	25
Appendix I. Baseline characteristics stratified by completer status	43
Appendix II. Assessment Materials	46
Appendix III. Interview Schedule	63
Appendix IV. Diagnostics for Regression Analyses	64
Appendix V. Description of the Hamilton Anxiety Scale and Short Form 36	65
Appendix VI. Additional Analyses	66
Curriculum Vitae	69

List of Tables

Table 1. Descriptive information for patients ($N = 42$)	34
Table 2. Intercorrelation matrix ($N = 42$)	36
Table 3. Regression analysis for anxiety severity at 12 weeks ($N = 42$)	37

List of Figures

Figure 1. Integration of guiding theories	38
Figure 2. Proposed cognitive-behavioral model	39
Figure 3. Main effect of avoidant coping on anxiety severity at 12 weeks in Step 2 of the full model	40
Figure 4. Significant interaction between anxiety sensitivity (AS) and avoidant coping on anxiety symptoms at 12 weeks	41
Figure 5. Significant interaction between baseline fear of pain (FP) and avoidant coping on anxiety symptoms at 12 weeks	42
Figure 6. Significant interaction between baseline shock anxiety (SA) and avoidant coping on anxiety symptoms at 12 weeks	43

Introduction

Implantable cardioverter defibrillators (ICDs) terminate potentially life-threatening arrhythmias by delivering electrical shocks to the heart, thereby normalizing cardiac activity and preventing sudden death. Despite the medical efficacy of ICDs, anxiety is a serious mental health problem among recipients. Left untreated, distress may exacerbate cardiac symptoms (Dunbar et al., 1999; Lampert et al., 2002) and impair quality of life (Dickerson, Kennedy, Wu, Underhill, & Othman, 2010). While psychological interventions have been examined as a means of treating anxiety in ICD patients (see Pedersen, van den Broek, & Sears, 2007), treatment effects vary and mechanisms are unclear. Research guided by a theoretical model of the development and maintenance of anxiety in ICD patients is needed to inform efforts to improve available treatments. This study examined a cognitive-behavioral model in which specific fears and avoidant coping contribute to anxiety severity in ICD patients.

Arrhythmias

Cardiac arrhythmias, characterized by abnormal electrical activity of the heart, vary depending on heart rate (normal, slow, fast), mechanism (type of electrical impulse malfunction), and origin (atrial, ventricular). Some arrhythmias, if untreated, can lead to cardiac arrest and sudden death, which kills approximately 325,000 people per year in the United States (Sovari, Kocheril, & Baas, 2010). American Heart Association treatment guidelines (Epstein et al., 2008) support the use of ICDs because multiple clinical trials demonstrate that ICDs reliably terminate ventricular tachycardia and improve survival compared with medication (Moss, 2010; Zipes et al., 2006). The number of devices implanted continues to rise each year (Zhan, Baine, Sedrakyan, & Steiner, 2008), with

close to 1 million devices implanted from 1993 to 2006 (Kurtz et al., 2010).

Anxiety in ICD Recipients

ICD shocks are unpredictable, uncontrollable, and aversive (Sears, Todaro, Lewis, Sotile, & Conti, 1999), which may account for the fact that ICD-specific fears and symptoms of anxiety (e.g., excessive worry, physiological arousal) are common psychological problems among ICD patients. Approximately 25% to 87.5% of recipients experience some form of anxiety (Bourke, Turkington, Thomas, McComb, & Tynan, 1997), 13% to 38% of recipients experience diagnosable levels of anxiety (Sola & Bostwick, 2005), and general anxiety in ICD patients seems to remain stable over time (Lemon & Edelman, 2007; Pedersen, Theuns, Jordaens, & Kupper, 2010). Hegel and colleagues (1997) reported that one-third of ICD recipients had clinically significant levels of anxiety and fear of symptoms of autonomic arousal that persisted, with 40% to 63% of subjects continuing to have difficulties for a year. As more people receive and live a longer portion of their lives with ICDs, the incidence, duration, and economic burden of comorbid anxiety can be expected to increase.

Guiding Theories

Barlow (2004) discusses three kinds of vulnerability factors in anxiety disorders: biological vulnerabilities (e.g., genetics), generalized psychological vulnerabilities (i.e., early learning experiences), and specific psychological vulnerabilities. The latter involve the focus of anxiety which may be physical sensations, social evaluation, or cognitions, (i.e., “bad” thoughts). Reiss expanded upon this third vulnerability in his expectancy theory (Reiss, 1991), positing three fundamental fears, including: (1) injury/illness sensitivity—fear of injury, illness, and death, (2) fear of negative evaluation—

apprehension or distress about being rejected or censured by others, and (3) anxiety sensitivity (AS)—fear of anxiety symptoms (Taylor, 1999). Fears are cognitive attributes that are conceptually and empirically distinct from trait anxiety; they are based on catastrophic expectations of harmful outcomes (Taylor, 1999). Research guided by an information processing approach indicates that individuals who are vulnerable to anxiety disorders have attentional biases for threatening information and interpretative biases for ambiguous information (Mathews & MacLeod, 1994). See **Figure 1** for a depiction of an integrative model that draws from these theories.

According to Reiss (1991), fundamental fears involve stimuli that are innately aversive for most people and may be activated in a wide range of situations. It should be noted that recent work suggests that humans may not be born with certain fears, but have an innate ability to learn them quickly (LoBue, 2010). Conversely, common fears (e.g., fear of heights, fear of eating in public) can be logically reduced to, or exacerbated by, fundamental fears (Reiss, 1991) and may not be acquired as quickly as fundamental ones (LoBue, 2010). Reiss (1991) argues that “fundamental fears provide reasons for fearing a wide range of stimuli, whereas ordinary fears do not have this characteristic” (p.147). For example, fear of flying may arise from feared consequences such as plane crashing (illness/injury sensitivity), fear of humiliating oneself by becoming motion-sick during the flight (fear of negative evaluation), or fear of panicking while enclosed in the plane (AS; Taylor, 1995). Fear of flying (common fear) therefore may be logically reduced to and potentially exacerbated by illness/injury sensitivity, fear of negative evaluation, or AS (fundamental fears).

Anxiety Sensitivity as a Risk Factor for Anxiety Symptoms

Patients who meet criteria for ICDs typically experience bodily sensations (e.g., palpitations) that actually reflect their heart condition. Inward-focused attention can be adaptive, but hypervigilance and worry can be problematic. Based on many laboratory and prospective studies (Maller & Reiss, 1992; Schmidt, Zvolensky, & Maner, 2006; Zvolensky, Goodie, McNeil, Sperry, & Sorrell, 2001), AS is now widely recognized as a risk factor for anxiety symptoms or diagnoses in the general population. Several investigators have examined AS as a potential determinant of anxiety symptoms in ICD populations. However, evidence to date among ICD recipients regarding the impact of AS on anxiety severity is inconsistent. Van den Broek (2008) found that greater AS for up to 3 weeks following ICD implantation predicted increased self-reported and interviewer-rated anxiety at 2 months follow-up, controlling for demographic and biomedical covariates. However, another study, by Lemon and Edelman (2007), indicated that AS was only associated with high levels of anxiety prior to device implantation, but not at follow-up assessments, suggesting that AS might be associated with distress only during high-threat situations. One purpose of this dissertation is to describe and test a more comprehensive theoretical model that may account for discrepant findings.

Fear of Pain as a Risk Factor for Anxiety Symptoms

Patients have compared the experience of a shock to a swift kick in the chest and have rated it 6 on a 0 to 10 pain scale (Ahmad, Bloomstein, Roelke, Bernstein, & Parsonnet, 2000; Pelletier, Gallagher, Mitten-Lewis, McKinley, & Squire, 2002). Chest pain can be experienced independently of shock if an arrhythmic episode lasts long

enough to affect cardiac function, although many ICD patients are asymptomatic or experience palpitations or fluttering sensations that are not necessarily painful (American Heart Association, 2011). Based on Reiss' (1991) working definitions, FP can be conceptualized as a fear of injury, illness, or death. As with SA, we suggest that FP be categorized as an injury/illness sensitivity that is not explicitly described by Reiss (1991). Although FP has not yet been examined in ICD patients to our knowledge, there is some support for the importance of FP in other populations. Findings indicate that FP is a better predictor of functional limitations than AS in the general population (Asmundson & Taylor, 1996; Norton & Asmundson, 2004) and that it is reported among patients with co-occurring trauma-related and social anxiety (Asmundson & Nicholas Carleton, 2005). Given that many ICD patients have functional limitations (Sears, Lewis, Kuhl, & Conti, 2005) and co-occurring conditions (Bourke et al., 1997), a model that explicitly incorporates FP may be useful.

Shock Anxiety as a Risk Factor for Anxiety Symptoms

The threat of an unpredictable electrical shock is a unique experience of ICD recipients. While Reiss' expectancy model (Reiss, 1991) only touches on injury/illness sensitivities, it can be adapted for ICD recipients to include an explicit focus on fears concerning potential shocks. To this end, researchers (Kuhl, Dixit, Walker, Conti, & Sears, 2006) have begun to examine shock anxiety (SA), which is defined as the fear or anticipation of an ICD shock. It has been proposed that ICD recipients who have a high level of concern about being shocked, regardless of whether they have been shocked, are those most likely to manifest heightened anxiety (Pedersen, van Domburg, Theuns, Jordaens, & Erdman, 2005b; Sears & Conti, 2003). For these reasons, there is a

theoretical basis for inclusion of SA in a modified version of Reiss' theory (Reiss, 1991).

Linking Fear Acquisition and Avoidant Coping to Anxiety

Although theories of anxiety disorders emphasize learning-based (Barlow, 2004) and cognitive (Taylor, 1999) factors in the development of anxiety disorders, the way in which they are linked to pathology is unclear. The cognitive-behavioral model that guided this study draws from Mowrer's two-factor theory (Mowrer, 1947) and contemporary conditioning theories, including Reiss' expectancy theory (Reiss & Bootzin, 1985; Reiss & McNally, 1985; Reiss, 1991) and Eysenck's incubation theory (Eysenck, 1985). Mowrer's two-factor theory (Mowrer, 1947) suggests that neutral stimuli become conditioned elicitors of fear when experienced in temporal contiguity with aversive events. It also suggests that avoidance responses are generated operantly via the negative reinforcement produced by reduced distress. Modern approaches to conditioning suggest that fear learning is more complex and that individuals use several cognitive faculties to "learn" fear (e.g., Martin, 1983; Mineka & Zinbarg, 1996), including cognitive learning (e.g., someone is told that the subway is dangerous), covert conditioning (repeated associations of imaginations or words), observational learning, and deductive reasoning (Reiss & Bootzin, 1985).

