



Published in final edited form as:

Behav Sleep Med. 2016 ; 14(1): 49–66. doi:10.1080/15402002.2014.941064.

Sleep, Psychosocial Functioning, and Device-specific Adjustment in Patients with Implantable Cardioverter Defibrillators (ICDs)

Christina S. McCrae¹, Alicia J. Roth¹, Jessica Ford², Earl C. Crew¹, Jamie B. Conti³, Richard B. Berry³, and Samuel F. Sears²

¹Department of Clinical and Health Psychology, University of Florida, Gainesville, FL

²Psychology and Cardiovascular Sciences, East Carolina University, Greenville, NC

³College of Medicine, University of Florida, Gainesville, FL

Abstract

Rates of sleep disorders and associated adjustment were examined in patients with implantable cardioverter defibrillators (ICDs; $n=42$; $M_{age}=61.57$, $SD=12.60$). One night of ambulatory polysomnography, 14-days of sleep diaries, and questionnaires (mood, sleepiness, fatigue, device acceptance) were administered. MANCOVA (controlling for ischemia) examined adjustment by sleep diagnosis. Apnea was most common-28.6%, followed by Insomnia-16.7% and Comorbid Insomnia/Apnea-11.9%. Patients with insomnia reported poorer mood, greater sleepiness, and lower device acceptance than good sleepers; they also demonstrated poorer mood and less ICD device acceptance than patients with sleep apnea. Patients with comorbid insomnia/apnea also exhibited poorer mood and less ICD device acceptance than good sleepers; however, comorbid patients did not significantly differ from insomnia or apnea patients on any measure. Those with disordered sleep (regardless of type) reported greater fatigue than good sleepers. Assessment (and treatment) of difficulties with sleep, mood, fatigue, and/or device acceptance may be important for the comprehensive clinical management of ICD patients. Further research appears warranted.

Cardiovascular disease affects close to one quarter of the general population and is the leading cause of death in the United States, accounting for 31.9% of mortalities in 2010 (Go et al., 2014). Cardiac arrhythmogenesis while sleeping is a concern in the context of advanced cardiac disease. Although sleep is generally thought of as a time of repair and restoration, it is also a time of vulnerability. During sleep, there is decreased respiratory control and surges in autonomic nervous system activity than can be detrimental (Chokroverty, 1999; Verrier & Josephson, 2005; Verrier & Mittleman, 2005). Fifteen percent of malignant ventricular arrhythmias episodes and 30% of atrial fibrillation episodes occur during sleep (Verrier & Josephson).

Corresponding author: Christina S. McCrae, PhD, Department of Clinical and Health Psychology, University of Florida, PO Box 100165, Gainesville, FL 32610-0165 Phone +1 352-273-6053; Fax +1 352-273-6156; csmccrae@php.ufl.edu.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NHLBI (Christina S. McCrae, Ph.D., PI).

Implantable cardioverter defibrillators (ICDs) are the treatment of choice for primary and secondary prevention of death associated with potentially-lethal ventricular arrhythmias (Al-Khatib et al., 2013; Connolly et al., 2000). ICDs use pacing and high energy shock to terminate arrhythmias; research has shown a demonstrable mortality advantage compared to medications in at-risk patients (AVID, 1997; Bardy et al., 2005; Moss et al., 1996). With the success of the ICD in preventing sudden cardiac death, researchers are increasingly turning their attention towards broader health factors that are impacting the lives and wellbeing of ICD patients, including the role of sleep. Clinically significant symptoms of sleep disturbance have been found in as many as 67% of patients with ICDs (without comorbidities such as congenital heart disease, genetic arrhythmia, psychiatric disorder requiring use of psychotropic medication, schizophrenia or bipolar disorder, debilitating musculoskeletal disease, or clinically significant cognitive problems; (Berg, Higgins, Reilly, Langberg, & Dunbar, 2012), compared to the approximate 30% of adults in the US who complain of one or more symptoms of sleep disturbance (Ancoli-Israel & Roth, 1999), 10% rate of insomnia in the general US population, and 35% rate of insomnia in older adults aged 65 and older (M. M. Ohayon, 2002). Sleep disturbances have also been observed to vary with symptoms of increased cardiac arrhythmia in device patients, indicating that sleep may be considerably affected by the cardiac condition (Serber et al., 2003). However, in order to fully understand and manage sleep problems in patients with ICDs, information regarding the specific types of disorders (i.e., obstructive sleep apnea, insomnia) experienced and their prevalence is needed.

Prevalence rates of sleep disordered breathing (SDB), primarily obstructive sleep apnea (OSA), in patients with ICDs are estimated at 40–77% (Fries et al., 1999; Grimm, Apelt, Timmesfeld, & Koehler, 2013; Serizawa et al., 2008; Tomaello, Zanolta, Vassanelli, LoCascio, & Ferrari, 2010). The pathophysiological consequences of OSA (e.g., increased heart rate and blood pressure, sympathetic nervous system activity) are particularly problematic to the patient with an ICD, as these cardiovascular events may increase risk of shock and subsequent shock-related psychological distress (Kasai & Bradley, 2011). Although some studies have found no significant association between sleep apnea and ICD shocks (Fries et al., 1999; Grimm et al., 2013), two key studies (Fichter et al., 2002; Serizawa et al., 2008) have indicated that the cumulative effects of disruptive apneas are significantly associated with arrhythmia.

