

DEPRESSION AND ILLNESS INTRUSIVENESS AS PREDICTORS OF QUALITY
OF LIFE AMONG IMPLANTABLE ATRIOVERTER DEFIBRILLATOR
RECIPIENTS

By

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The Implantable Atrial Defibrillator (IAD) corrects atrial and ventricular fibrillation via a high energy defibrillation shock. Because the application of shock is aversive and atrial fibrillation (AF) is not an immediately life-threatening indication, the inter-relationship of shock, AF symptoms, illness intrusiveness and quality of life outcome will determine the potential value and future direction of IAD development. The purpose of this study was to examine a biopsychosocial model of illness for illness intrusiveness and quality of life in drug-refractory IAD patients. IAD adjustment was evaluated in 96 patients enrolled in the Jewel AF-AF Only Study ≥ 3 months follow up (mean=19 months). Patients were mostly men (72%) and were 62 \pm 12 years. A questionnaire and national clinical database characterized patient demographics, AF disease burden, atrial defibrillation therapy, and psychological distress. Within a biopsychosocial design, multiple hierarchical regressions indicated depression as a

unique predictor of variance on illness intrusiveness scores, accounting for 11.4% of variance. Illness intrusiveness and depression together predicted 11.1% of variance on physical quality of life. Beta weights revealed that illness intrusiveness and age were the only predictors of variance of physical quality of life. Regarding mental quality of life, results indicated that 32.3% of variance was accounted for by depression and illness intrusiveness together. Beta weights revealed that depression was the only unique contributor of variance to mental health. Maladjustment to the physical aspects of defibrillation may result from the presence of psychological distress. Psychological symptoms such as depression and illness intrusiveness are largely responsible for AF patients' declines in quality of life. Acceptance of IAD therapy may be facilitated by successful treatment of psychological distress among IAD patients and multi-disciplinary care that routinely addresses the psychological impact of AF and device treatment.

CHAPTER 1 INTRODUCTION

Cardiac arrhythmias are a prominent cause of death, hospitalizations, and healthcare costs in the United States. Each year cardiac arrhythmias play a role in over 500,000 deaths and 724,000 hospitalizations, while also accounting for 11.9 billion dollars spent annually on healthcare costs (American Heart Association, 2001). An arrhythmia is characterized by abnormal electrical impulse conduction in the heart (American Heart Association, 2001). A sustained rapid heartbeat (usually 160-280 beats/minute) is referred to as tachycardia. Tachycardia can begin in the atria or the ventricles and is often accompanied by symptoms such as chest pain, fainting, and dizziness. Prolonged tachycardia may result in fibrillation, which is an uncoordinated movement of electrical impulses through the heart. These impulses cause the heart chambers to twitch rapidly, resulting in inefficient blood flow to the rest of the body, and have the potential to significantly affect mortality risk and quality of life (Allan & Scheidt, 1996).

The implantable atrioverter defibrillator (IAD) is a device that corrects fibrillation in the atria. Correcting these irregular heartbeats requires a shock from the device, similar to the shock received during external cardioversion. Shock can be an aversive experience for patients, but the effects of untreated atrial fibrillation can be more detrimental. Therefore, the degree of intrusion from the illness may be an important index to understanding both patients' willingness to get shocked and the effects of having

been shocked. In this study, a biopsychosocial model including disease and treatment variables as well as predictors of illness intrusiveness and quality of life in atrial fibrillation patients who have been implanted with the IAD were examined.

Atrial Fibrillation

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia, occurring in over 2 million Americans. AF refers to rapid contractions of the atria, or upper heart chambers, and illicit an irregular response from the ventricles. This irregular rhythm causes a reduction in blood flow, and increases the chances of formation of a blood clot that could travel to the brain, causing stroke and possibly death (Luderitz & Jung, 2000). Fifteen percent of all strokes are caused by AF (American Heart Association, 2001). The prevalence of AF increases with age from less than 1% at 50 to 59 years to 9% at 80 to 89 years (Luderitz & Jung, 2000).

The majority of hospitalizations from cardiac arrhythmias are due to AF. Besides increasing the risk of blood clots and stroke, the hemodynamic effects of AF may cause decreased exercise tolerance and heart failure. Disorders that may result in atrial fibrillation include: ischemic heart disease, rheumatic heart disease, hypertension, sick sinus syndrome, cardiomyopathy, and other structural abnormalities. Atrial fibrillation can be paroxysmal or sustained; however, the majority of patients have paroxysmal atrial fibrillation, denoting a transient occurrence of AF (Lip, 2001). The initial impairment caused by atrial fibrillation is less obvious than that caused by ventricular fibrillation, or rapid contractions of the lower heart chambers, because atrial fibrillation only mildly affects cardiac output. In fact, a patient may be unaware that he/she is in atrial fibrillation because various medications can keep the heart rate normal during atrial fibrillation

(Allan & Scheidt, 1996). Approximately one-third of AF patients do not experience any symptoms, while the other two-thirds may experience heart palpitations, fatigue, dizziness, and presyncopal episodes (American Heart Association, 2001).

Although the physical symptoms of AF may not be immediately apparent, significant psychological distress often accompanies this condition. The Ablate and Pace Trial (Kay, Ellenbogen & Giudici, 1998) included a sample of highly symptomatic, drug-refractory AF patients. Baseline assessment revealed significantly lower quality of life among the AF patients as compared to patients with heart failure or a recent myocardial infarction. This illustrates that AF patients may experience unique psychological issues that are not as prominent for other cardiac populations. Because multiple studies have illustrated that psychological intervention is effective in improving quality of life and physical symptoms among various cardiac patient populations (Bennett & Carol, 1994; Hill, Kelleher, & Shumaker, 1992; Linden, Stossel, & Maurice, 1996), this study suggests that AF patients may receive similar benefit from psychological intervention.