Despite differences, these theories all acknowledge that fear motivates avoidance responses, which in turn, maintain fears and anxiety via operant negative reinforcement. When avoidance responses are successful, there is a temporarily relief of anxiety and discomfort that arises in the context of fearful stimuli. Because the danger was supposedly averted, catastrophic thoughts—i.e., fears—are reinforced. However, the individual misattributes the lack of catastrophic outcome to the avoidant strategy rather

than to the low probability of the catastrophe happening. For example, a woman who fears nausea and avoids eating certain foods attributes her gastrointestinal comfort to her avoidance of those foods rather than to the unlikely event that the foods would cause nausea. This reinforces the avoidant coping strategy, solidifies the utility of fear in provoking the avoidance, and maintains or even exacerbates anxiety.

Eysenck's incubation theory (Eysenck, 1985) posits that when an unconditioned stimulus (e.g., fear of nausea) is exceptionally strong, associated fear is likely to persist because the extinction process may be weaker than the reinforcement process (i.e., avoidance). Incubation will result, demonstrated by an increase in the strength of the conditioned response (e.g., anxiety), when an individual is presented several times with only a conditioned stimulus (e.g., ingestion of feared food without accompanying nausea). That is, with intense fear, avoidance is so reinforcing that exposure to the feared stimulus not only fails to result in extinction but aggravates anxiety and punishes the individual for approaching it, thereby reinforcing the cycle. Even when reinforcement does not trump extinction, feared stimuli are often inevitably encountered and endured with distress. Moreover, when an individual attempts to block fears (e.g., attempts to inhibit intrusive thoughts about nausea), the failure to avoid them typically leads to unbearable increases in anxiety that can progress to panic-like intensity (Levis, 1985).

Proposed Model

There is a need for a comprehensive theoretical model and tests of processes that link cognitive and affective factors to anxiety symptoms in ICD recipients. **Figure 2** depicts the model that guided this dissertation. An ICD recipient may avoid physical exertion because he or she fears it will trigger shock. Persistent avoidance of safe

situations negatively reinforces avoidance responses and prevents the natural abatement of fear that occurs when individuals confront feared situations in controlled circumstances (e.g., systematic desensitization). ICD recipients would be prevented from learning that feared stimuli do not typically provoke a shock. With the passage of time and the absence of a threatening event (i.e., a shock), individuals may begin to feel that a shock is “due” (Eysenck, 1985). Eysenck clarifies this point by providing the “old story about the man who could not go to sleep when the neighbor living in the room above him dropped one shoe on the floor when going to bed. He kept waiting the drop of the other shoe” (Eysenck, 1985, p.98). As the fear of a shock intensifies, imagined or inescapable exposure to physical exertion (conditioned stimulus) in the absence of a shock (unconditioned stimulus) will lead to incubation of the anxiety (conditioned response) rather than to the extinction of the fear (Eysenck, 1985). When a shock is imagined or inevitably encountered, there will be a surge of anxiety that is then maintained by the escape or avoidance response that follows it. The number of neutral stimuli (e.g., a staircase, household chores, having to rush to keep an appointment) paired with the imagined fear will continue to rise over time, thereby creating a more pervasive and less context-specific fear. Failed attempts to stop worrying about shocks will be frustrating and further increase anxiety (Levis, 1985).

Several of the processes described above point to the prediction that fears are more likely to lead to increased anxiety when accompanied by avoidance than when not. Based on our model, it is hypothesized that one or more of the relevant fears, in combination with avoidant coping, will contribute to the most severe anxiety symptoms among ICD recipients, as compared to elevations in one or neither of these factors. ICD

patients who are fearful (i.e., of bodily sensations, shocks, and pain) will experience worsening anxiety if they avoid feared stimuli (e.g., exercise, sexual activity, working in the garden) in the absence of bodily sensations, shocks, or pain; or, their failure to avoid those stimuli and block their own fears will result in increased distress.

Preliminary support for our model comes from evidence supporting the impact of fears on anxiety that was described previously (e.g., Maller & Reiss, 1992; Schmidt, Zvolensky, & Maner, 2006; Zvolensky, Goodie, McNeil, Sperry, & Sorrell, 2001; Asmundson & Nicholas Carleton, 2005; Sears & Conti, 2003). It also comes from evidence linking avoidant coping to fear and distress (Costa & Pinto-Gouveia, 2010; Hori et al., 2010). Several reports suggest that individuals who use avoidant coping during biological challenge (e.g., exposure to carbon dioxide enriched air) show higher levels of anxiety, affective distress (Feldner, Zvolensky, Eifert, & Spira, 2003), and panic symptoms (Spira, Zvolensky, Eifert, & Feldner, 2004) as compared to individuals who do not tend to use avoidant coping.

There is little available evidence of avoidant coping as a moderator of fear in promoting anxiety. We do know that ICD patients have avoidant tendencies; their avoidance is highest for activities (39%), followed by objects (27%) and places (17%), independent of extent of prior experience with shocks (Lemon, Edelman, & Kirkness, 2004). It has also been demonstrated that patients who interpret their illness as severe and use emotion-focused coping (e.g., avoidance of situations) are more at risk for poor adjustment to the ICD than those who minimize consequences of the device and use proactive problem-focused coping (Hallas, Burke, White, & Connelly, 2010). Despite this information, there are no published studies investigating the synergistic role of fear

and avoidant coping in exacerbating anxiety among ICD recipients.

Aims and Hypotheses

A longitudinal cohort study of 42 patients who received an ICD was conducted in order to test the foregoing reasoning. The first goal was to examine baseline AS, FP, SA and avoidant coping as risk factors for anxiety symptoms 12 weeks following the electrophysiologist visit. We hypothesized that greater AS, FP, and SA in the context of inevitable medical and psychosocial stressors will predict increased anxiety severity 12 weeks later. The second main goal was to examine avoidant coping as a moderator, such that it influences the way in which AS, FP, and SA promote the development of anxiety symptoms. We hypothesized that avoidant coping will interact with AS, FP, and SA to increase their association with increased anxiety severity 12 weeks later.

Methods

Participants

Eighty-five patients who were either scheduled or had already received an ICD and were seen by one of three participating electrophysiologists were selected as a convenience sample at Robert Wood Johnson University Hospital in New Brunswick, New Jersey. Main indications for the device included current or prior symptoms of heart failure and a left ventricular ejection fraction $\leq 35\%$ as well as a reasonable expectation of survival with good functional status for more than 1 year. Individuals were excluded if they did not speak English or had neurological difficulties that would interfere with interviewing. Of the 85 patients, 7 patients (8.2%) did not complete any assessments because they consented but then either withdrew (1), died (1), or were no longer eligible for an ICD (4) before completing the baseline assessment; in one instance, technical problems with the interview software led to the loss of data (1). Of the 78 patients who completed the baseline assessment, 42 patients (54%) also completed the 12-week time-point. Reasons for drop-out included patients' decision to withdraw due to loss of interest (15), unsuccessful attempts to contact (17), and reported sickness/death (4). See **Table 1** for demographic and biomedical information for our sample. See **Appendix I** for patient characteristics stratified by completer status; there were no significant differences due to completer status.

Measures

Anxiety sensitivity was measured with the Anxiety Sensitivity Index (ASI; Peterson & Reiss, 1992), a 16-item self-report measure of fear of bodily sensations associated with arousal. Each item consists of a possible negative consequence of

anxiety symptoms, e.g., “It scares me when I feel shaky.” Psychometric properties of the ASI have been replicated across diverse populations (Zvolensky et al., 2001). Internal consistencies have been demonstrated to be high for the total score ($\alpha = .83$; Vujanovic, Arrindell, Bernstein, Norton, & Zvolensky, 2007). Cronbach’s alphas for our sample were .85 (baseline) and .91 (follow-up).

Fear of pain was measured with a 10-item subscale of the Pain Anxiety Symptoms Scale Form (PASS; McCracken, Zayfert, & Gross, 1992), a self-report measure of anxiety associated with pain symptoms. Each item (e.g., “Pain sensations are terrifying”) is rated on a 6-point Likert scale. Factorial validity has been demonstrated for 4 dimensions, including fear of pain, pain-related escape/avoidance, physiological symptoms, and cognitive symptoms of anxiety scores (Coons, Hadjistavropoulos, & Asmundson, 2004). Several studies demonstrated internal consistency (McCracken, Gross, Sorg, & Edmands, 1993) and convergent validity (McCracken, Gross, Aikens, & Carnrike, 1996). Cronbach’s alphas for the fear of pain subscale in our sample were .70 (baseline) and .75 (follow-up).

Shock anxiety was measured with the Florida Shock Anxiety Scale (FSAS; Kuhl, Dixit, Walker, Conti, & Sears, 2006), a 10-item self-report measure of fear of experiencing a shock. Items (e.g., “I worry about the ICD firing and creating a scene” or “When I notice my heart beating rapidly, I worry that the ICD will fire”) are rated on a 5-point Likert scale. The FSAS has good reliability ($\alpha = .91$) and convergent validity (Kuhl, Dixit, Walker, Conti, & Sears, 2006). Cronbach’s alphas for our sample were .85 (baseline) and .91 (follow-up).

Given the paucity of well-established measures of avoidant coping relevant to the

ICD, we constructed a new measure by adapting and integrating items from the Panic Disorder Severity Scale (PDSS; Shear et al., 1997) and the ICD and Avoidance Survey (Lemon, Edelman, & Kirkness, 2004). Avoidant coping was conceptualized as repeated attempts to eliminate or minimize activities in order to reduce the likelihood of experiencing distress. Six items varied with regard to whether strenuous activity, playing sports, exciting sports events, working in the garden, having an argument, or sexual activity was avoided. Higher scores indicated more avoidant coping. Psychometric analyses supported our scale's validity and reliability (α s = .74 and .75; test-retest reliability from baseline to 12-week follow-up, $r = .57$, $p < .001$; convergent validity with a pain-related avoidance subscale of the PASS, $r = .36$, $p < .05$).

Self-reported anxiety severity was measured with the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988). The BAI is a widely-used instrument that consists of twenty-one questions about how the subject has been feeling in the last week. Each item represents an anxiety symptom (e.g., numbness or tingling) and is rated based on how much the symptom has bothered the individual, ranging from 0 (Not at all) to 3 (Severely; I could barely stand it). Cronbach's alpha for our sample were .86 (baseline) and .89 (follow-up).

Biomedical variables (see **Appendix II**) were acquired from hospital medical charts. Several studies were examined to identify potentially relevant biomedical variables that are specific to ICD patients, including studies assessing psychosocial factors implicated in ICD patients (Pedersen et al., 2007; Sears et al., 2005) and large, well-known studies examining the efficacy of ICD treatment (Zaman et al., 2009).

See **Appendix II** for assessment materials.

Procedure

The treating electrophysiologist (EP) determined which patients were eligible based on the inclusion criteria described above and asked them if they were interested in participating. The research assistant informed interested patients about the nature of study and, if the patient agreed to participate, obtained written informed consent. Patients had the option of completing the baseline assessment at that time or at the next convenient time. Baseline assessments (i.e., demographic information, measures of fears, avoidant coping, and anxiety symptoms) took between 45 and 120 minutes, depending on the patient's anxiety level and health status. The follow-up interview (i.e., measures of fears, avoidant coping, and anxiety symptoms) was conducted approximately 12 weeks ($M = 11.7$ weeks) after the visit. Each of these assessments took approximately 45 to 120 minutes to complete. See **Appendix III** for the interview schedule.