The potential for ICD patients to develop insomnia is a critical concern, because insomnia is associated with numerous negative consequences, including mood disturbances, dependence on sleep medication, decreased quality of life, and impaired social interactions (Roth & Ancoli-Israel, 1999). Comorbid insomnia—insomnia occurring concurrently with another medical or psychiatric condition—accounts for the majority of insomnia cases, with insomnia observed in approximately 38% of individuals with a comorbid condition and only 8% of individuals without a comorbid condition (Taylor et al., 2007). Insomnia is commonly observed among individuals with medical problems, such as cancer, hypertension, cardiovascular disease, and chronic pain (Quesnel, Savard, Simard, Ivers, & Morin, 2003; Redeker et al., 2010; Taylor et al., 2007). Insomnia is also highly comorbid with psychiatric disorders, with approximately 40–50% of people diagnosed with insomnia diagnosed with a concurrent psychiatric disorder. (M.M. Ohayon, 1997) Taylor et al. (Taylor, Lichstein,

Durrence, Reidel, & Bush, 2005) found that people with chronic insomnia are approximately 10 times more likely to be depressed and 17 times more likely to be anxious than people without insomnia, and that symptoms were more severe in people with insomnia compared to people without sleep disturbances. (Taylor et al., 2005) Additionally, insomnia has been shown to decrease quality of life in patients across a range of medical and psychiatric illnesses (Katz & McHorney, 2002) thus understanding the connection between treating insomnia and associated health-related outcomes is indispensable for care of these patients. A meta-analytic investigation of 21 studies examining depression and insomnia demonstrated that non-depressed individuals who develop insomnia have a 2.60 times risk of also developing depression compared to individuals without sleep disturbance (Baglioni et al., 2011).

Comorbidity rates between sleep disturbances and psychological distress, in particular, depression and anxiety (Buysse et al., 1994; Mendelson, 1997), can range from 40–60% (D. E. Ford & Kamerow, 1989). Similarly, the rates of depression and anxiety in patients with ICDs are high, but comparable to other cardiac disease populations (Sears, Todaro, Lewis, Sotile, & Conti, 1999; W. Whang et al., 2005) found that 14% of a sample of ICD patients were categorized as mildly depressed, while 3.9% were moderately to severely depressed, with depression significantly predicting risk for an ICD shock. Dunbar et al. (1999) found similar results; ICD patients with greater mood disturbances had a greater likelihood of receiving a shock, cardioversion, or tachycardia pacing. In particular, more experiences of anxiety, fatigue, and confusion and fewer experiences of energy increased the possibility of an arrhythmia event. Anxiety symptoms may be the most universal yet debilitating experience of the ICD patient; 24–87% of ICD recipients experienced increased anxiety as a result of ICD implantation, with approximately 13–38% meeting criteria for clinically significant anxiety disorders (Sears et al., 1999). Individuals with insomnia may also experience impaired daytime functioning, such as fatigue and excessive daytime sleepiness (K. L. Lichstein, Means, Noe, & Aguillard, 1997; Ustinov et al., 2010). ICD patients are already at risk population for distress and functional impairment; the addition of poor sleep may serve to further exacerbate these vulnerabilities and impede recovery and adjustment to life following ICD implantation. However, whether the level of psychological adjustment and daytime functioning displayed by ICD patients varies as a function of sleep disorder diagnosis is unknown.

Compared to the body of research reporting on OSA and SDB in ICD patients, there is a paucity of research examining insomnia in patients with ICDs. Only one such study, performed by Cross, McCrae, Smith, Conti and Sears (2010), has looked at the prevalence of diagnosable insomnia in this population. That study found that ICD patients reported mean sleep onset latencies (33.8 min) and wake times after sleep onset (32.6 min) consistent with empirically-validated quantitative criteria for diagnosing insomnia (K. L. Lichstein, Durrence, Taylor, Bush, & Riedel, 2003). The potential for ICD patients to develop insomnia is of critical concern, because insomnia is associated with numerous negative consequences including psychological distress (M.M. Ohayon, Caulet, & Lemoine, 1998) and impaired daytime functioning (e.g., fatigue, excessive daytime sleepiness; K. L. Lichstein et al., 1997; Ustinov et al., 2010).

Given the role that arousal and distress play in the development of chronic insomnia, ICD patients may be particularly vulnerable as they experience a considerable amount of distress related to coping with cardiac disease, device implantation, and the potential for unexpected shock. In patients with ICDs, the severity of mood disturbance is found to predict risk for shock (William Whang et al., 2005) and likelihood of cardioversion or tachycardia pacing (Dunbar et al., 1999). Anxiety symptoms may be the most universal yet debilitating experience of the ICD patient; 24–87% of ICD recipients experienced increased anxiety as a result of ICD implantation, with approximately 13–38% meeting criteria for clinically significant anxiety disorders (Magyar-Russell et al., 2011; Sears et al., 1999).