Medical/Pharmacological Treatments for AF

The treatment of cardiac arrhythmias varies based on the rhythm's characteristics, etiology, and the patient's experience of symptomatology. The most efficient way to describe treatment options is to consider them on a scale of physical and mental intrusiveness to the patient. The least severe, a non-life-threatening, and asymptomatic paroxysmal arrhythmia, may be treated with simple behavioral interventions such as dietary modifications and smoking cessation. A more severe symptomatic paroxysmal arrhythmia, (e.g., ventricular tachycardia or atrial flutter), that results from a manageable disease process may be treated with anti-arrhythmic medications such as beta-blockers

(Canobbio, Fassio, & Gasparini, 1986). In addition to suppressing premature contractions that cause arrhythmias, beta-blockers also reduce heart rate, blood pressure, and strength of cardiac contraction. Atrial fibrillation becomes more severe when the episodes are sustained or paroxysmal, symptomatic, not drug-responsive, and/or life-threatening. These may call for more invasive interventions such as catheter ablation of conduction pathways, surgical ablation, or resection of conduction pathways (Canobbio et al., 1986).

Although the treatment of AF varies widely, the majority of symptomatic patients are successfully treated with dual chamber pacemaker therapy and/or antiarrhythmic drugs. Most AF patients receive anticoagulants, such as aspirin or warfarin, which help prevent the formation of blood clots. However, AF patients whose symptoms are recurrent and require external cardioversion may benefit most from an implantable device called the implantable atrioverter defibrillator (IAD; Lip, 2001). The IAD alleviates symptoms but does not cure the underlying disorder. Currently, there are no absolute indications for the implantation of an IAD; yet, the patients involved in clinical trials using the IAD have paroxysmal atrial fibrillation that is symptomatic and drug-refractory (Wellens, Lau, Luderiz, et al., 1998).

Device Therapies: The IAD

The technology of the IAD is similar to that of the implantable cardioverter defibrillator (ICD), which terminates life-threatening ventricular arrhythmias (Lip, 2001). The ICD re-establishes normal sinus rhythm in response to ventricular fibrillation, whereas the IAD is designed to re-establish normal sinus rhythm in individuals with atrial arrhythmias. The ICD gained FDA approval in 1985, and has been researched in

numerous trials since 1996 (Davidson, VanRiper, Harper & Wenk, 1994). In contrast, the IAD is a much newer device, and IAD patients have not been extensively researched.

The IAD is similar to the size of a pacemaker, and consists of an atrioverter can which is pectorally implanted, and three electrical leads which connect to three different parts of the heart: the coronary sinus, the right atrium, and the right ventricle (Lip, 2001). The IAD is capable of delivering two different types of shocks: a defibrillation shock for the atrium, and a pacing discharge to the ventricle to prevent a bradycardiac response after defibrillation. The IAD can be programmed to shock automatically, or can be activated by the patient or physician with a hand-held activator (Lip, 2001). A recent trial illustrated that the Dual-Chamber ICD, which is essentially an ICD with atrial therapies, is well-tolerated in drug-refractory symptomatic AF populations (Gold, Sulke, Schwartzman, Mehra & Euler, 2001). The researchers found that the dual-chamber ICD was successfully implanted in 99% of the sample (N = 146), and illustrated 98% survival at 12-month follow-up. Additional results indicated that 99% of atrial arrhythmias among this sample were correctly predicted by the device, and 87% of atrial arrhythmias were successfully terminated. Perhaps even more critical, 7.6% of the sample required ventricular shocks for VT/VF which would have been fatal (Gold et al., 2001). This study suggests that patients with atrial fibrillation receive substantial physical benefit from implantable defibrillation devices such as the IAD.

Although the IAD has been shown to provide relief from the physical symptoms of AF, to date no study has examined the psychological implications of device therapy for AF patients. An important difference between patients with atrial fibrillation and patients with ventricular fibrillation is that atrial fibrillation does not present a threat of

immediate death, and a defibrillation charge from the IAD does not represent a life-saving procedure as it does for ICD patients with life-threatening ventricular arrhythmias. Therefore, the psychological stress associated with receiving a defibrillation shock may be different for IAD patients, a concept that was examined in this study.

Psychological Effects of Shock

Although both the IAD and the ICD have demonstrated to be effective life-saving devices (Gold et al., 2000), researchers continue to examine the issue of patient adaptation to this therapy. Recent studies reveal that there is a strong fear component associated with defibrillation, especially among patients receiving multiple shocks (Murgatroyd & Camm, 1997; Sears, Todaro, Saia Lewis, Sotile, & Conti, 1999; Sears & Conti, 2002). A recent major clinical trial, the CABG Patch Trial, examined the value of prophylactic ICD implantation in patients undergoing coronary artery bypass graft surgery versus no ICD after CABG surgery (Namerow, Firth, Heywood, Windle, Parides, et al., 1999). Data indicated that the mental and physical quality of life outcomes for the ICD patients were significantly worse compared to no-ICD patients. Further analyses revealed that there were no differences in quality of life for non-shocked ICD patients vs. no-ICD patients. These results indicated that the ICD group who had received shocks was responsible for the significantly worse mental and physical quality of life outcome scores between the groups.