Results

Preliminary Analyses

Descriptive information for the final sample is presented in **Table 1**. There were 36 (86%) men and 6 (14%) women. Patients ranged in age from 45 to 93, with a mean of 66.9 years. Patients were White (73.8%), Black (16.7%), Asian (7.1%), or American Indian (2.4%); married (61.9%), separated or divorced (16.7%), widowed (19.0%), or single (2.4%); and well-educated ($M = 15.2$ years). Correlations among main independent and dependent variables for each major time-point are presented in **Table 2**. As can be seen, correlations are small to moderately large in magnitude and mostly similar for each time-point; avoidant coping was correlated with fears to a greater extent at 12 weeks ($r_s = .29$ to $.37$) than at baseline ($r_s = .21$ to $.28$).

We conducted bivariate correlational analyses to identify potential covariates which also were selected on the basis of previous research. Main demographic factors (age, gender, marital status) were not significantly correlated with 12-week anxiety ($r_s = .06$ to $.20$), but were included as covariates nonetheless given their demonstrated influence on anxiety and anxiety-related dimensions in ICD patients (Hamilton & Carroll, 2004; Shea, 2004; Sowell, Sears, Walker, Kuhl, & Conti, 2007; Spindler, Johansen, Andersen, Mortensen, & Pedersen, 2009; Vazquez et al., 2008). Biomedical variables were not significantly correlated with 12-week anxiety ($r_s = +/-.05$ to $+/-0.3$). They were not included as covariates in the main model to conserve degrees of freedom given the lack of consistent preexisting data and theory to support their role in anxiety.

Predictors of Change in Anxiety Severity

Hierarchical regression analyses were used to predict anxiety symptom severity

measured at the 12-week follow-up. AS, FP, SA, avoidant coping and all anxiety scores were first centered around their means. Three product terms were created to represent interactions by multiplying avoidant coping by each of the fear constructs: (1) AS x avoidant coping, (2) FP x avoidant coping, and (3) SA x avoidant coping. In the first step, baseline anxiety, age, gender, and marital status were entered. In the second step, fear constructs (e.g., AS, FP, SA) and avoidant coping were entered as main effect terms.¹ In the third step, all three product terms were entered to evaluate interaction effects. See **Appendix IV** for a description of diagnostics that were examined for each regression model.

Results for the full model are shown in **Table 3**. Results for step 1 indicated a significant main effect for baseline anxiety, where greater baseline anxiety predicted increased anxiety severity at 12 weeks ($\beta = .35, t(4, 37) = 2.10, p < .05, sr^2 = .32$). There were no significant main effects of age, gender, and marital status ($ps > .53$).

Results for step 2 indicated a significant main effect of avoidant coping ($\beta = .31, t(8, 33) = 2.12, p < .05, sr^2 = .28$). As shown in **Figure 3**, greater avoidant coping predicted increased anxiety severity at 12 weeks. There was also a marginally significant main effect of SA ($\beta = .31, t(8, 33) = 1.75, p = .09, sr^2 = .22$), such that higher levels of SA were associated with greater anxiety severity at 12 weeks. There were no significant

¹ Analyses were repeated to examine independent main effects of each main risk factor when reducing overlapping variance. Baseline anxiety severity, age, gender, and marital status were entered in step 1. In step 2, one of the risk factors was entered. There were significant main effects of AS (*standardized* $\beta = .46, t(5, 36) = 2.93, p < .01$), SA (*standardized* $\beta = .51, t(5, 36) = 3.28, p < .01$), and avoidant coping (*standardized* $\beta = .44, t(5, 36) = 2.96, p < .01$) on 12-week anxiety severity. There was no significant main effect of FP ($p = .27$). Analyses of the full model were also repeated with the fears entered simultaneously in a separate step from avoidant coping. This rendered a significant main effect for SA (*standardized* $\beta = .37, t(5, 36) = 2.06, p < .05$) and a marginally significant main effect for AS (*standardized* $\beta = .29, t(5, 36) = 1.70, p = .10$).

or marginally significant main effects of AS or FP ($ps > .13$).

Results for step 3 indicated a significant interaction between AS and avoidant coping ($\beta = .38, t(11, 30) = 2.41, p < .05, sr^2 = .27$). As shown in **Figure 4**, higher levels of avoidant coping strengthened the effect of baseline AS on 12-week anxiety severity. There was also an interaction between FP and avoidant coping ($\beta = .31, t(11, 30) = 2.05, p < .05, sr^2 = .23$). **Figure 5** illustrates that higher levels of avoidant coping strengthened the effect of baseline FP on 12-week anxiety severity. A third interaction, involving SA and avoidant coping, depicted in **Figure 6**, indicated that higher levels of avoidance weakened the effect of baseline SA on 12-week anxiety severity ($\beta = -.60, t(11, 30) = -3.18, p < .01, sr^2 = .36$).

See **Appendix VI** for additional analyses examining: (1) independent biomedical predictors of anxiety severity at 12 weeks, (2) preliminary findings for the role of pre-implant fears and avoidant coping in predicting post-implant anxiety, and (3) associations between anxiety and quality of life.

Discussion

The aims of this study were to examine the contributions of AS, FP, SA, and avoidant coping to anxiety symptoms in a longitudinal study of patients with ICDs. The expectation that avoidant coping would amplify the anxiety-promoting effects of fears in ICD patients was derived from a cognitive-behavioral model drawing from several theories of anxiety (Eysenck, 1985; Levis, 1985; Mathews & MacLeod, 1994; Mowrer, 1947; Reiss, 1991). As hypothesized, there was a significant interaction between AS and avoidant coping, as well as between FP and avoidant coping, such that avoidant coping strengthened associations linking higher baseline AS and FP to increased 12-week anxiety severity. A significant interaction between SA and avoidant coping, while not necessarily inconsistent with cognitive-behavioral theory, was not of the predicted form. Nonetheless, the overall findings have implications that may facilitate the understanding and treatment of anxiety in ICD patients.

Main Findings

Our study is novel in its investigation of avoidant coping as a moderator of fears involved in the course of anxiety symptoms in ICD patients. The findings suggest that avoidant coping activates AS and FP, such that a high level of avoidance in combination with the presence of either of these fears operates as an anxiety-enhancing factor. It is surprising that there are such limited empirical data on this topic given the number of theories that suggest these interactive effects (Barlow, 2004; Eysenck, 1985; Levis, 1985; Mathews & MacLeod, 1994; Mowrer, 1947; Reiss & McNally, 1985). The only previous prospective study of which we are aware found no evidence for an interaction between fear of negative evaluation and harm avoidance in predicting anxiety at 6 month follow-

up among 157 patients with social phobia (Faytout et al., 2007). However, this may reflect the fact that all the patients were receiving psychotherapeutic treatment, and a majority of them were also receiving antidepressant medication (typically an SSRI). These treatments likely blunted fears, avoidance, and anxiety, and reduced variability in these factors, such that the findings may not have provided a good test of the role of the anxiety-promoting effects of fears and avoidance.

A cross-sectional study of 304 patients with Type 2 diabetes showed that what was referred to as a "negative coping style" strengthened the association between worrying about decline in body/physical function and anxiety symptoms (Zhang et al., 2009). An avoidant coping style in the presence of diabetes-related interpersonal crisis appeared to worsen depression, but it did not moderate the effect of worrying on anxiety. Although these findings seem to converge with our findings to some extent, the data were not prospective, negative and avoidant coping were not clearly defined or distinguished, and psychometric attributes of the avoidant coping scale were poor. There is a large literature on other coping constructs such as rumination (e.g., Marks, Sobanski, & Hine, 2010), worry (e.g., Stapinski, Abbott, & Rapee, 2010), and denial (e.g., Elliott, 1980) that have been examined for possible moderating effects on relationships between fear-like constructs and anxiety outcomes. However, these studies generally examine coping as a covert, cognitive process, whereas our model conceptualizes coping as an overt, behavioral response.

Whereas avoidant coping amplified the anxiogenic effects of AS and FP, it weakened the effects of SA on anxiety. This finding was not anticipated, but may not be incompatible with theory underlying our model. A basis for expecting discrepant

findings for SA, on the one hand, and AS and FP, on the other might be derived from consideration of differential effects of avoidant coping in the presence of recent-onset versus longstanding fears. Our patients received their devices an average of 31 months prior to baseline assessment. SA is therefore most likely a more newly acquired fear than AS or FP, which are stable trait-like characteristics (Schmidt, Lerew, & Jackson, 1997) that have been shown to be partly heritable (Stein, Jang, & Livesley, 1999; Vassend, Roysamb, & Nielsen, 2011) and are thought to originate from early life experiences (Scher & Stein, 2003; Turk & Wilson, 2010). Mineka (2004) distinguishes between processes underlying early versus late learning about fears that may account for the differential effects of avoidant behaviors for longstanding (e.g., AS, FP) versus recently acquired (e.g., SA) fears. Some empirical data also suggest that avoidance provides relief from recent-onset distress, whereas it may be maladaptive for chronic distress (Hackett & Cassem, 1976; Holmes & Stevenson, 1990; Suls & Fletcher, 1985). Although post-hoc analyses not described in this dissertation demonstrated that avoidant coping was not particularly protective for patients who received their devices recently as compared to those who received them less recently, the small sample size precludes firm conclusions. The issue of recency of fear acquisition warrants further study in ICD patients.

Implications for the ICD Literature

AS has received considerable empirical support as a risk factor for anxiety psychopathology in the general population (e.g., Schmidt et al., 2006). While these findings have been replicated in some ICD patients (Lemon & Edelman, 2007), this effect has not always been attained (Van den Broek et al., 2008). Our data suggest that these discrepant findings may be due to the heretofore unexamined role of avoidant

coping. It is possible that differences between studies in the degree to which patients engaged in avoidant coping may account for inconsistencies in the reported effects of AS.

FP has not been examined among ICD patients. However, effects of FP on anxiety have been found in patients with functional limitations (Asmundson & Taylor, 1996; Norton & Asmundson, 2004) and patients with co-occurring trauma-related and social anxiety (Asmundson & Nicholas Carleton, 2005). Based on our findings, it would be interesting to determine whether these effects in other populations are moderated by patients' avoidant coping behaviors in a manner similar to that seen in the present study.

While the predictive utility of SA has not previously been examined, there are reports indicating that ICD recipients who have a high level of concern about being shocked, even if they have not been, are those most likely to manifest heightened anxiety (Pedersen, van Domburg, Theuns, Jordaens, & Erdman, 2005a; Sears & Conti, 2003)). Consistent with Pedersen (2005a), post-hoc analyses not described in this dissertation showed that, with statistical control of the frequency of experienced shocks, high SA continued to contribute to increased anxiety, and avoidant coping remained a significant moderator of the effect. Based on these findings, our data suggest that the device concerns should be examined in combination with avoidant coping.