ICD patients' also have unique device-related aspects of functioning – how well they accept their device, and how much shock specific anxiety they have – that have been shown to impact their quality of life (Burns, Serber, Keim, & Sears, 2005; Kuhl, Dixit, Walker, Conti, & Sears, 2006). However, these have yet to be examined in the context of specific sleep disorders. The increased risk for ventricular arrhythmia and shock associated with disordered sleep and psychological distress can negatively affect patients' ability to live comfortably with their device. Patients' implanted with ICDs are asked to live with the potential for defibrillation and adjust to this potential life-disruption by developing an acceptance of their device, while minimizing worry and anxiety related to the potential for shock. Patients with device acceptance understand and psychologically accommodate the advantages and disadvantages of having an ICD and derive biomedical, psychological, and social functioning benefits from the ICD. These patients demonstrate better quality of life and fewer symptoms of anxiety and depression than ICD patients who do not accept their device (Burns et al., 2004; Burns et al., 2005; Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008). Unfortunately, whether the device-specific level of adjustment (acceptance, fear of shock) that ICD patients display varies as a function of sleep disorder diagnosis has yet to be explored.

If ICD patients are already an at-risk population for distress and functional impairment, the addition of poor sleep may serve to further exacerbate these vulnerabilities and impede recovery and adjustment to life following ICD implantation. However, whether the level of psychological adjustment and daytime functioning displayed by ICD patients varies as a function of sleep disorder diagnosis is unknown. The primary aim of the present study was to investigate the rates of sleep disorders in ICD patients. We hypothesized that OSA and insomnia would be the two most prevalent disorders. The secondary aim of this study was to examine potential differences in functioning and adjustment as a function of sleep disorder diagnosis. We hypothesized that ICD patients with insomnia would have poorer psychological (anxiety, depression), daytime (sleepiness, fatigue), and device-specific (device acceptance, shock anxiety) functioning and adjustment than patients with OSA followed by good sleepers. Information about the prevalence of diagnosable sleep disorders in patients with ICDs holds significant clinical relevance, as it may guide treatment planning around the sleep of these patients to improve their overall adjustment to living with chronic cardiac disease, the ICD device, and the on-going threat of future shock.

Methods

Participants

Forty-two patients ($Mage = 61.57$ years, $SD = 12.60$) were recruited from a university-based cardiac clinic. Inclusion criterion included having an ICD device (single chamber, dual chamber, or combined with a biventricular pacing device). Exclusion criteria included severe cognitive impairment measured by the Mini Mental Status Exam (MMSE; if 9th grade education or higher: < 23 , if less than 9th grade education: < 17 ; Folstein, Folstein, & McHugh, 1975) as well as performing shift work (i.e., working third shift hours). See Table 1 for additional demographic data.

Procedure

All study procedures were IRB approved, and written informed consent was obtained from each participant before enrollment in the study. Potential participants were recruited by study staff after physician referral to the research study. If interested, participants attended a baseline visit involving an in-depth clinical interview to evaluate the presence of sleep disturbances and establish a probable diagnosis of insomnia, and all outcome questionnaires were administered (see Measures). At the end of the visit, participants were provided with paper-based daily diary sheets to be completed over the next 14 days and outfitted with the ambulatory polysomnography (PSG) device to record their sleep that night. The ambulatory PSG equipment was returned the following day, while daily diaries were returned after 14 days had been recorded. Post-baseline assessment, authorized study staff conducted an electronic medical record review of each participant's medical history.

Our board certified sleep physician and sleep psychologist reviewed the ambulatory PSG and 14-day sleep diary records. Sleep disorders were diagnosed in accordance with criteria of the International Classification of Sleep Disorders-2nd ed. (ICSD-2; AASM, 2005), and (in the case of insomnia) Research Diagnostic Criteria (RDC) established by the American Academy of Sleep Medicine (Iber, Ancoli-Israel, Chesson, & Quan, 2007). Diagnoses of OSA (apnea/hypopnea index [mean apneas and hypopneas, or partial apneas, per hour] >10) and periodic limb movement disorder (PLMD; myoclonus arousals per hour >10) were derived from ambulatory PSG data. Diagnoses of insomnia were derived from inspection of 14-day sleep diaries and included: 1) report of difficulty (> 30 minutes) with sleep onset, awake time during night, or waking up too early; 2) complaint of sleep that is chronically non-restorative or poor in quality; 3) items 1 and 2 occur despite adequate opportunity and circumstances for sleep; 4) insomnia present at least 3 nights per week for more than 1 month; 5) and a complaint of at least 1 sleep-related daytime impairment, including: fatigue/malaise; impaired cognition; social/vocational dysfunction or poor school performance; mood disturbance/irritability; daytime sleepiness; motivation/energy/initiative reduction; proneness for errors/accidents at work or while driving; tension headaches, and/or GI symptoms in response to sleep loss; and concern/worry about sleep.

Measures

Clinical Interview—Participants completed an in-depth clinical and sleep history interview at their baseline assessment. Sleep-related questions assessed participants'

potential for insomnia (e.g., Approximately how long does it take you to fall asleep at night?) and sleep apnea (e.g., Do you snore?), symptoms or environmental conditions indicative of other sleep problems (e.g., currently working third shift, leg jerks or restless legs in the middle of the night [PLMD or restless leg syndrome], diurnal sleep attacks [narcolepsy]), and any other unusual sleep experiences or factors that influence sleep (e.g., alcohol and caffeine consumption).

Other information obtained during this interview included demographics, cardiac- and ICD-specific health history, presence or history of other health conditions that may affect sleep or cardiac functioning (e.g., cancer, neurological diseases, diabetes, chronic pain), and whether currently taking prescription or over-the-counter medications (including sleep aides). A formal review of medical records obtained prior to the baseline visit was performed separately in order to verify cardiovascular-specific history (i.e., date of ICD implantation, cardiac etiology, ejection fraction, and pre-baseline medication usage).