The Antiarrhythmics Versus Implantable Defibrillators (AVID) trial represents the first major comparison of self-perceived quality of life among ICD patients and antiarrhythmic drug (AAD) therapy patients. AVID researchers concluded that ICD and AAD therapy have similar effects on self-perceived quality of life among patients with

ventricular arrhythmias. Although all patients had poor baseline quality of life, a significant finding was that adverse symptoms were associated with major impairment in quality of life, regardless of the type of therapy and sporadic shocks received from the ICD. Specifically, adverse symptoms among AAD patients were associated with reductions in physical functioning, and both physical functioning and mental well-being in ICD patients (Schron, Exner, Yao et al., 2002). The AVID study illustrated that frequent ICD shocks (>5) were associated with increased psychological distress and lower quality of life. Additionally, the study demonstrated that ICD patients receiving at least one shock in the first year of follow-up had significant declines in physical functioning and mental well-being, along with increased patient concerns. This effect of shock was present independently of other markers of disease severity (Schron et al., 2002). Such research highlights the fact that shock can be a frightening experience for ICD patients, and has implications for clinical interventions with IAD patients.

The Canadian Implantable Defibrillator Study (CIDS) (Irvine, Dorian, Baker, O'Brien, Roberts, Gent, Newman, & Connolly, 2002) yielded similar results regarding the negative effects of shock. In a longitudinal quality of life comparison between shocked vs. non-shocked ICD patients, researchers concluded that non-shocked patients experienced improved quality of life at 2, 6, and 12 months follow-up. More specifically, patients receiving 5 or more shocks within the first year of device implantation experienced significant declines in generic quality of life (Irvine et al., 2002). These results imply the existence of a "shock threshold," or maximum number of shocks that can be tolerated before patients' quality of life is significantly compromised.

Conversely, a number of studies have illustrated that shock is not a unique

contributor to decreased psychological well-being. Several investigators have examined patients with ICDs and compared them to patients with permanent pacemakers on generic measures of quality of life. Very few consistent differences were demonstrated between these two populations. For example, Duru and colleagues (2001) found no differences in generic quality of life score, anxiety or depression when comparing ICD patients with and without shock experience and pacemaker patients. ICD patients with a shock history were more likely to report limitations in leisure activities and anxiety about the ICD, but they also viewed the ICD as a “life extender.” However, this study did not use a disease-specific quality of life measure, and therefore measurement may have been too gross to determine a difference between groups. Herbst, Goodman, Feldstein, and Reilly (1999) recently compared the quality of life and psychological distress of four patient groups: ICD only (n = 24) vs. ICD + anti-arrhythmic drug (n = 25) vs. anti-arrhythmic drug only (n = 35) vs. a general cardiac sample (n = 73). Quality of life was assessed via the SF-36 and three supplementary scales examining sleep, marital and family functioning, and sexual problems. Comparisons were made between ICD groups and drug groups. Results indicated that there were no significant differences on the 11 quality of life scales, even after controlling for age, gender, disease severity, and duration of treatment. Yet, significant differences were found in drug groups vs. no drug groups, such that the drug treated group consistently reported greater impairment in physical functioning, vitality, emotional, and sleep functioning, as well as psychological distress. Overall, these results suggest that quality of life was maintained in ICD treated groups, while anti-arrhythmic drug therapy was associated with diminished quality of life and increased psychological distress.

Although study results vary, it is important to recognize that ICD-related fears are universal and may be the most pervasive psychosocial adjustment challenge ICD patients face. Psychological theory suggests that symptoms of fear and anxiety can result from a classical conditioning paradigm in which certain stimuli or behaviors are coincidentally paired with an ICD shock and are thereby avoided in the future (Sears & Conti, 2002). Due to fear of present and/or future discharges, some patients increasingly limit their range of activities and inadvertently diminish the benefits of the ICD in terms of quality of life (Sears & Conti, 2002). Collectively, these data implicate that the experience of shock is often strongly associated with psychological distress and diminished quality of life (Sears et al., 1999). The experience of shock may be different for IAD patients, who have the option of administering the shocks manually, and thus eliminate receiving an unexpected defibrillation charge that may lead to fear or anxiety. Atrial shocks are unpleasant and possibly frequent; subsequently IAD patients are likely to view shock as negatively as ICD patients do, and to experience similar symptoms of psychological distress.

Depression

Depression has been identified as a significant characteristic related to health outcomes among various cardiac populations (Frasure-Smith, Lesperance, & Talajic, 1995). Among ICD patients, prevalence rates of depressive symptomatology range from 24% to 87% at various follow-up intervals (Hegel, Griegal, Black & Goulden, 1997; Konstam, Colburn & Butts, 1995; Sears et al., 1999). Early research highlights correlations between declines in physical ability/functioning and the development of depression in ICD patients (Pycha, Gullede, Hutzler, Kadri, & Maloney, 1986). More

recently, similar findings within the ICD patient population indicate that depression and mood disturbance post-implant may increase the likelihood of an arrhythmia requiring a shock from the device (Dunbar, Kimble, Jenkins, et al., 1999). Sears and colleagues (1999) postulate that depression among device patients may result from the patient's perceived lack of control over the defibrillation charges. These symptoms may eventually lead patients to have increased negative beliefs and hopelessness about their current and future health status. This negative view of the future is often reflected by a reduction in mental quality of life. Although many IAD patients maintain control over when a defibrillation charge is administered, a single charge may not always correct an atrial arrhythmia. Thus, it is often necessary for IAD patients to experience multiple shocks, contributing to psychological distress (Irvine et al., 2002; Schron et al., 2002). Further, the after-effects of receiving a painful shock are likely similar for ICD and IAD patients. Due to the prevalence of depression among ICD patients and the relationship between shock, depression, and quality of life, this study predicts that depression among IAD patients will present similarly to ICD patients.