Theoretical Implications

Our data support a model that draws from several theories (Eysenck, 1985; Levis, 1985; Mathews & MacLeod, 1994; Mowrer, 1947; Reiss, 1991b) that offer somewhat different explanations of anxiety, but nonetheless all lead to the prediction that avoidant coping moderates the effect of fear on anxiety. More work is needed to tease apart these theories. In the presence of AS and FP, avoidance may be so reinforcing that, even with

exposure to the feared sensations, there is no extinction of avoidant behavior. Instead, they aggravate anxiety and punish the individual for approaching situations associated with anxiety and pain, thereby reinforcing the cycle. Anxiety appears to be exacerbated by inevitable encounters with feared bodily sensations and pain as well as by failed attempts to inhibit intrusive fears (Levis, 1985). The number of neutral stimuli paired with AS and FP likely rises over time since their inception, thereby creating a more pervasive, persistent, and less context-specific fear. This does not appear to be the case for SA, which seems to be a more recently acquired fear for ICD patients. As learning theorists have posited (see Barlow, 2004), an ICD patient's fear of his own anxiety- or pain-related symptoms does not necessarily guarantee the development of anxiety symptoms. Rather, negative perceptions of ambiguous bodily sensations and pain may only exacerbate anxiety when they are chronic and coped with ineffectively.

Clinical Implications

Existing treatments show promise for reducing anxiety in ICD patients, but may benefit from theoretically-based and empirically-tested information about psychological processes and their discrepant manifestation in patients with different profiles of relevant fears and coping predilections. Identification of individuals with both elevated fears and avoidant coping should facilitate the tailoring of existing nonpharmacologic interventions designed to controvert the exacerbation of anxiety (see Freedenberg, Thomas, & Friedmann, 2011 for review). It might be expected that emphasis on exposure to avoided activities within a controlled, therapeutic setting would disconfirm the belief that they are harmful, thus reducing the negatively reinforcing effects of overt avoidant coping, fears, and anxiety. Attempts to replace avoidant coping strategies with an acceptance of the

existence of negative affect or sensations may also be effective in addressing covert avoidant coping strategies.

Limitations

These data were collected from a modest number of patients ($N = 42$) and dropout rates were higher than expected. Despite an absence of significant differences between completers and non-completers on any biomedical, demographic, or psychological factor in attrition analyses, the small sample size precludes conclusions regarding the generalizability of findings and non-findings. It is possible that selective recruitment and dropout may have contributed spuriously to the findings that were obtained.

Additionally, avoidance data were derived from a new measure that has not been widely used. However, our data supported the psychometrics of this measure, and it appears to have been successful in tapping avoidant tendencies that are commonly observed among ICD patients. Another limitation is that depression was not assessed as an outcome.

Although anxiety is the main source of distress in ICD patients, it would be of interest in future studies to examine additional consequences of avoidant coping, including fewer opportunities to experience the benefits of exercise (e.g., elevated mood, stress reduction, health-promoting effects), reduced psychosocial functioning (e.g., restricting leisure pursuits), diminished quality of life (e.g., reducing pleasurable experiences; Campbell-Sills & Barlow, 2007), and reduce the likelihood of gaining mastery or self-efficacy in the context of frightening situations.

Summary and Conclusions

Little is known about how the experience of receiving an ICD contributes to the development of anxiety disorders. This study focused on fears that are specific to the

experience of ICD patients and are theoretically expected to account for the amplification of, or temporary relief from, anxiety symptoms through effects of avoidant coping. The study of patients with ICDs presented a unique opportunity to examine the role of AS, FP, SA, and avoidant coping in the exacerbation of anxiety symptoms and to further the integration of cognitive and behavioral theories of anxiety. The present study was novel in its: (1) test of a cognitive behavioral model of anxiety in a population with comorbid medical and psychological symptoms, (2) focus on a patient population whose beliefs, behaviors, and anxiety problems have been understudied, (3) specification of avoidant coping as a moderator responsible for translating risk into comorbidity, and (4) construction of an avoidant coping measure designed to tap main sources of ICD patients' avoidance. Continued investigation of the psychological processes that impose anxiety risk in ICD patients may be beneficial for their mental and physical health.

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Table 1

Descriptive information for patients (N = 42)

<i>Demographics</i>	
Age, mean (SD)	67 (11)
Sex	
Male	36 (86)
Female	6 (14)
Ethnicity	
Non-Hispanic	41 (98)
Hispanic	1 (2)
Race	
American Indian/Native American/Alaskan	1 (2)
Asian	3 (7)
African-American	7 (17)
Caucasian	31 (74)
Marital status	
Married	26 (62)
Single	1 (2)
Divorced/Separated	7 (17)
Spouse Deceased	8 (19)
Yearly Household Income	
< \$15K	3 (7)
\$15K-25K	3 (7)
\$25K-40K	6 (14)
\$40K-50K	13 (31)
> \$100K	11 (26)
Unwilling to disclose	6 (14)
Years of education, mean (SD)	15 (4)
<i>Biomedical Variables</i>	
Etiology	
Non-ischemic	11 (26)
Ischemic	31 (74)
Indication	
Primary prophylaxis	34 (81)
Secondary prevention	8 (19)
Status	
Pre-ICD baseline	14 (33)
Post-ICD baseline	28 (67)
Months since implant, mean (SD)	31 (35)
Received Replacement Device	14 (33)
Readmission	22 (52)
Deceased	1 (2)

Congestive Heart Failure	22 (52)
Left Ventricular Ejection Fraction, mean (SD)	28 (6)
Experienced Shock	10 (24)
Cardiac Resynchronization Therapy	17 (41)
Device-related Complications	1 (3)
Ventricular Tachyarrhythmia	23 (55)
Previous Myocardial Infarction	16 (38)
Previous Percutaneous Coronary Intervention	22 (52)
Previous Coronary Bypass Graft Surgery ²	17 (41)
Diabetes	11 (26)
Obesity	11 (26)
Hypertension	24 (57)
Hypercholesterolemia	9 (21)

Numbers are presented as *n* (%) unless otherwise stated.

Table 2

Intercorrelation matrix (N = 42)

	M (SD)	1	2	3	4	5	6	7	8	9
Baseline										
1. AS	18.6 (11.7)									
2. FP	11.9 (6.6)	.30								
3. SA	16.6 (6.4)	.56***	.43**							
4. Avoidant Coping	1.8 (1.7)	.21	.22	.28						
5. Anxiety Severity	9.4 (8.5)	.24	.36**	.38**	.30					
Follow-up										
6. AS	15.3 (11.5)	.67***	.47**	.67***	.12	.35*				
7. FP	12.3 (7.7)	.18	.59***	.45**	.21	.38*	.47**			
8. SA	15.7 (7.2)	.39*	.48***	.62***	.24	.22	.51***	.44**		
9. Avoidant Coping	1.5 (1.7)	.17	.13	.21	.19	.57***	.29	.37*	.32*	
10. Anxiety Severity	8.1 (7.2)	.46**	.25	.52***	.35*	.49***	.46**	.38*	.41**	.24

AS = anxiety sensitivity; FP = fear of pain; SA = shock anxiety

* $p \leq .05$; ** $p < .01$; *** $p < .001$

Table 3

Regression analysis for anxiety severity at 12 weeks (N = 42)

Predictor set and individual predictor	ΔR^2 for step	β	sr^2
1. Covariates			
Baseline Anxiety		.353*	.102
Severity		.104	.009
Age		.040	.001
Gender	.142	.037	.001
Marital Status			
2. Main Effects		.250	.038
Anxiety Sensitivity		.010	.000
Fear of Pain		.303†	.049
Shock Anxiety	.326***	.309*	.076
Avoidant Coping			
3. Interactions			
AS x Avoidant Coping		.383*	.074
FP x Avoidant Coping		.311*	.054
SA x Avoidant Coping	.149***	-.602**	.130

Note. Betas are taken from each of the respective steps and reflect independent effects controlling for all other predictors.

† $p < .10$. * $p < .05$. ** $p < .01$. *** $p \leq .001$.

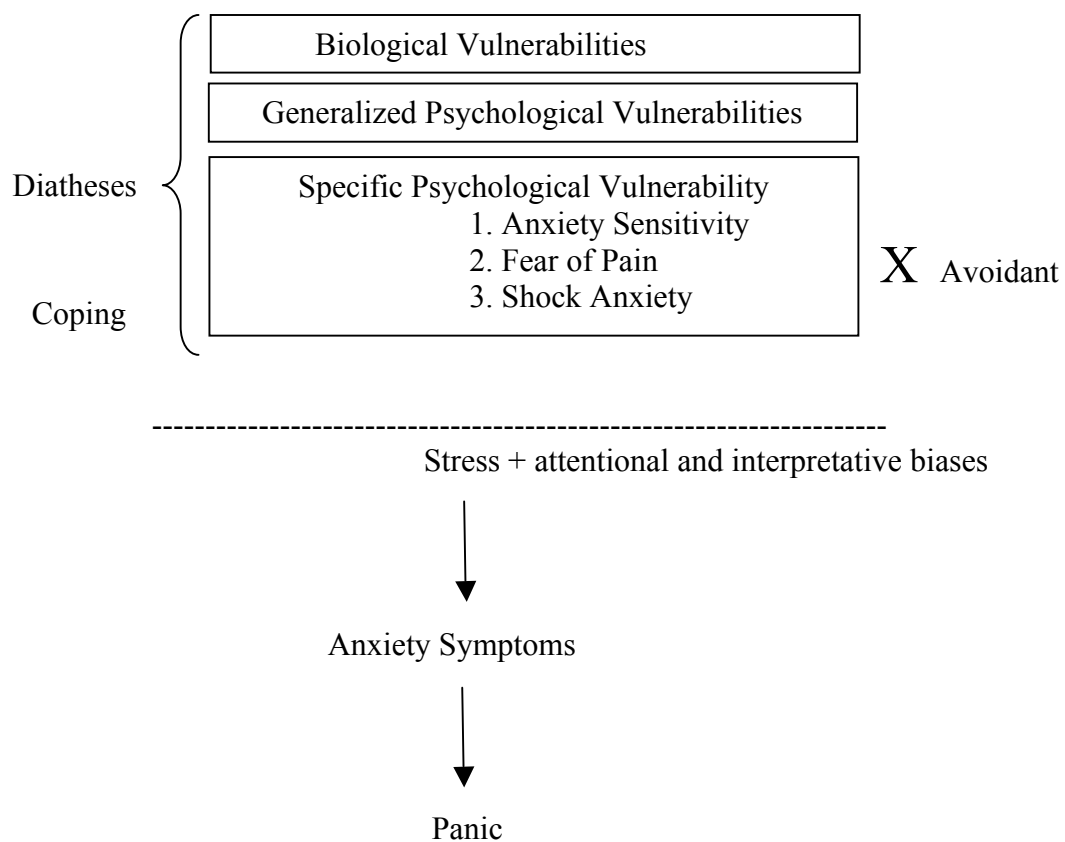


Figure 1. Integration of guiding theories.