Of note, we ascertained which participants had pre-morbid sleep difficulties prior to ICD implantation by subtracting (Years of Insomnia Complaint) from (Years since ICD Implantation) questions taken from the clinical interview, with negative values indicative of a sleep problem that preceded ICD implantation. We also ascertained pre-morbid psychological disorder diagnosis utilizing electronic medical record review; participants who had a psychiatric diagnosis (e.g., depression, anxiety) at the time of baseline assessment were categorized as having a psychiatric diagnosis at the time of screening.

Sleep Assessment

Ambulatory Polysomnography: A single night of ambulatory PSG was collected at the baseline visit. A 25-channel AURA Portable Recording System (Grass Technologies) was used to conduct in-home overnight sleep monitoring. Consistent with ambulatory PSG recommendations (Collop et al., 2007; Iber et al., 2007) monitoring consisted of 10 electroencephalography (EEG) measures (F2, C2, O2, ground, reference, M1, M2), 2 electro-oculography (EOG), and 3 chin electromyography (EMG) according to standard placements (Chesson, Berry, & Pack, 2003; Iber et al., 2007). Other standardized PSG monitoring included respiratory inductance plethysmography (thoracic & abdominal effort), oximeter (pulse & oxygen saturation), electrocardiogram (ECG), right and left anterior tibialis EMG (R & L), oral-nasal airflow thermocouple, and nasal cannula pressure transducer. PSGs were scored by a registered polysomnograph technologist and reviewed by a board certified sleep physician (RBB) based on procedures described by the Sleep Heart Health Study (SHHS; Redline et al., 1998).

Sleep Diaries: Participants completed daily sleep diaries each morning for 14-days, beginning on the morning following their overnight PSG, to produce the following variables used to diagnose insomnia: 1) sleep onset latency (SOL; time it took to fall asleep); 2) number of awakenings during the night; 3) wake after sleep onset (WASO; total time spent awake during the night); and 5) sleep efficiency (ratio of total sleep time to total time in bed x 100, expressed as a percentage). The daily diary used was adapted from that developed by Lichstein and colleagues (1999) to include questions assessing device-related worry and

symptoms of cardiac events that each patient currently feels prior to falling asleep each night. These latter device-related items were not examined in the current set of analyses.

Psychological Adjustment—The Beck Depression Inventory- II (BDI; Beck, Steer, & Brown, 1996) was used to assess severity of depressive symptomatology over the past 14 days. The BDI is a 21-item self-report questionnaire, each item is scored on a 0 (absence of symptoms) to 3 (most severe) scale, with higher scores indicating greater maladjustment. The State Trait Anxiety Inventory, Form Y2 (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983) is a 20-item questionnaire that measures general levels of anxiety over the past 14 days. Items consist of a self-descriptive statement (“I feel calm”), and participants are asked to rate their agreement on a 1 (not at all) to 4 (extremely) scale to derive a total score ranging from 20–80. The BDI and STAI demonstrate good reliability ($\alpha > 0.8$) and have been used extensively in populations with chronic medical conditions.

Daytime Functioning—The Epworth Sleepiness Scale (ESS; Johns, 1991) is an 8-item, self-report measure of daytime sleepiness that asks participants to rate their chances of falling asleep on a 0 (would never doze) to 3 (high chance of dozing) point scale in eight different sedentary situations (e.g., watching TV). The mean ESS score of normal sleepers is 4.6 (SD = 2.8), with insomnia complaints significantly correlated with ESS scores (Johns & Hocking, 1997). For the current study, a cutoff score of 7.3 (1 standard deviation above the mean score of normal sleepers) was used as evidence of a daytime functioning complaint.

The Fatigue Severity Scale (FSS; Krupp, LaRocca, Muir-Nash, & Steinberg, 1989) measures the degree to which fatigue interferes in daily functioning across nine items (e.g., “Exercise brings on my fatigue,”) rated on a 1 (strongly disagree) to 7 (strongly agree) scale. There is no formal normative data for the FSS; however, Lichstein et al. (1997) found that insomnia patients averaged an FSS score of 6.0 (SD = 0.5), and suggest scores of 5.4 (1 standard deviation below the mean FSS scores of patients with an insomnia complaint) as a cutoff score for evidence of daytime impairment (criteria used herein).

Device-related Adjustment—The Florida Shock Anxiety Scale (FSAS; Kuhl et al., 2006) is a 10-item assessment of shock anxiety that was initially developed to evaluate patient fears and anxieties surrounding shock from an ICD. Psychometrically, the FSAS exhibits high internal consistency (Cronbach’s $\alpha=.91$), and is significantly positively correlated with the Multidimensional Fear of Death Scale (Kuhl et al., 2006), history of ICD shocks, and self-reported ICD-shock related life disruption (J. Ford et al., 2012). The FSAS is significantly negatively correlated with self-reported emotional well-being, sense of security, quality of life, and general health. FSAS scores ranging 10–12 indicate no shock anxiety, while scores >41 indicate having shock anxiety almost all of the time (Morken et al., 2012).