Quality of Life

To date the largest study examining quality of life among symptomatic AF patients found that both disease specific and generic quality of life were significantly lower for AF patients than for healthy controls (Dorian, Jung, Newman et al., 2000). AF patients scored significantly lower on all scales of the SF-36 except for the Bodily Pain scale. However, much of the current research regarding quality of life among patients with defibrillators has focused on ICD patients. Although ICD patients primarily report desirable quality of life, it is well established that psychosocial distress contributes to a

reduction in quality of life (Heller, Ormont, Lidagoster et al., 1998; Luderitz, Jung, Deister & Manz, 1996; Pycha et al., 1986; Sears et al., 1999, 2000). Among the most common patient complaints regarding quality of life are social isolation, psychological distress, and physical complaints (Heller et al., 1998; Luderitz et al., 1996; Pycha et al., 1986; Sears et al., 1999). Poorer quality of life is more prevalent among patients who receive shocks from the ICD as compared to patients who have not received shocks from the ICD (Dunbar et al., 1999; Heller et al., 1998; Herbst et al., 1999; Kohn, Petrucci, Baessler, Soto & Movsovitz, 2000; Reid, Nagy & McKinley, 1999; Sears et al., 1999). Because shock has been established as a negative experience (Namerow et al., 1999; Sears et al., 1999; Sears & Conti, 2002), it may be hypothesized that patients receiving shocks will also experience higher levels of illness intrusiveness as compared to patients who have received no shocks, which has been shown in previous research (Schron et al., 2002; Irvine et al., 2002). Therefore, this study examined the relationship between factors affecting illness intrusiveness and subsequent quality of life within a biopsychosocial model that accounted for both psychological and medical data.

Illness Intrusiveness

The construct of illness intrusiveness is described as lifestyle disruptions, resulting from an illness and/or its treatment, that hinder participation in valued activities and interests (Devins et al., 1983). Because illness intrusiveness limits participation in valued activities, it may in turn decrease psychosocial well-being as it lowers an individual's exposure to positively-valued interactions. Illness intrusiveness may cause further psychosocial decline by reducing an individual's personal control over both

positive and negative outcomes in important situations, especially among patients with chronic conditions (Devins et al., 1993).

Studies indicate varying degrees of illness intrusiveness across treatment modalities and illnesses (Devins et al., 1993). Among chronic illness populations, a number of illness-related factors contribute to the construct of illness intrusiveness, including disease factors, such as pain and disability, and treatment factors such as time required for treatment and mode of treatment (Devins, 1994). Illness intrusiveness among chronic illness populations has been shown to have a significant and unique relationship to several psychological variables, including positive and negative mood, life satisfaction, and depression, and is further influenced by psychological and social characteristics such as social support and coping resources (Binik, Devins & Orme, 1989; Devins, 1994). Devins' (1994) model hypothesizes that factors of an individual's disease and treatment psychosocially impact quality of life through their relationship with illness intrusiveness. The model also accounts for direct effects of psychological and social factors on both illness intrusiveness and quality of life.

Research on illness intrusiveness among AF patients found that symptomatic AF patients had significantly higher illness intrusiveness than same-aged non-AF patients (Dorian et al., 2002). Consistent with Devins' model, this study also found lower quality of life on several SF-36 scales among AF patients as compared to angioplasty, myocardial infarction and congestive heart failure patients, even when controlling for physical impairment (Dorian et al., 2002). Despite AF patients experiencing a variety of physical symptoms, these data suggest that psychological distress is an equally limiting aspect of the condition. The influence of psychological constructs such as illness

intrusiveness on quality of life often overpowers the influence of AF's unique physical limitations, and emphasizes the importance of psychological intervention in conjunction with standard medical care for AF patients. In this regard, illness intrusiveness emerges as an important target for multidisciplinary interventions.

Relationship Between Illness Intrusiveness and Quality of Life

The Devins (1994) model stems from research involving the role of illness intrusiveness in quality of life among End-Stage Renal Disease patients, and has indicated that perceived illness intrusiveness was significantly correlated with three quality of life measures including satisfaction/happiness, pessimism/illness-related concerns, and depression/distress (See Figure 1; Devins, Mandin, Hons et al., 1990). Specifically, higher levels of perceived illness intrusiveness were significantly correlated with decreased life satisfaction and happiness, increased pessimism and illness-related concerns, and increased depression and distress. These results remained stable over time, even after controlling for response style and background variables (Devins et al., 1990). Similarly, an additional study with rheumatoid arthritis patients revealed a statistically significant relationship between illness intrusiveness and physical disability, such that after controlling for physical disability, illness intrusiveness maintained a unique, significant relationship with depression (Devins, Edworthy, Guthrie et al., 1992). These data illustrate the role of illness intrusiveness as a mediator of the psychosocial impact of chronic illness, although no study to date has examined this potentially valuable construct in IAD patients. The current study will examine illness intrusiveness among IAD patients using analyses influenced by Devins' (1994) model.