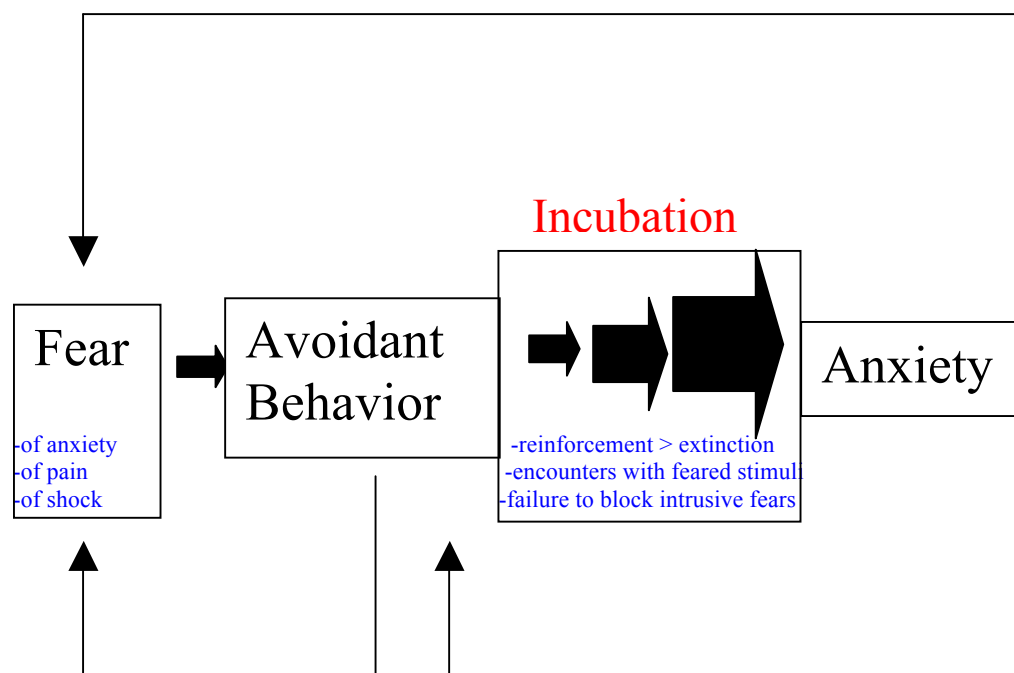


Figure 2. Proposed cognitive-behavioral model.

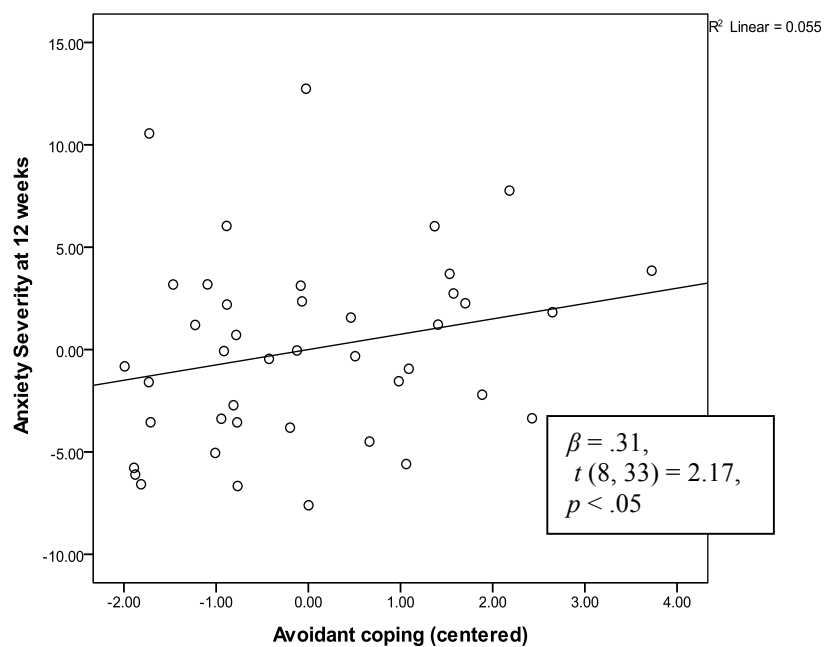


Figure 3. Main effect of avoidant coping on anxiety severity at 12 weeks in Step 2 of the full model.

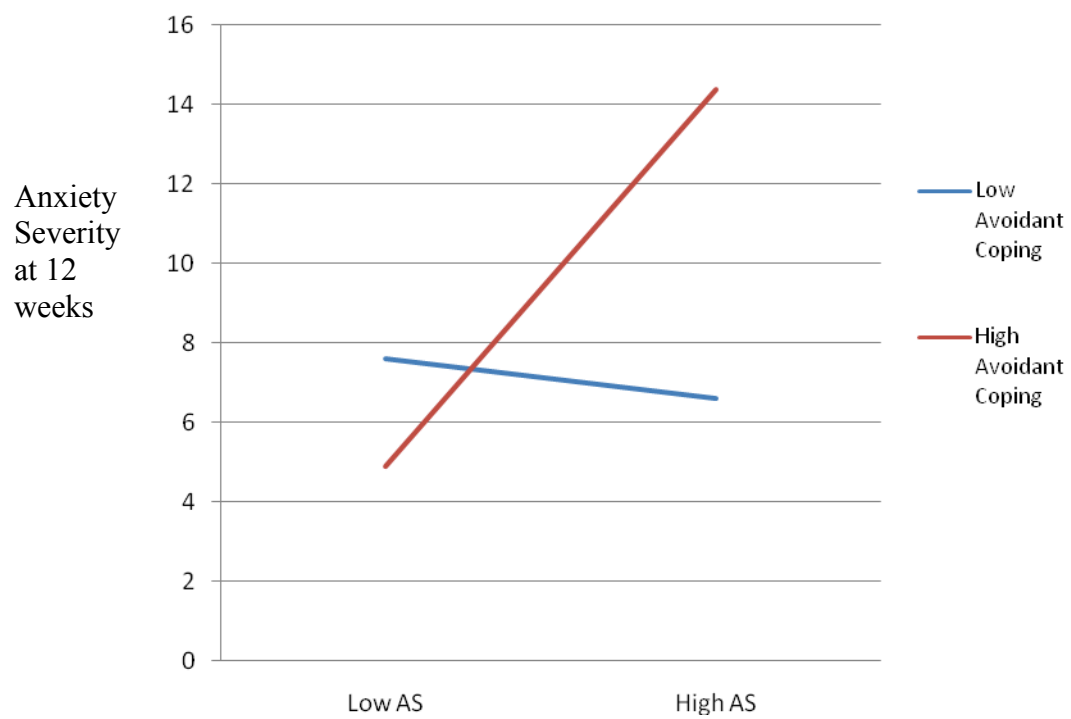


Figure 4. Significant interaction between anxiety sensitivity (AS) and avoidant coping on anxiety symptoms at 12 weeks.

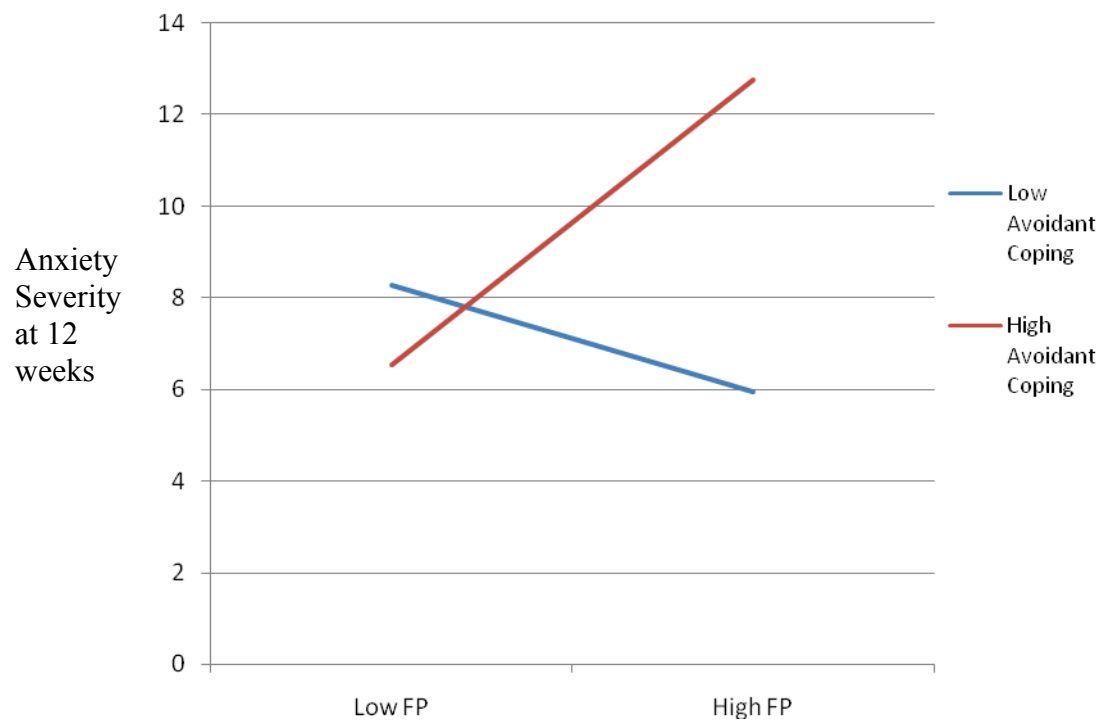


Figure 5. Significant interaction between baseline fear of pain (FP) and avoidant coping on anxiety symptoms at 12 weeks.

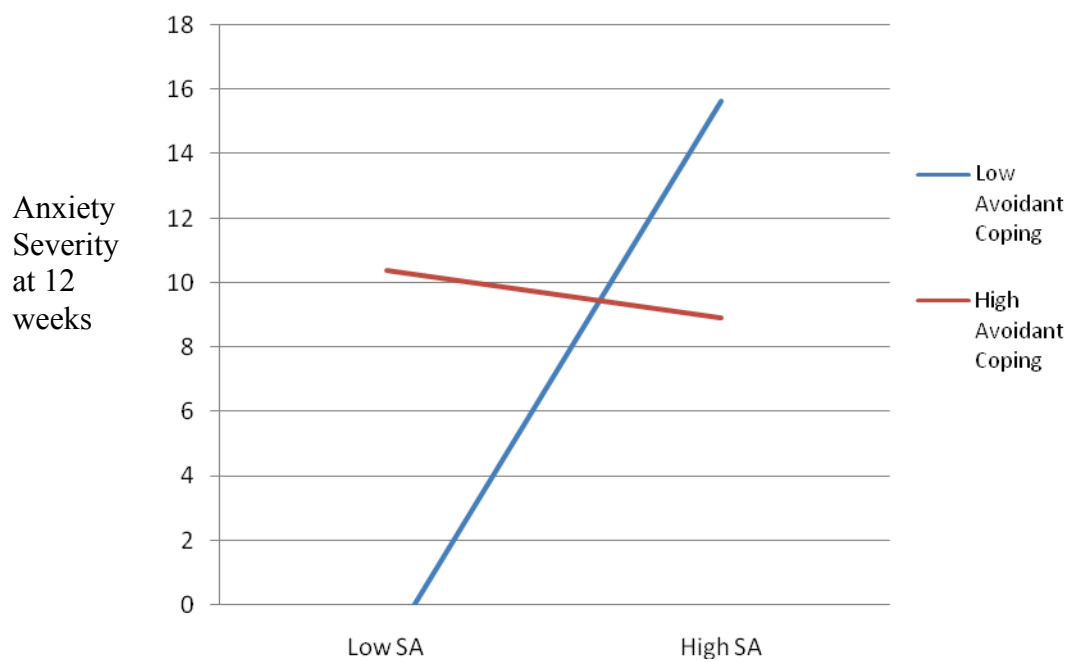


Figure 6. Significant interaction between baseline shock anxiety (SA) and avoidant coping on anxiety symptoms at 12 weeks.