The Florida Patient Acceptance Survey (FPAS; Burns et al., 2005) is a device-specific quality of life measure intended to evaluate how well ICD patients have accommodated the ICD into their lives. Psychometric evaluation of the FPAS has yielded four distinct factors related to patient functioning that are measured by the questionnaire: Return to Function (e.g., I am not able to do things for my family the way I used to; I have returned to a full

life), Device-Related Distress (e.g., When I think about the device, I avoid doing things I enjoy; Thinking about the device makes me depressed), Positive Appraisal (e.g., The positive benefits of this device outweigh the negatives; My device was my best treatment option), and Body Image Concerns (e.g., I feel less attractive because of my device; I feel that others see me as disfigured by my device). The measure includes 18 items on a scale of 1 (strongly disagree) to 5 (strongly agree), yielding a Total ICD Patient Acceptance score (ranging from 20 to 90). The FPAS demonstrates satisfactory internal consistency (Cronbach's $\alpha = .74-.89$) for the total questionnaire and all of the scales, is significantly correlated with measures of general quality of life, is negatively correlated with measures of psychosocial distress (e.g., anxiety, depression), and can successfully discriminate between groups of device patients (e.g., ICDs, pacemakers).

Analyses—IBM SPSS Statistics Version 20 was used for all statistical analyses. Participants were categorized by sleep disorder diagnosis based on their sleep diaries and PSG. Descriptive statistics were calculated for demographic variables (age, gender, race, and years of education). Pearson correlations were calculated between all dependent variables to demonstrate the degree of multicollinearity/independence of these constructs. A 4 (Diagnoses: Good Sleeper, Insomnia, Obstructive Sleep Apnea, or Comorbid Insomnia and Apnea) x 6 (Adjustment variables: BDI, STAI, ESS, FSS, FPAS, and FSAS) MANCOVA was performed to detect an overall effect of sleep disorder diagnosis on adjustment variables, with ischemia diagnosis (ischemic vs. non-ischemic) and sleep medication use (yes or no) designated as covariates. The separation of ischemic vs. non-ischemic calls attention to the etiology of the cardiac condition (i.e., ischemic disease denotes a chronic process of atherosclerosis, non-ischemic disease denotes a more idiopathic or variable etiology that is marked by sudden onset and beyond one's control). In order to further distinguish differences in adjustment between sleep disorder diagnoses, follow-up univariate post-hoc tests were conducted.

Results

Sleep Disorder Diagnoses and Demographics

Participants were categorized into one of four groups: Obstructive Sleep Apnea (OSA; $n = 12, 28.6\%$), Insomnia ($n = 7, 16.7\%$), Comorbid Insomnia and Apnea ($n = 5, 11.9\%$), and Good Sleepers ($n = 18, 42.9\%$). No participants met criteria for other sleep disorders.

Demographic information for the total sample as well as the three groups can be found in Table 1. There were no significant differences between groups on any demographic variables, including age, gender, education, MMSE score, number of current medications, sleep medicine use, cardiac ejection fraction, ischemia diagnosis, or years since ICD implantation.

Chi-Square tests of independence were conducted to ascertain potential group differences with regards to pre-ICD implantation sleep complaint, history of receiving ICD shocks, and pre-morbid psychiatric diagnosis (See Table 1). 15.9% of the total sample indicated a sleep complaint occurred prior to ICD implantation; the Insomnia and Comorbid Insomnia/Apnea groups had the greatest percentage of participants reporting prior sleep complaint, with

Good Sleepers having the lowest percentage. These group differences were non-significant, however (χ^2 (N = 36, df = 3) = 5.73, $p = .13$). There were also no significant group differences with regards to shock history (i.e., defined as ever experiencing a shock; χ^2 (N = 42, df = 3) = .16, $p = .98$). Moreover, 30% of the entire sample had pre-existing psychiatric diagnoses at the time of data collection (41.7% Apnea; 30% Good Sleepers; 28.6% Insomnia; 20% Comorbid Insomnia/Apnea), though no significant group differences were found χ^2 (N = 42, df = 3) = .87, $p = .83$).

Correlations of Adjustment Variables

Pearson correlations were conducted between the psychological adjustment, daytime functioning, and ICD-specific adjustment variables (Table 2). While there were significant correlations between many of the outcome variables, they were not strong enough to preclude examination as separate outcomes (BDI and STAI were examined separately based on their routine usage as separate measures in clinical settings).

Group Comparisons

A between-subjects MANCOVA controlling for diagnosis of ischemia was significant, $F(6,33) = 5.41$, $p < 0.01$, $\eta^2 = 0.50$, indicating an overall moderate main effect of diagnosis on the outcome variables. The effects of sleep disorder diagnosis did not vary based on either ischemia diagnosis, $F(6,31) = 0.46$, $p = 0.83$ or use of sleep medications $F(6,31) = 1.27$, $p = .30$.

Six follow-up ANOVAs and subsequent pairwise comparisons (adjusted for multiple comparisons using Fisher's least significant differences test; Hayter, 1986) indicated several differences between groups on the outcome measures (Table 3). The Insomnia group and the Comorbid Insomnia/Apnea group demonstrated significantly higher scores on the BDI-II [$F(3,36) = 5.88$, $p = .002$, $\eta^2 = .33$] than good sleepers or individuals with apnea. Participants with Comorbid Insomnia/Apnea also had significantly greater BDI-II scores than individuals with apnea. Both the Insomnia and Comorbid Insomnia/Apnea groups demonstrated significantly higher scores on the STAI [$F(3,36) = 2.92$, $p = .047$, $\eta^2 = .20$]. Moreover, both the Insomnia and Comorbid Insomnia/Apnea group exhibited clinically significant levels of depression and anxiety, while the OSA and Good Sleeper groups did not experience clinically significant levels of either.