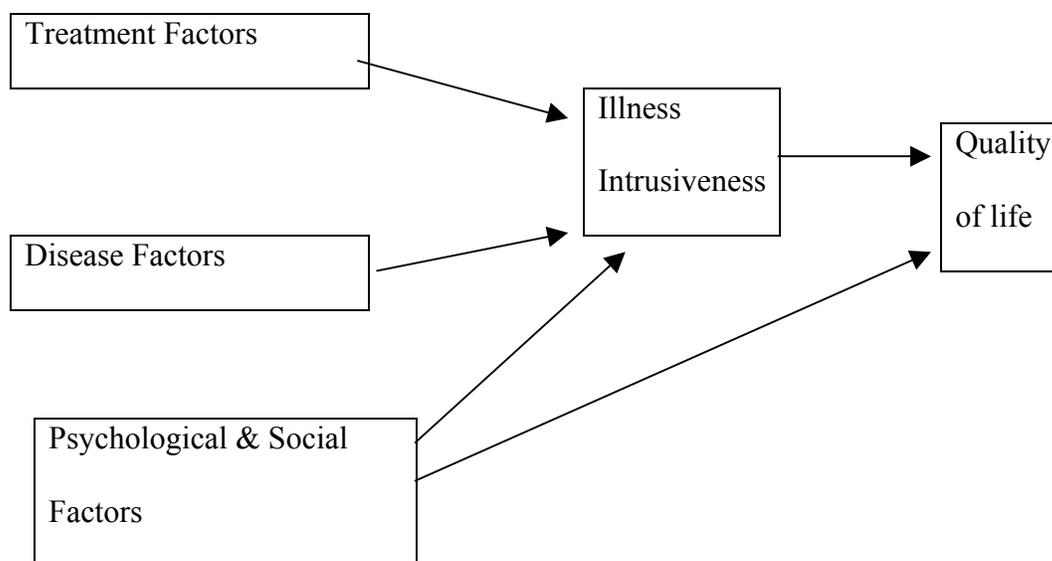


Figure 1. Hypothesized relations among illness intrusiveness, its determinants, and quality of life in AF patients (Devins, 1994).

Aims and Study Justification

The purpose of this study was to test a biopsychosocial model of illness intrusiveness and quality of life in a sample of drug-refractory IAD patients. Using hierarchical multiple regression analyses controlling for demographic and biomedical data, this study explored predictors of illness intrusiveness and physical and mental quality of life. This model was adapted to identify areas of possible psychological intervention among IAD patients.

Hypotheses

The following hypotheses were investigated in this study:

1. It was hypothesized that CES-D ratings of depression would be significantly associated with Illness Intrusiveness Rating Scale scores among IAD patients, while controlling for demographics, number of shocks, and biomedical variables.
2. It was hypothesized that Illness Intrusiveness Rating Scale scores would significantly predict variance in the Physical Functioning Scale of the SF-36 Quality of life Measure

among IAD patients, while controlling for demographics, number of shocks, biomedical variables, and psychological variables.

3. It was hypothesized that CES-D ratings of depression would significantly predict variance in the Mental Scale of the SF-36 Quality of life Measure among IAD patients, while controlling for demographics, number of shocks, biomedical variables, and psychological variables.

CHAPTER 2 METHOD

Participants

The participants (N = 96) were recruited from an ongoing multi-site FDA study spanning 23 IAD-implanting facilities. Participants were recruited by the research coordinator at each implanting facility. Each participant had undergone a full medical workup prior to recruitment.

In order for a patient to qualify for inclusion in the study, he/she must have had lone AF, indicating AF was his/her only major heart condition. All participants were also drug-refractory, defined as having tried and failed at least one anti-arrhythmic drug within the year prior to the study. Participants must have had at least one AF episode lasting 48 hours. At the time of the study, all subjects were taking an anti-coagulant such as warfarin.

Participant exclusion criteria included documented risk of sudden death from ventricular fibrillation, which would indicate implantation of a traditional ICD. Table 1 provides a summary of the demographic and medical characteristics of the study sample.

Table 1. Patient Demographics and Relevant Medical Variables

	Mean (SD) or %		
	<u>Total</u>	Manual Shock	Automatic Shock
	(N = 96)	(n = 42)	(n = 35)
Demographics			
Age	62.2 (11.8)	59.8 (12.1)	64.3 (10.9)
Gender (% Male)	72%	64%	80%
Marital Status (% Married)	83.3%	83.3%	82.9%
Ejection Fraction (N = 54)	52.1 (15.8)	56 (15.1)	45.3 (15.6)
Pre-Implant Cardioversions	2.2 (2.1)	2.2 (2.1)	2.1 (2)
Pre-Implant AF episodes	9.1 (13)	8.4 (12.3)	12.5 (20.7)
AF Symptom Score	15.6 (8.49)	14.4 (8.2)	18.2 (9.2)
Device Data			
Years Since Implant	1.6 (.87)	1.6 (.84)	1.6 (.81)
Detected AF Episodes	176 (337)	167 (306)	191 (337)
Total Atrial Shocks	12.8 (18.4)	13 (21.1)	12.5 (14.9)
Manual Shock/month	0.93 (2.7)	1.4 (3.5)	0.46 (1.3)
Automatic Shock/month	0.22 (.76)	0.0 (0.0)	.57 (1.2)
Atrial Shock Energy (J)	15.2 (7.8)	15 (7.9)	15.9 (7.9)

Note: 18 patients did not receive any shocks or received both manual and automatic shocks, and therefore were not included in the statistical analyses

Assessment

Generic Quality of Life

The Medical Outcomes Study Short-Form 36 Health Survey (SF-36; Ware, Snow, Kosinski & Gandek, 1993) was used to measure quality of life. This is a widely used and well-validated generic measure of health-related quality of life, and was shown to be the most effective measure for evaluating quality of life among pacemaker patients in a recent comparison study (Stofmeel, Post, Kelder et al., 2000). Because of its widespread application to cardiac patients and its role in validating other measures of cardiac illness, the SF-36 has become the standard measure of quality of life among cardiac populations (Stofmeel, et al., 2001; Hamilton & Haennel, 2000). Items included in the SF-36 were constructed by Ware and colleagues (1993), who used a sample of over 20,000 U.S. residents to assess perceptions of 40 mental and physical health concepts in the Medical Outcome Study (MOS). The SF-36 contains scales to measure the eight most salient concepts represented by this survey: Physical Functioning, Physical Role, Bodily Pain, General Health, Vitality, Social Functioning, Emotional Role, and Mental Health. To avoid inflating experiment-wise error, the current study examined scores on only three scales of the SF-36: Physical Functioning, Mental Health, and Social Functioning.