Appendix I. Baseline characteristics stratified by completer status

	Total Sample (<i>n</i> = 78)	Completers (<i>n</i> = 42)	Non- completers (<i>n</i> = 36)	<i>p</i>
<i>Demographics</i>				
Age, mean (SD)	66 (11)	67 (11)	66 (11)	.83
Sex				.77
Male	66 (85)	36 (86)	30 (83)	
Female	12 (15)	6 (14)	6 (17)	
Ethnicity				.24
Non-Hispanic	74 (95)	41 (98)	33 (92)	
Hispanic	4 (5)	1 (2)	3 (8)	
Race [†]				.71
American Indian/Native	1 (1)	1 (2)	0 (0)	
American/Alaskan	5 (6)	3 (7)	2 (6)	
Asian	15 (19)	7 (17)	8 (22)	
African-American	54 (69)	31 (74)	28 (64)	
Caucasian				
Marital status ²				.73
Married	50 (64)	26 (62)	24 (67)	
Single	3 (3.8)	1 (2)	2 (6)	
Divorced/Separated	11 (14)	7 (17)	4 (11)	
Spouse Deceased	13 (17)	8 (19)	5 (14)	
Yearly Household Income ²				.43
< \$15K	6 (8)	3 (7)	3 (8)	
\$15K-25K	9 (12)	3 (7)	6 (17)	
\$25K-40K	10 (13)	6 (14)	4 (11)	
\$40K-50K	18 (23)	13 (31)	5 (14)	
\$50K-60K	24 (31)	11 (26)	13 (36)	
> \$60K	10 (3)	6 (14)	4 (11)	
Unwilling to disclose				
Years of education, mean (SD) ³	15 (4)	15 (4)	14 (3)	.53
<i>Biomedical Variables</i>				
Etiology ⁴				.39
Non-ischemic	23 (30)	11 (26)	12 (33)	
Ischemic	53 (70)	31 (74)	22 (62)	
Indication	61 (80)			.87
Primary prophylaxis	61 (78)	34 (81)	27 (75)	
Secondary prevention	15 (19)	8 (19)	7 (19)	
Status				.80
Pre-ICD baseline	27 (35)	14 (33)	13 (36)	
Post-ICD baseline	51 (65)	28 (67)	23 (64)	
Months since implant,	31 (34)	31 (35)	31 (34)	.60

mean (SD)				
Received Replacement Device	21 (27)	14 (33)	7 (21)	.22
Rehospitalization	40 (51)	22 (52)	18 (50)	.96
Deceased	2 (3)	1 (2)	1 (3)	.88
Congestive Heart Failure	45 (58)	22 (52)	23 (64)	.18
Left Ventricular Ejection Fraction, mean (SD) ⁴	27 (7)	28 (6)	27 (8)	.28
Experienced Shock	20 (26)	10 (24)	10 (28)	.58
Cardiac Resynchronization Therapy	25 (32)	17 (41)	8 (22)	.12
Device-related Complications				
Ventricular Tachyarrhythmia	3 (4)	1 (3)	1 (3)	.69
Previous Myocardial Infarction	42 (54)	23 (55)	19 (53)	.99
Previous Percutaneous Coronary Intervention	31 (40)	16 (38)	15 (42)	.60
Previous Coronary Bypass Graft Surgery	36 (46)	22 (52)	14 (39)	.33
Diabetes	27 (35)	17 (41)	10 (28)	.32
Obesity	26 (33)	11 (26)	15 (42)	.10
Hypertension	24 (31)	11 (26)	13 (36)	.26
Hypercholesterolemia	43 (55)	24 (57)	19 (53)	.91
	19 (24)	9 (21)	10 (28)	.42

Numbers are presented as *n* (%) unless otherwise stated.

¹ Data from 3 non-completers were missing in the total sample; ² Data from 1 non-completer were missing; ³ Data from 4 non-completers were missing in the total sample; ⁴ Data from 2 non-completers were missing in the total sample

Appendix II. Assessment Materials

Demographics and Basic Information

1. Research ID Number
2. Medical Records Number
3. Interviewer
4. Date of Interview
5. Interview Start Time
6. Timing of Interview (consult; over the phone; pre-admission; in-hospital; other)
7. Date of Implantation
8. Last Name
9. First Name
10. Address
11. Home Phone Number
12. Cell Phone Number
13. Work Number
14. Secondary contact person Name
15. Secondary contact person relationship
16. Secondary contact person phone number
17. Primary Physician
18. City/State of Primary Physician
19. Electrophysiologist
20. Gender
21. Ethnicity (Hispanic/Latino or Not)
22. Race (American/Indian/Alaska Native; Asian; Native Hawaiian/Pacific Islander; Black/AA; White; Multiracial; other)
23. DOB
24. Marital Status
25. Education in years (HS = 12)
26. Household Income (< 15K, 15-25K, 25-40K, 40-50K greater than 100K; not willing to disclose)
27. What occupation did you have for the majority of your life
28. Current occupational status (currently employed, unemployed and looking, unemployed and not looking, retired, never employed professionally, other)
29. Interview End time
30. Questions/Comments

Reiss-Epstein-Gursky Anxiety Sensitivity Index (Peterson & Reiss, 1992)

Rate each item by selecting one of the five phrases for each of the sixteen questions.

Very Little	Little	Some	Much	Very Much
1	2	3	4	5

1. It is important to me not to appear nervous.
2. When I cannot keep my mind on a task, I worry that I might be going crazy.
3. It scares me when I feel shaky.
4. It scares me when I feel faint.
5. It is important to me to stay in control of my emotions.
6. It scares me when my heart beats rapidly.
7. It embarrasses me when my stomach growls.
8. It scares me when I am nauseous.
9. When I notice my heart is beating rapidly, I worry that I might have a heart attack.
10. It scares me when I become short of breath.
11. When my stomach is upset, I worry that I might be ill.
12. It scares me when I am unable to keep my mind on a task.
13. Other people notice when I feel shaky.
14. Unusual body sensations scare me.
15. When I am nervous, I worry that I might be mentally ill.
16. It scares me when I am nervous.

PASS Original, Fear of Pain Subscale (McCracken et al., 1992)

Rate each item by selecting how often you are bothered by the following thoughts.

Never Always	Rarely	Sometimes	Often	Almost Always
1	2	3	4	5
6				

_____ If it gets too severe, it will never decrease. (F)

_____ I think that I might be seriously ill when in pain. (F)

_____ I think I might become paralyzed when in pain. (F)

_____ I dread feeling pain. (F)

_____ If an activity causes pain, I know it will decrease later. (F)

_____ I think that I have a serious medical problem. (F)

_____ I am afraid of dying. (F)

FSAS (Florida Shock Anxiety Scale; (Kuhl, Dixit, Walker, Conti, & Sears, 2006)

Rate each item by selecting how often you are bothered by the following thoughts.

Not at all	Rarely	Some of the time	Most of the time	All the time
1	2	3	4	5

_____ 1. I am scared to exercise because it may increase my heart rate and cause my device to fire.

_____ 2. I am afraid of being alone when the ICD fires and I need help.

_____ 3. I do not get angry or upset because it may cause my ICD to fire.

_____ 4. It bothers me that I do not know when the ICD will fire.

_____ 5. I worry about the ICD not firing sometime when it should.

_____ 6. I am afraid to touch others for fear I'll shock them if the ICD fires.

_____ 7. I worry about the ICD firing and creating a scene.

_____ 8. When I notice my heart beating rapidly, I worry that the ICD will fire.

_____ 9. I have unwanted thoughts of my ICD firing.

_____ 10. I do not engage in sexual activities because it may cause my ICD to fire.

Panic Severity and Avoidance Scale
(adapted from the Panic Disorder Severity Scale; Shear et al., 1997 and the
ICD and Avoidance Survey; (Lemon, Edelman, & Kirkness, 2004)

Instructions: Please respond “yes” or “no” to the following questions.

Baseline

1. Have you ever had a panic attack?
2. Have you ever avoided places because you thought you may have a panic attack?

3. **Over the past month have you avoided the following things because you thought it would cause uncomfortable physical sensations?**

Items in
bold
comprise
the
Avoidance
Scale
we
construct
-ed

- a. **Strenuous activity?**
- b. **Playing sports?**
- c. **Exciting sports events?**
- d. **Working in the garden?**
- e. Frightening movies?
- f. **Having an argument?**
- g. **Sexual activity?**

4. Over the past month have you avoided any food, drink, or other substances because you thought it would cause uncomfortable physical sensations?
5. Did you ever not go to work because of panic?
6. Were you ever afraid of being at home alone or completely alone in other places because of panic?
7. Were you ever unable to get things done as quickly and effectively because of panic?
8. Did you ever take short cuts or request assistance to get things done because of panic?
9. Did you turn down opportunities to socialize because of panic?
10. Did you have restrictions about where or how long you would socialize because of panic?
11. Have you ever taken anxiety medication before?

Follow-up

1. Since having an ICD have you experienced a panic attack?
2. Since having an ICD have you begun to avoid places because you thought you may have a panic attack?
3. Was this avoidance due to an ICD discharge happening in that place?
4. Since having an ICD, have you avoided the following things because you thought it would cause uncomfortable physical sensations?
 - a. Strenuous activity?
 - b. Playing sports?

- c. Exciting sports events?
 - d. Working in the garden?
 - e. Frightening movies?
 - f. Having an argument?
 - g. Sexual activity?
5. Since having an ICD, have you avoided any food, drink, or other substances because you thought it would cause uncomfortable physical sensations?
 6. Since having an ICD, did you ever not go to work because of panic?
 7. Were you ever afraid of being at home alone or completely alone in other places because of panic?
 8. Since having an ICD, were you ever unable to get things done as quickly and effectively because of panic?
 9. Since having an ICD, did you ever take short cuts or request assistance to get things done because of panic?
 10. Since having an ICD, did you turn down opportunities to socialize because of panic?
 11. Since having an ICD, did you have restrictions about where or how long you would socialize because of panic?
 12. Since having an ICD have you begun to avoid any activities because you thought you may have a panic attack?
 13. Was this avoidance due to an ICD discharge happening during that activity?
 14. Since having an ICD, did you start taking anxiety medication?
 15. Are you currently taking any anxiety medication?

Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988)

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the PAST WEEK, including today, by circling the number in the corresponding space in the column next to each symptom.

	Not At All	Mildly but it didn't bother me much.	Moderately - it wasn't pleasant at times	Severely – it bothered me a lot
Numbness or tingling	0	1	2	3
Feeling hot	0	1	2	3
Wobbliness in legs	0	1	2	3
Unable to relax	0	1	2	3
Fear of worst happening	0	1	2	3
Dizzy or lightheaded	0	1	2	3
Heart pounding/racing	0	1	2	3
Unsteady	0	1	2	3
Terrified or afraid	0	1	2	3
Nervous	0	1	2	3
Feeling of choking	0	1	2	3
Hands trembling	0	1	2	3
Shaky / unsteady	0	1	2	3
Fear of losing control	0	1	2	3
Difficulty in breathing	0	1	2	3
Fear of dying	0	1	2	3
Scared	0	1	2	3
Indigestion	0	1	2	3
Faint / lightheaded	0	1	2	3
Face flushed	0	1	2	3
Hot/cold sweats	0	1	2	3

HAMILTON ANXIETY RATING SCALE (HAM-A; Hamilton, 1959))

1. Anxious mood

This item covers the emotional condition of uncertainty about the future, ranging from worry, insecurity, irritability and apprehension to overpowering dread.

- 0 The patient is neither more or less insecure or irritable than usual.
- 1 Doubtful whether the patient is more insecure or irritable than usual.
- 2 The patient expresses more clearly to be in a state of anxiety, apprehension or irritability, which he may find difficult to control. However, the worrying still is about minor matters and thus without influence on the patient's daily life.
- 3 At times the anxiety or insecurity is more difficult to control because the worrying is about major injuries or harms which might occur in the future. Has occasionally interfered with the patient's daily life.
- 4 The feeling of dread is present so often that it markedly interferes with the patient's daily life.

2. Tension

This item includes inability to relax, nervousness, bodily tensions, trembling and restless fatigue.

- 0 The patient is neither more nor less tense than usual
- 1 The patient seems somewhat more nervous and tense than usual.
- 2 Patient expresses clearly unable to relax and full of inner unrest, which he finds difficult to control, but it is still without influence on the patient's daily life.
- 3 The inner unrest and nervousness is so intense or frequent that it occasionally interferes with the patient's daily work.
- 4 Tensions and unrest interfere with the patient's life and work at all times.

3. Fears

This item includes fear of being in a crowd, of animals, of being in public places, of being alone, of traffic, of strangers, of dark etc. It is important to note whether there has been more phobic anxiety during the present episode than usual.

- 0 Not present.
- 1 Doubtful whether present.
- 2 The patient experiences phobic anxiety but is able to fight it.
- 3 It is difficult to fight or overcome the phobic anxiety, which thus to some extent interferes with the patient's daily life and work.
- 4 The phobic anxiety clearly interferes with the patient's daily life and work.

4. Insomnia

This item covers the patient's subjective experience of sleep duration and sleep depth during the three preceding nights. Note: Administration of hypnotics or sedatives is disregarded

0 Usual sleep duration and sleep depth

1 Sleep duration is doubtfully or slightly reduced (e.g. due to difficulties falling asleep), but no change in sleep depth.

2 Sleep depth is also reduced, sleep being more superficial. Sleep as a whole is somewhat disturbed.

3 Sleep duration and sleep depth is markedly changed. Sleep periods total only a few hours per 24 hours.

4 Sleep depth is so shallow that the patient speaks of short periods of slumber or dozing, but no real sleep.

5. Difficulties in concentration and memory

This item covers difficulties in concentration, making decision about everyday matters, and memory

0 The patient has neither more nor less difficulty in concentration and/or memory than usual.

1 Doubtful whether the patient has difficulty in concentration and/or memory.

2 Even with a major effort it is difficult for the patient to concentrate on his daily routine work.

3 The patient has pronounced difficulties with concentration, memory, or decision making, e.g. in reading a newspaper article or watching a television program to the end.

4 During the interview the patient shows difficulty in concentration, memory or decision making.

6. Depressed mood

This item covers both the verbal and the non-verbal communication of sadness, depression, despondency, helplessness and hopelessness

0 Not present.

1 Doubtful whether the patient is more despondent or sad than usual, or is only vaguely so.

2 The patient is more clearly concerned with unpleasant experiences, although he still lacks helplessness or hopelessness.

3 The patient shows clear non-verbal signs of depression and/or hopelessness.

4 The patient remarks on despondency and helplessness or the non-verbal signs dominate the interview and the patient cannot be distracted.

7. General somatic symptoms: muscular weakness, stiffness, soreness or real pain, more or less diffusely localized in the muscles, such as jaw ache or neck ache.

0 The patient is neither more nor less sore or stiff in the muscles than usual.

1 The patient seems somewhat more stiff or sore in the muscles than usual.

2 The symptoms have the character of pain.

3 Muscle pain interferes to some extent with the patient's daily work and life.

4 - Muscle pain is present most of the time and clearly interferes with the

patient's daily work and life.

8. General somatic symptoms: Sensory

This item includes increased fatigability and weakness or real functional disturbances of the senses, including tinnitus, blurring of vision, hot and cold flashes and prickling sensations

0 Not present.

1 Doubtful whether the patient's indications of symptoms are more pronounced than usual

2 The sensations of pressure reach the character of buzzing in the ears, visual disturbances and prickling or itching sensations in the skin.

3 The generalized sensory symptoms interfere to some extent with the patient's daily life and work.

4 The generalized sensory symptoms are present most of the time and clearly interfere with the patient's daily life and work.

9. Cardiovascular symptoms

This item includes tachycardia, palpitations, oppression, chest pain, throbbing in the blood vessels, and feelings of faintness.

0 Not present.

1 Doubtful whether present.

2 Cardiovascular symptoms are present, but the patient can still control them.

3 The patient has occasional difficulty controlling the cardiovascular symptoms, which thus to some extent interfere with his daily life and work.

4 Cardiovascular symptoms are present most of the time and clearly interfere with the patient's daily life and work.

10. Respiratory symptoms

Feelings of constriction or contraction in throat or chest, dyspnea or choking sensations and sighing respiration

0 Not present.

1 Doubtful whether present.

2 Respiratory symptoms are present, but the patient can still control them.

3 The patient has occasional difficulty controlling the respiratory symptoms, which thus to some extent interfere with his daily life and work.

4 Respiratory symptoms are present most of the time and clearly interfere with the patient's daily life and work.

11. Gastro-intestinal symptoms

This item covers difficulties in swallowing, sinking sensation in stomach, dyspepsia (heartburn or burning sensation in the stomach, abdominal pains related to meals, fullness, nausea and vomiting), abdominal rumbling and diarrhea.

0 Not present.

1 Doubtful whether present (or doubtful whether different from usual).

- 2 One or more gastro-intestinal symptoms are present, but the patient can still control them.
- 3 The patient has occasional difficulty controlling the gastro-intestinal symptoms, which to some extent interfere with his daily life and work.
- 4 The gastro-intestinal symptoms are present most of the time and interfere clearly with the patient's daily life and work.

12. Genito-urinary symptoms

This item includes non-organic or psychic symptoms such as frequent or more pressing passing of urine, menstrual irregularities, anorgasmia, dyspareunia, premature ejaculation, loss of erection.

- 0 Not present.
- 1 Doubtful whether present (or doubtful whether different from usual).
- 2 One or more genito-urinary symptoms are present, but do not interfere with the patient's daily life and work.
- 3 Occasionally, one or more genito-urinary symptoms are present to such a degree that they interfere to some extent with the patient's daily life and work.
- 4 The genito-urinary symptoms are present most of the time and interfere clearly with the patient's daily life and work.

13. Other autonomic symptoms This item includes dryness of the mouth, blushing or pallor, sweating and dizziness

- 0 Not present.
- 1 Doubtful whether present.
- 2 One or more autonomic symptoms are present, but they do not interfere with the patient's daily life and work.
- 3 Occasionally, one or more autonomic symptoms are present to such a degree that they interfere to some extent with the patient's daily life and work.
- 4 Autonomic symptoms are present most of the time and clearly interfere with the patient's daily life and work.

14. Behaviour during interview

The patient may appear tense, nervous, agitated, restless, tremulous, pale, hyperventilating or sweating during the interview. Based on such observations a global estimate is made.

- 0 The patient does not appear anxious.
- 1 It is doubtful whether the patient is anxious.
- 2 The patient is moderately anxious.
- 3 The patient is markedly anxious.
- 4 Patient is overwhelmed by anxiety, for example with shaking and trembling all over.

Total score _____

HAM-A score level of anxiety

<17 mild; 18 – 24 mild to moderate; 25 – 30 moderate to severe

SF-36 Health Survey (Ware, 1996)

Instructions for completing the questionnaire: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

1. In general, would you say your health is:

- q Excellent
- q Very good
- q Good
- q Fair
- q Poor

2. Compared to one year ago, how would you rate your health in general now?

- q Much better now than a year ago
- q Somewhat better now than a year ago
- q About the same as one year ago
- q Somewhat worse now than one year ago
- q Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

- q Yes, limited a lot.
- q Yes, limited a little.
- q No, not limited at all.

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?

- q Yes, limited a lot.
- q Yes, limited a little.
- q No, not limited at all.

c. Lifting or carrying groceries.

- q Yes, limited a lot.
- q Yes, limited a little.
- q No, not limited at all.

d. Climbing several flights of stairs.

- q Yes, limited a lot.
- q Yes, limited a little.
- q No, not limited at all.

e. Climbing one flight of stairs.

- q Yes, limited a lot.
- q Yes, limited a little.
- q No, not limited at all.

f. Bending, kneeling or stooping.

q Yes, limited a lot.

q Yes, limited a little.

q No, not limited at all.

SF-36 2

g. Walking more than one mile.

q Yes, limited a lot.

q Yes, limited a little.

q No, not limited at all.

h. Walking several blocks.

q Yes, limited a lot.

q Yes, limited a little.

q No, not limited at all.

i. Walking one block.

q Yes, limited a lot.

q Yes, limited a little.

q No, not limited at all.

j. Bathing or dressing yourself.

q Yes, limited a lot.

q Yes, limited a little.

q No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down the amount of time you spent on work or other activities?

c Yes c No

b. Accomplished less than you would like?

c Yes c No

c. Were limited in the kind of work or other activities

c Yes c No

d. Had difficulty performing the work or other activities (for example, it took extra time)

c Yes c No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Cut down the amount of time you spent on work or other activities?

c Yes c No

b. Accomplished less than you would like

c Yes c No

c. Didn't do work or other activities as carefully as usual

c Yes c No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- q Not at all
- q Slightly
- q Moderately
- q Quite a bit
- q Extremely

7. How much bodily pain have you had during the past 4 weeks?

- q Not at all
- q Slightly
- q Moderately
- q Quite a bit
- q Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- q Not at all
- q Slightly
- q Moderately
- q Quite a bit
- q Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. did you feel full of pep?

- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time

b. have you been a very nervous person?

- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time

c. have you felt so down in the dumps nothing could cheer you up?

- q All of the time
- q Most of the time

- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time
- d. have you felt calm and peaceful?
- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time
- e. did you have a lot of energy?
- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time
- f. have you felt downhearted and blue?
- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time
- SF-36 4
- g. did you feel worn out?
- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time
- h. have you been a happy person?
- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time
- q None of the time
- i. did you feel tired?
- q All of the time
- q Most of the time
- q A good bit of the time
- q Some of the time
- q A little of the time

q None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

q All of the time

q Most of the time

q Some of the time

q A little of the time

q None of the time

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people

q Definitely true

q Mostly true

q Don't know

q Mostly false

q Definitely false

b. I am as healthy as anybody I know

q Definitely true

q Mostly true

q Don't know

q Mostly false

q Definitely false

c. I expect my health to get worse

q Definitely true

q Mostly true

q Don't know

q Mostly false

q Definitely false

d. My health is excellent

q Definitely true

q Mostly true

q Don't know

q Mostly false

q Definitely false

Biomedical Information

Hospital medical charts were used to obtain the following biomedical variables.

Etiology	Indication	Status
Months since implant	Received Replacement Device	Readmission
Deceased	Congestive Heart Failure	Left Ventricular Ejection Fraction
Experienced Shock	Cardiac Resynchronization Therapy	Device-Related Complications
Ventricular Tachyarrhythmia	Previous Myocardial Infarction	Previous Percutaneous Coronary Intervention
Previous Coronary Bypass Graft Surgery	Diabetes	Obesity
Hypertension	Hypercholesterolemia	

Appendix III. Interview Schedule

Variable	Modality	Completion Time (min)	Baseline	Follow-up Interval (wks)
Sociodemographics	Pt interview	5	X	--
Anxiety Sensitivity Index	Self-report	5	X	12
Florida Shock Anxiety Scale	Self-report	5	X	12
Pain Anxiety Symptoms Scale	Self-report	5	X	12
Beck Anxiety Inventory	Self-report	10	X	12
Hamilton Anxiety Scale	Clinician-administered	30	X	12
Short-Form 36	Self-report	10	X	12
Biomedical data	Chart review	N/A	N/A	N/A

Appendix IV. Diagnostics for Regression Analyses

Distributions, plots, and descriptive statistics were used to examine the data thoroughly prior to conducting inferential analyses. Attention was paid to outliers and distributions that departed from normality, and appropriate actions were taken (e.g., analyses with and without outliers; transformations). Cook's distance was used to identify unduly influential outliers. Residual plots were examined to establish that there was no violation of heteroscedasticity. Reliability for scales (described in Methods section) was indicated based on conventional statistical standards (e.g., $> .70$ for Cronbach's alpha). Assumptions of regression analyses (e.g., noncollinearity) were tested and accounted for in inferential analyses.

Appendix V. Description of the Hamilton Anxiety Scale and Short Form 36

Clinician-rated anxiety severity was measured with the Hamilton Anxiety Scale (HAM-A; (M. Hamilton, 1959). The HAM-A is a widely-used and well-validated rating scale developed to quantify the severity of anxiety symptomology. It consists of 14 items, each of which is rated by a clinician on a 5-point scale, ranging from 0 (not present) to 4 (severe). The Ham-A has been used in ICD patients as an indicator of clinically significant anxiety at 1-year follow up (Schiffer, Pedersen, Widdershoven, & Denollet, 2008), and was used to monitor symptom severity in the proposed study. Only trained clinicians administered the HAM-A. For follow-up HAM-As conducted via telephone, item 14 was recorded based on the patient's behaviors that could be interpreted over the phone and based on the patient's subjective report of how he/she was feeling at the present moment. Evidence supports the psychometric validity of a telephone-administered HAM-A (see Kobak, Greist, Jefferson, Mundt, & Katzelnick, 1999). Cronbach's alphas for our sample were .82 (baseline) and .85 (follow-up).

Quality of Life was measured with the Short Form 36 (SF-36; Ware, 1996). The SF-36 is a multipurpose, 36-item survey that yields scale scores for eight subjective health domains: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. It has been useful in assessing the health of several populations, comparing the relative burden of diseases, differentiating the benefits produced by a range of treatments, and screening patients. The widespread applicability of the SF-36 is apparent in the

more than 5,000 publications that have used this measure. Cronbach's alphas for our sample ranged from .64 (baseline) to .70 (follow-up).

Appendix VI. Additional Analyses

Independent biomedical predictors of anxiety severity at 12 weeks

Univariate hierarchical regression models were used to determine the influence of biomedical variables on 12-week anxiety, controlling for baseline anxiety scores. Previous percutaneous coronary interventions ($\beta = .32, t(2, 39) = 2.21, p < .05$) and etiology ($\beta = .35, t(2, 39) = 2.5, p < .05$) significantly predicted increased 8-week self-reported anxiety severity, controlling for initial self-reported anxiety levels. All other biomedical variables, when controlling for initial self-reported anxiety levels, were not significant predictors of 8-week self-reported anxiety ($ps > .11$).

Univariate hierarchical regression models were used to determine the influence of biomedical variables on 12-week clinician-rated anxiety, controlling for baseline clinician-rated anxiety levels. Hypertension (*standardized* $\beta = .567, t(2, 24) = 3.43, p < .01$), and hypercholesterolemia (*standardized* $\beta = .43, t(2, 24) = 2.41, p < .05$) significantly predicted increased 12-week clinician-rated anxiety severity, controlling for initial anxiety levels. Baseline clinician-rated anxiety and all other biomedical variables, when controlling for initial clinician-rated anxiety levels, were not significant predictors of 12-week clinician-rated anxiety ($ps > .18$).

Preliminary findings for the role of pre-implant fears and avoidant coping in predicting post-implant anxiety

The sample size was not large enough to draw firm conclusions based on analyses stratified by status (i.e., new patients = completed the baseline assessment pre-ICD implantation and the follow-ups at 4 and 12 weeks after the implant; former patients = completed baseline and follow-up assessments after the ICD implantation). However, we conducted exploratory analyses to determine the extent to which the ICD implantation may exacerbate fears and activate patients' vulnerability for post-ICD implantation anxiety severity. Among patients who completed all 3 assessments ($N = 42$), univariate regression analyses were repeated separately for new ($n = 15$) and former patients ($n = 27$), and the Beta weights were examined to determine relative risk estimates among new vs. old patients. For anxiety risk, the standardized Beta weight for new patients was higher than for old patients for AS ($\beta_s = .62$ versus $.09$) and for avoidant coping ($\beta_s = .45$ versus $.15$); the standardized Beta weights for new patients were lower than those for old patients for SA ($\beta_s = .32$ versus $.40$), FP ($\beta_s = -.50$ versus $.03$), respectively. Taken together, pre-implant AS and avoidant coping seems to pose a greater risk for anxiety following the ICD implantation, whereas SA and FP seems to pose a greater risk for anxiety following a follow-up electrophysiology visit.

Association between anxiety severity and quality of life.

Correlational analyses were conducted to examine the extent to which anxiety played a role in quality of life in general, and in regard to its specific dimensions. See table below for correlation coefficients and their p values. Anxiety severity was consistently associated with concurrent poorer physical functioning, more role limitations due to physical health and worse general health

($ps < .05$), thereby suggesting a role for emotional disturbance on perceived health and functioning.

Associations between quality of life dimensions and anxiety severity
($N = 42$).

	Baseline Anxiety	12-week Anxiety
Baseline		
Better Physical Functioning	-.37*	-.40**
More Role Limitations		
Due to Physical Health	.34*	.49**
Due to Emotional Health	.37*	.45***
More Fatigue	.35*	.33*
Greater Emotional Well-Being	-.20	-.33*
Better Social Functioning	-.14	-.32*
More Pain	.02	.34*
Better General Health	-.48**	-.35*
Overall Quality of Life	-.29	-.27
12 weeks		
Better Physical Functioning	-.21	-.46**
More Role Limitations		
Due to Physical Health	.13	.33*
Due to Emotional Health	.16	.28
More Fatigue	.13	.13
Greater Emotional Well-Being	-.36*	-.28
Better Social Functioning	-.13	-.16
More Pain	.01	.29
Better General Health	-.34*	-.33*
Overall Quality of Life	-.31*	-.40**

* $p < .05$. ** $p < .01$. *** $p < .001$.

Curriculum Vitae

EDUCATION

- | | |
|--------------------|---|
| 2006 – 2012
NJ. | Rutgers, The State University of New Jersey. Piscataway,
Clinical Psychology
Doctor of Philosophy, October 2012
Master of Science, October 2008 |
| 2000 – 2004 | New York University. New York, NY
Psychology
Bachelor of Arts, May 2004 |

POSITIONS

- | | |
|------------------------------|---|
| March 2011 – present | Memorial Sloan-Kettering Cancer Center,
New York, NY.
<i>Research Counseling Consultant</i> |
| June 2010 - present | AHRC New York City, New York, NY.
<i>Fee for Service Psychologist</i> |
| August 2008 – present
NY. | Institute for Behavior Therapy, New York,
<i>Clinician</i> |
| April 2008 – present | Rutgers University, Clinical Health
Psychology Program, New Brunswick, NJ
<i>Principal Investigator, Dissertation</i> |
| August 2009 - June 2010 | Palliative Care and Oncology Services,
Bellevue Hospital, NYU Medical Center,
New York, NY.
<i>Clinician</i> |
| August 2007 – May 2010 | Rutgers Psychological Clinic, Graduate
School of Applied and Professional
Psychology, New Brunswick, NJ.
<i>Clinician</i> |
| September 2009 – May 2010 | Rutgers University, Department of
Psychology, New Brunswick, NJ
<i>Teaching Assistant, Infant and Child
Development Lab</i> |

September 2008 – May 2009	Rutgers University, Department of Psychology. New Brunswick, NJ <i>Head Teaching Assistant, Cognition Lab</i>
June 2007 – July 2008	University Behavioral Healthcare Center, University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School. Piscataway, NJ. <i>Clinical Interviewer & Therapist</i>
September 2007 – May 2008	Rutgers University, Department of Psychology. New Brunswick, NJ <i>Teaching Assistant, Cognition Lab</i>
September 2006 - October 2008	Rutgers University, Clinical Health Psychology Program, New Brunswick, NJ <i>Principal Investigator, Master's Thesis</i>
February 2007 – October 2007	Internal Medicine, Cardiology, Robert Wood Johnson Medical Center, University of Medicine and Dentistry of New Jersey. New Brunswick, NJ <i>Clinical Interviewer</i>
July 2004 – July 2006	The Zucker Hillside Hospital, North Shore-Long Island Jewish Health System, Glen Oaks, NY <i>Assistant Research Coordinator</i>

PUBLICATIONS

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