With regards to daytime functioning measures, Good Sleepers had significantly lower fatigue ratings on the FSS than the Insomnia, Apnea, and Comorbid Insomnia/Apnea groups; the latter groups did not differ from each other, except for the Comorbid group experiencing significantly greater fatigue than the Apnea group. There were no significant group differences on the ESS.

Examination of the device-specific adjustment measures revealed significant group differences on the FPAS, with both the Insomnia and Comorbid Insomnia/Apnea groups reporting significantly less ICD device acceptance than the Good Sleeper group ($F(3,36) = 6.21$, $p = 0.002$, $\eta^2 = 0.34$). Additionally, the Apnea group demonstrated greater device

acceptance than the Insomnia group, but not the Comorbid Insomnia/Apnea group. There were no significant group differences on the FSAS.

Discussion

This study demonstrated that insomnia and obstructive sleep apnea are highly prevalent (~57%) amongst patients with ICDs, and that insomnia (alone or comorbid with sleep apnea) is associated with poorer psychological adjustment and poorer device-related acceptance relative to ICD-patients with good sleep or those with obstructive sleep apnea only. We also found that good sleepers and patients with diagnosed sleep disorders did not differ in their report of daytime sleepiness, but daytime fatigue was significantly more prominent in patients with apnea, insomnia, or both disorders than in ICD patients with good sleep.

Based on empirically-derived diagnoses for organic sleep disorders (AASM, 2005; Edinger et al., 2004) using self-report (14-day sleep diaries) and objective (1 night ambulatory PSG) sleep measures, we established four analysis groups with disparate functioning and adjustment profiles: (1) Good Sleepers (42.9% of the sample), (2) Insomnia (16.7%), (3) Obstructive Sleep Apnea (28.6%), and (4) Comorbid Insomnia and Obstructive Sleep Apnea (11.9%). The prevalence rate of OSA in our sample (40.5%) is consistent with previous findings in the literature (40–77%; Fries et al., 1999; Grimm et al., 2013; Mehra et al., 2006; Serizawa et al., 2008; Tomaello et al., 2010), although our rate of OSA and comorbid insomnia (11.9%) is low relative to previously reports in ICD patients with nocturnal ventricular arrhythmias (22–54.9%; Al-Jawder & Bahammam, 2011). Our prevalence rate for insomnia within the sample (28.6%) is lower but somewhat comparable to previous findings in heart failure patients (44%; Taylor et al., 2007), and suggests that insomnia is a considerable problem with these patients as a less-recognized and/or treated condition that until recently has received little attention (Cross et al., 2010).

Together, these prevalence findings may have clinical implications for the coordinated care of ICD patients. The identification of an under-recognized condition, such as insomnia, could warrant the inclusion of psychological and/or hypnotic therapy to the constellation of medical care ICD patients receive which could substantially improve their cardiovascular functioning and/or quality of life. Apnea, whether alone or comorbid with insomnia, is particularly problematic for ICD patients as the aggregate cardiovascular effects of apnea (Kasai & Bradley, 2011) have been associated with arrhythmia and subsequent ICD discharge (Fichter et al., 2002; Serizawa et al., 2008; Tomaello et al., 2010). The finding that insomnia and apnea have the potential to co-occur suggests that concurrent psychological treatment for insomnia and respiratory therapy (i.e., continuous positive airway pressure [CPAP], the gold standard treatment for sleep apnea) in this population may be indicated; previous research demonstrates both the cardiovascular and psychological benefit of this dual approach (Abe et al., 2010). In particular, the cardiovascular benefits of treating sleep disorders in ICD patients may be substantial, especially for attenuating the pathophysiological effects of heart disease exacerbated by sleep apnea (Kaneko et al., 2003).

The presence of insomnia within our sample (~29%), whether alone or comorbid with obstructive sleep apnea, was found to be significantly associated with poorer psychological adjustment and device-related functioning in patients with ICDs. Of note, both the Insomnia and Comorbid Insomnia and Apnea group demonstrated clinically significant levels of depression (i.e., group mean of 18.9 is indicative of moderate depressive symptoms; Beck et al., 1996) and anxiety (i.e., group mean of 44.8 indicates clinically elevated anxiety symptomatology; Spielberger et al., 1983); whereas, mood ratings for neither Good Sleepers nor the Apnea only group were in clinically significant ranges. This is not surprising, given that insomnia has been previously associated with greater mood disturbances, especially anxiety and depression (Buysse et al., 1994). However, as mood disturbances increase the risk of shock in ICD patients (Dunbar et al., 1999; William Whang et al., 2005), this finding draws attention to the possibility that patients with concurrent insomnia (alone or with OSA) and mood symptoms are at greater risk for an arrhythmia event or ICD discharge than those with apnea alone and good sleepers, and may also coincide with mood disturbances significant enough to warrant psychological or pharmacological intervention. Furthermore, the fact that participants with Insomnia deviate from Good Sleepers and Apneics on device-specific functioning indicates there may be some degree of relationship between poor sleep and adjustment to the ICD device. Our results suggest that ICD patients with Insomnia or Comorbid Insomnia and Apnea are less likely to endorse acceptance of the device. Therefore, these patients may also be less likely to adapt to the disadvantages of the ICD while embracing its benefits, which include psychological, social, and physical advantages.