Center for Epidemiological Studies Depression Scale

Depression was measured using the Center for Epidemiological Studies – Depression Scale (CES-D), a 20-item self-report measure of depressive symptomatology (Radloff, 1977). Participants are asked how frequently over the past week they have experienced various depressive symptoms, and responses range from 0 (less than one day) to 3 (5-7 days). Total scores range from 0 to 60, and a standard cut-off score of 16

indicates clinically significant depressive symptoms (Radloff, 1977). The CES-D reflects the number and duration of depressive symptoms. The CES-D has a high internal reliability coefficient of .85, and has been reported as a more generally useful self-report measure of depression than the Beck Depression Inventory, the MMPI Depression Scale, and the Zung Self Rating Scale of Depression (Turk & Okifuji, 1994).

Illness Intrusiveness Rating Scale

The Illness Intrusiveness Rating Scale (IIRS; Devins, Orme & Costello, 1988) is a 19-item self-report measure that asks respondents to rate how much their illness and consequent treatment interferes with each of 13 life domains. Ratings occur along a 7-point Likert scale, ranging from 1 (Not Very Much) to 7 (Very Much). The domains pertain to health, recreation, diet, work, financial situation, self-expression, family relations, relations with spouse, sex life, social relations, religious expression and community involvement. A total intrusiveness score and a score for each of the 13 domains can be calculated. Total scores range from 13 (where the illness is not intrusive) to 91 (where the illness is extremely intrusive in all domains). Exploratory and confirmatory factor analyses across eight different patient groups have revealed three underlying factors comprising the scale (Relationships and Personal Development, Intimacy, and Instrumental Life Domains). Recent research indicates that the total IIRS score may be preferable for use in basic analyses (Devins et al., 2001). The IIRS has been shown to have adequate to high internal consistency, reliability, and validity (Devins et al., 1993). Coefficient alpha ranges from 0.80 to 0.95 have been found across diagnoses (Devins et al., 2001).

State-Trait Anxiety Inventory

The STAI is a 40-item self-report questionnaire designed to measure both state and trait anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). For the purposes of this study, only the 20-item trait scale of this questionnaire was administered. Trait anxiety is defined as a relatively enduring personality characteristic, or more specifically, as anxiety proneness. The internal reliability of both the state and trait anxiety scales has been shown to be uniformly high across samples of adults ranging from .89 to .96. Test-retest reliability coefficients for multiple samples of college students ranged from .73 to .86, with test-retest validity specifically for the trait scale being reported at .73 for males and .77 for females. Concurrent validity between the STAI and IPAT Anxiety Scale and the Taylor Manifest Anxiety Scale ranged from .83 to .73 (Spielberger et al., 1983).

Pain and Intensity Ratings

Subjective ratings of pain and intensity were taken from the Patient Acceptance Scale (PAS), which provides statements about the pain and intensity of a defibrillation charge, and provides responses ranging from *Strongly Disagree* to *Strongly Agree* (Burns et al., 2002).

Device Data

Information was collected to address several aspects of patients' IAD history. The device data included number of years since device implantation at the time of survey, number of treated episodes, and number of manual and automatic shocks received per month.

Demographic Measures

This measure was developed to assess: marital status, age, religion, ethnicity, education level, employment status, number of doctor visits, exercise habits, smoking habits and alcohol consumption.

This study used baseline data for quality of life measures only. All other data was collected at the follow-up in the closest proximity to the survey data (M = 4.7 months since last device interrogation, SD = 2.8 months).

CHAPTER 3 RESULTS

Sample Descriptives

Illness intrusiveness scores for this sample ranged from 13 to 73 ($M = 27$; $SD = 14$). Additional descriptive data was gained by using t-tests to compare this sample with the group of End Stage Renal Disease patients upon which Devins' (1994) original work was based. The IAD sample's mean illness intrusiveness rating was significantly lower than a published mean for patients receiving hemodialysis ($p < .001$), but not significantly different from a published mean for patients of successful renal transplantation ($p = .504$; Devins, 1994). In the present sample, 42% had illness intrusiveness scores above cut-off scores for an AF-only sample, but sample differences were insignificant. Results also indicate that IAD recipients may experience levels of illness intrusiveness similar to those experienced by transplant recipients. Thus, the IAD may be considered analogous to a lifesaving "organ" which is capable of prolonging and improving life.

Additional descriptive data was computed using t-tests. CES-D scores ($M = 11.1$; $SD = 8.5$; $n = 81$) were significantly different from healthy normals ($M = 9.3$; $SD = 8.6$; $p < 0.05$), although these differences are likely not clinically significant (Radloff, 1977). Regarding anxiety levels, the STAI scores of this sample ($M = 33.9$; $SD = 10.8$; $n = 88$) were not significantly different from scores of healthy normals (healthy males, $M =$

34.9; $SD = 9.9$; healthy females, $M = 34.8$; $SD = 9.2$) (Speilberger, Gorsuch, Lushene, Vagg & Jacobs, 1983). Mean total symptom score (16.0) and mean AF symptom number (8.2) was also calculated. Means for all participants in this study are located in Table 2.