We were surprised that the Insomnia, Comorbid Insomnia and Apnea, and Apnea alone groups did not differ statistically on fatigue or self-reported daytime sleepiness as we had predicted. However, it is important to note that our findings are not accounted for by the apnea present in some of the patients in the combined Insomnia and Comorbid Insomnia, and Apnea groups. There were no significant differences in fatigue or daytime sleepiness (or any other demographic, health, or adjustment variable) between participants with Insomnia only and those with Comorbid Insomnia and Apnea. A previous study looking at these variables in heart failure patients found that—consistent with our study—insomnia symptoms were associated with increased daytime sleepiness and fatigue, while symptoms of SDB had no significant relationship with either variable (inconsistent with our findings; Redeker et al., 2010). The presence of contradictions between studies suggests that additional research is clearly needed to better delineate the relationships between sleep and fatigue in different cardiac populations and to examine the mechanism(s) by which insomnia may exacerbate fatigue in the context of cardiac disease, and how this may differentially impact cardiac functioning in patients with ICDs.

Taken collectively, the results from this preliminary study appear to suggest that poor sleep may worsen the vulnerabilities of ICD patients (e.g., distress, functional impairment) and subsequent adjustment to life following ICD implantation. Although the exact causal nature of these relationships are yet to be determined, they may be reciprocal; ICD implantation may contribute to anxiety specifically related to the device that contributes to chronic insomnia, which leads to further generalized anxiety and poor device-specific adjustment. The combination of greater levels of generalized anxiety (including knowledge of the likelihood of defibrillation occurring at night) paired with low device acceptance allows for

a context disposed to development of chronic insomnia. Models that attempt to elucidate factors that lead to the development of chronic insomnia suggest that the exacerbation of symptoms can become contingent on worry and rumination regarding poor sleep (Harvey, 2005); therefore, it is possible that worry about device discharge during the night may perpetuate poor sleep.

Given the high rate of sleep disorders found in this study (approximately 57% of the sample), research to further discern the clinical and physiological correlates of sleep disturbances to inform treatment approaches for ICD patients is warranted. These sleep disorders are highly treatable. Understanding this population's potential to develop insomnia or SDB and its associated repercussions can inform treatment approaches for patients with ICDs pre- and post-implantation, prevent negative physiological and psychological consequences, and improve overall quality of life.

As this was a preliminary investigation into the relationships between cardiovascular disease, ICD implantation, and sleep, a major limitation of this study was a small sample size. Moreover, the data gathered in this preliminary study did not allow for precise observation of the temporal progression of psychiatric diagnosis, sleep difficulties, and ICD implantation. For example, many participants had a preexisting diagnosis of a psychological disorder (see Table 1); however, the temporal relationship between psychological disorder onset and ICD implantation was relatively unclear. We were able to discern the temporal relationship between onset of sleep difficulties and ICD implantation; as such, we observed that Insomnia and Comorbid Insomnia/Apnea groups had the greatest percentage of patients with pre-existing sleep complaint at ICD implantation. Although the results of this study demonstrate differences between sleep diagnostic groups regarding mood and device-specific functioning, we cannot make conclusions regarding the causal relationships therein. The sequence of disease and insomnia will need to be closely examined in future research to determine the causal relationships between ICD device implantation, sleep, and adjustment. Furthermore, the heterogeneity of disease severity and etiology of ICD patients was only controlled by disease type (i.e. ischemic vs. non-ischemic). Future research and larger samples will allow for greater control of cardiac variables (e.g., ICD as primary vs. secondary prevention, heart failure status, disease severity, medical comorbidity, medication use). As such, any conclusions drawn from the findings of this research should be viewed in light of these limitations and used to inform the need for future research in this area.

Insomnia and sleep apnea are highly prevalent in ICD patients, and these diagnoses may differentially impact daytime functioning. Mood difficulties and acceptance of the ICD device may be more problematic for individuals with insomnia – either when experienced alone or concurrently with sleep apnea – than for those with sleep apnea only. Fatigue, however, may be a problem for ICD patients across different sleep disorder diagnoses. These preliminary findings suggest the need for future research in this area, with an emphasis on thorough assessment and subsequent treatment of sleep disorders in patients with ICDs in specific and likely in cardiac patients in general.

Acknowledgments

The project described was supported by Award Number R21HL087831 from the National Heart, Lung, and Blood Institute.

Special thanks to Jason Craggs, PhD (database designer and developer); Keith Fridel, PhD and Joseph Dzierzewski, PhD (recruiters); Zach Zedar and Caterina Mosti (polysomnographic technicians); Susan Purdy (registered polysomnographic technician), and the undergraduate research assistants of the UF Sleep Research Laboratory.