Table 2. Means for Psychosocial Measures

	<u>M</u>	<u>SD</u>	n	Min.	Max.
<u>Depression (CES-D)</u>	11.07	8.57	81	0	35
<u>Trait Anxiety (STAI)</u>	33.99	10.8	88	20	70
<u>Illness Intrusiveness (IIRS)</u>	27.00	14.4	93	13	73
<u>Quality of life (SF-36)</u>					
Physical	67.01	25.5	82	15	100
Mental	72.76	17.7	84	16	100
<u>Total Symptom Score</u>	15.95	8.50	82	1	41
<u>Total Symptom Number</u>	8.16	3.37	83	1	12

Correlations and Collinearity Evaluation

Correlations were run among several of the independent and dependent variables to determine the inter-correlations between variables. These results are presented in Table 3. Although there were significant correlations between some psychosocial variables, none exceeded $r > .7$, which is a cut-off to determine multicollinearity (Kleinbaum, Kupper, Muller & Nizam, 1998). Therefore, all variables were included in the planned analyses.

Regression Analyses: Illness Intrusiveness

A three-step multiple hierarchical regression analysis was conducted to examine the relationships between demographic, shock, and symptom variables, along with patient ratings of pain and discomfort, and the psychological construct of illness intrusiveness as

the dependent variable. Specifically, number of shocks and AF symptom score were included as disease-specific factors that may influence illness intrusiveness. Significance was set at $\alpha = .05$.

Table 3. Correlations of Key Assessment Instruments

	CES-D	IIRS	Physical Scale	Mental Scale
CES-D	_____			
IIRS	.447**	_____		
Physical Scale	-.298*	-.263*	_____	
Mental Scale	-.604**	-.275*	.300**	_____

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

On the first step of the analysis, sex and age were insignificant predictors of illness intrusiveness (F change (2, 52) = 1.847, $p = .168$), accounting for 6.6% of the variance. Number of manual and automatic atrial shocks, AF symptom score, and patient ratings of pain and discomfort were entered on the second step of the analysis. These factors contributed 18.3% of variance, although this variance was not significant (F change (5, 47) = 2.295, $p = .060$). On step three, CES-D scores were entered, significantly predicting 11.4% of variance in illness intrusiveness scores (F change (1, 46) = 8.202, $p = .006$). Specifically, higher depression was associated with higher illness intrusiveness. The overall model was significant (F (8, 54) = 3.279, $p = .005$), and accounted for 36.3% of variance in illness intrusiveness.

Table 4. Regression Analysis: Illness Intrusiveness.

<u>Model</u>	<u>R Square Change</u>	<u>F Change</u>	<u>df1</u>	<u>df2</u>	<u>Sig F Change</u>
1	.066	1.847	2	52	.168
2	.183	2.295	5	47	.060
3	.114	8.202	1	46	.006

Regression Analyses: Physical Quality of Life

A three-step multiple hierarchical regression analysis examined demographics, baseline physical quality of life scores, number of atrial shocks, and psychological variables (depression and illness intrusiveness) with post physical quality of life as the dependent variable. Pain and discomfort were excluded since they failed to contribute significant variance to illness intrusiveness in the presence of depression (F change (5, 47) = 2.295, p = .060). In step one of the analysis, baseline physical quality of life scores, age and sex were not significant predictors of post physical quality of life (F change (3, 64) = 1.634, p = .190). Step two of the analysis included number of total atrial shocks, which also failed to contribute significant variance (F change (1, 63) = .608, p = .439). Psychological variables (depression and illness intrusiveness) were entered on the third step of the analysis; they significantly added 12.0% of the variance (F change (2, 61) = 4.575, p = .014). Specifically, higher age and higher illness intrusiveness predicted lower post physical quality of life. Therefore, illness intrusiveness uniquely predicted post physical quality of life above and beyond a host of demographic, biomedical, and psychological variables. The overall model significantly accounted for 20.0% of variance in post physical quality of life (F (6, 67) = 2.542, p = .029).

Table 5. Regression Analysis: Physical Quality of Life.

<u>Model</u>	<u>R Square Change</u>	<u>F Change</u>	<u>df1</u>	<u>df2</u>	<u>Sig F Change</u>
1	.071	1.634	3	64	.190
2	.009	.608	1	63	.439
3	.120	4.575	2	61	.014

Regression Analyses: Mental Quality of Life

The last three-step multiple hierarchical regression was conducted to examine demographic, baseline mental quality of life scores, total atrial shocks and psychological variables (depression and illness intrusiveness), with post mental quality of life as the dependent variable. On step one, baseline mental quality of life, sex, and age did not contribute significant variance in post mental quality of life (F change (3, 64) = .814, p = .491). Step two included total atrial shocks, which also failed to explain significant variance in post mental quality of life (F change (1, 63) = .029, p = .865). Depression and illness intrusiveness were entered on the third step of the analysis, and significantly predicted post mental quality of life (F change (2, 61) = 15.412, p < .001), contributing 32.3% of the variance. Specifically, higher depression was associated with lower post mental quality of life. The overall model accounted for 36% of variance in post mental quality of life (F (6, 67) = 5.729, p < .001). As stated earlier, multicollinearity statistics were calculated to ensure that these results were not influenced by the correlation between depression and mental quality of life. The tolerance value (.774) indicates an acceptable correlation level (Kleinbaum et al., 1998). Therefore, depression uniquely predicted mental quality of life within this biopsychosocial model, but no demographic or

disease-specific variables were significant predictors of mental quality of life. The overall model accounted for 36.0% of variance in post mental quality of life.

Table 6. Regression Analysis: Mental Quality of Life.

<u>Model</u>	<u>R Square Change</u>	<u>F Change</u>	<u>df1</u>	<u>df2</u>	<u>Sig F Change</u>
1	.037	.814	3	64	.491
2	.000	.029	1	63	.865
3	.323	15.412	2	61	.000

CHAPTER 4 DISCUSSION

The current study investigated the utility of Devins' (1994) biopsychosocial model regarding the relationships between psychological variables and their influence on physical and mental quality of life within a sample of IAD patients. It was hypothesized that the psychological constructs of depression and illness intrusiveness would impact physical and mental quality of life above and beyond the influence of demographic, biomedical and disease-related variables. A series of three-step multiple hierarchical regression analyses indicated that the hypotheses regarding the impact of depression on illness intrusiveness and mental quality of life, and the impact of illness intrusiveness on physical quality of life were supported.

Previous research in similar populations has established that depression and illness intrusiveness are related constructs (Hegel et al., 1997; Konstam et al., 1995; Sears et al., 1999). This study extends the literature to include IAD patients, who have been shown to have unique psychological distress associated with their condition (Kay et al., 1998). A decline in physical abilities that hinders participation in valued activities is an integral part of Devins (1983) definition of illness intrusiveness. IAD patients whose illness causes a decline from previous functioning may subsequently develop depression, and view their illness as more intrusive. The correlation between illness intrusiveness

and physical quality of life is consistent with Devins' (1983) theory that the construct of illness intrusiveness is a disruption of lifestyle that hinders participation in valued activities. Patients whose functioning is significantly limited due to their illness will most likely report a reduction in the quality of their physical abilities. Additionally, the correlation and predictive relationship between the psychological construct of depression and mental quality of life is consistent with Devins' (1983) biopsychosocial model. With regard to the relationships between disease, treatment, and psychological factors, this sample of IAD patients rated illness intrusiveness and quality of life similarly to the End-Stage Renal Disease patients comprising Devins' original sample.

Implications for the Experience of Shock

Collectively, these results suggest that shock is not the factor most responsible for reducing quality of life among IAD patients as it has been illustrated to be among ICD patients (Namerow et al., 1999; Schron et al., 2002; Irvine et al., 2002). This discrepancy may result from differences in perceived lack of control between these two populations. IAD patients have the option of delivering the defibrillation charge manually, whereas all shocks received by ICD patients are automatically received with little warning. Since AF is not a life-threatening condition, IAD patients also have the option of avoiding the defibrillation charge and experiencing the AF episode. In this way, IAD patients are able to mentally separate the act of shock from other physical aspects of their illness. Even IAD patients who receive automatic shocks can receive advanced warning and therefore maintain a sense of control. Further, a defibrillation charge for IAD patients does not indicate a life-threatening arrhythmia as it does for ICD patients, suggesting that ICD patients may have a more emotional response to shock.

Most of the literature in this area indicates that, overall, shock is a physically aversive experience (Murgatroyd & Camm, 1997; Sears et al., 1999; Sears & Conti, 2002; Namerow et al., 1999; Schron et al., 2002). Pauli and colleagues' (1999) research clarified and disputed this idea by distinguishing the psychological effects of shock from the physical effects. The present study, in conjunction with the work of Pauli and colleagues (1999), indicates that IAD recipients will benefit from being psychologically prepared for the emotional impact of defibrillation. Results suggest that IAD therapy is well accepted, but may be hindered by psychological factors such as depression. Depression and illness intrusiveness are related among IAD patients, lending support to early research among ICD patients that highlights correlations between declines in physical ability and the development of depression (Hegel et al., 1997; Konstam et al., 1995). Most patients who are provided with appropriate cognitive-behavioral interventions should adapt well to receiving an IAD, and will likely not experience clinically significant levels of depression, illness intrusiveness, or reduced quality of life (Kohn et al., 2000).

Clinical Implications

Clinically, this study highlights the need for healthcare providers to recognize, acknowledge, and refer psychological treatment for symptoms of distress among IAD patients in an attempt to reduce illness intrusiveness and optimize quality of life. The majority of these patients do not experience clinically significant depression or illness intrusiveness, but those who do will likely also experience reductions in physical and mental quality of life. Clinicians should be educated about the effects that psychological factors have on quality of life, and subsequently pay routine attention to both general and

disease-specific quality of life among IAD patients. Since AF is a non-life-threatening condition, IAD patients can experience improved quality of life through various levels of psychosocial intervention, such as in-patient psychological consultation, support groups with other patients, and individual psychotherapy. This process will be facilitated by the integration of psychologists as essential parts of IAD patient treatment teams, and by future research exploring additional aspects of defibrillation, including a comparison between the patient's subjective experience of shock and the objective shock data recorded by the device

Strengths and Weaknesses of the Study

The current study has specific strengths and weaknesses to take into account when interpreting this data. The comprehensive biopsychosocial design including both objective medical information and subjective psychological testing data provide a more complete view of the outcomes of interest than previous work with the IAD designed to establish its efficacy (Gold, et al., 2001). Further, the effects of shocks were well examined in the current data set and did not indicate the cumulative, detrimental effects that one might expect. A weakness of the study includes the highly selected sample utilized. Patients in this study were volunteers who were drug-refractory and failed at least one anti-arrhythmic drug. Therefore, the results cannot be generalized to all patients with AF. The willingness to participate as a subject in this trial certainly selects for some personality variables that cannot be fully understood. The study also included baseline medical variables but did not include baseline psychosocial variables other than quality of life. In fact, because FDA investigators did not expect the significance of psychological factors at the beginning of the study, the remaining psychosocial factors are measured at

only a single point in time. Therefore, we are unable to determine the course of patient acceptance from the current data.

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BIOGRAPHICAL SKETCH

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