References

- AASM. International classification of sleep disorders 2nd ed: Diagnostic and coding manual. Westchester, IL: American Academy of Sleep Medicine; 2005.
- Abe H, Takahashi M, Yaegashi H, Eda S, Tsunemoto H, Kamikozawa M, Ikeda U. Efficacy of continuous positive airway pressure on arrhythmias in obstructive sleep apnea patients. *Heart and Vessels*. 2010; 25(1):63–69.10.1007/s00380-009-1164-z [PubMed: 20091401]
- Al-Jawder SE, Bahammam AS. Comorbid insomnia in sleep-related breathing disorders: an under-recognized association. *Sleep & Breathing*. 2011;10.1007/s11325-011-0513-1
- Al-Khatib SM, Hellkamp MA, Bardy GH, Hammill S, Hall WJ, Mark DB, Curtis LH. Survival of patients receiving a primary prevention implantable cardioverter-defibrillator in clinical practice vs clinical trials. *The Journal of the American Medical Association*. 2013; 309(1):55. [PubMed: 23280225]
- Ancoli-Israel S, Roth T. Characteristics of insomnia in the United States: results of the 1991 National Sleep Foundation Survey. I. *Sleep*. 1999; 22(Suppl 2):S347–353. [PubMed: 10394606]
- AVID. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. *The New England Journal of Medicine*. 1997; 337(22):1576–1583.10.1056/NEJM1997112733722202 [PubMed: 9411221]
- Baglioni C, Battagliese G, Feige B, Spiegelhalder K, Nissen C, Voderholzer U, Riemann D. Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. *J Affect Disord*. 2011; 135(1–3):10–19.10.1016/j.jad.2011.01.011 [PubMed: 21300408]
- Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Johnson G. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *New England Journal of Medicine*. 2005; 352(3):225–237. [PubMed: 15659722]
- Beck, AT.; Steer, RA.; Brown, G. Manual for the Beck Depression Inventory-II. San Antonio, TX: Psychological Corporation; 1996.
- Berg SK, Higgins M, Reilly CM, Langberg JJ, Dunbar SB. Sleep quality and sleepiness in persons with implantable cardioverter defibrillators: outcome from a clinical randomized longitudinal trial. *Pacing Clin Electrophysiol*. 2012; 35(4):431–443.10.1111/j.1540-8159.2011.03328.x [PubMed: 22303998]
- Burns JL, Sears SF, Sotile R, Schwartzman DS, Hoyt RH, Alvarez LG, Ujhelyi MR. Do patients accept implantable atrial defibrillation therapy? Results from the Patient Atrial Shock Survey of Acceptance and Tolerance (PASSAT) Study. *Journal of Cardiovascular Electrophysiology*. 2004; 15(3):286–291.10.1111/j.1540-8167.2004.03406.x [PubMed: 15030417]
- Burns JL, Serber ER, Keim S, Sears SF. Measuring patient acceptance of implantable cardiac device therapy: Initial psychometric investigation of the Florida Patient Acceptance Survey. *Journal of Cardiovascular Electrophysiology*. 2005; 16(4):384–390.10.1046/j.1540-8167.2005.40134.x [PubMed: 15828880]
- Buysse DJ, Reynolds CF 3rd, Kupfer DJ, Thorpy MJ, Bixler E, Manfredi R, et al. Clinical diagnoses in 216 insomnia patients using the International Classification of Sleep Disorders (ICSD), DSM-IV and ICD-10 categories: A report from the APA/NIMH DSM-IV Field Trial. *Sleep*. 1994; 17(7): 630–637. [PubMed: 7846462]
- Chesson AL, Berry RB, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. *Sleep*. 2003; 26(7):907–913. [PubMed: 14655928]

- Chokroverty, S. *Sleep Disorders Medicine: Basic science, technical considerations and clinical aspects*. 2. New York: Butterworth/Elsevier; 1999.
- Collop N, Anderson W, Boehlecke B, Claman D, Goldberg R, Gottlieb DJ, Schwab R. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *Journal of Clinical Sleep Medicine*. 2007; 3(7):737–747. [PubMed: 18198809]
- Connolly S, Hallstrom A, Cappato R, Schron E, Kuck KH, Zipes D, Follmann D. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. *European Heart Journal*. 2000; 21(24):2071–2078. [PubMed: 11102258]
- Cross NJ, McCrae CS, Smith KM, Conti JB, Sears SF. Comparison of actigraphic and subjective measures of sleep in implantable cardioverter defibrillator and coronary artery disease patients. *Clinical Cardiology*. 2010; 33(12):753–759.10.1002/clc.20827 [PubMed: 21184559]
- Dunbar SB, Kimble LP, Jenkins LS, Hawthorne M, Dudley W, Slemmons M, Langberg JJ. Association of mood disturbance and arrhythmia events in patients after cardioverter defibrillator implantation. *Depression and Anxiety*. 1999; 9(4):163–168.10.1002/(sici)1520-6394(1999)9:4<163::aid-da3>3.0.co;2-b [PubMed: 10431681]
- Edinger JD, Bonnet MH, Bootzin RR, Doghramji K, Dorsev CM, Espie CA. American Academy of Sleep Medicine Work G. Derivation of research diagnostic criteria for insomnia: Report of an American Academy of Sleep Medicine Work Group. *Sleep*. 2004; 27(8):1567–1596. [PubMed: 15683149]
- Fichter J, Bauer D, Arampatzis S, Fries R, Heisel A, Sybrecht GW. Sleep-related breathing disorders are associated with ventricular arrhythmias in patients with an implantable cardioverter-defibrillator. *Chest*. 2002; 122(2):558–561.10.1378/chest.122.2.558 [PubMed: 12171831]
- Folstein MF, Folstein SE, McHugh PR. “Mini-mental state”: A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*. 1975; 12(3):189–198. [PubMed: 1202204]
- Ford DE, Kamerow DB. Epidemiologic study of sleep disturbances and psychiatric disorders. An opportunity for prevention? *Journal of the American Medical Association*. 1989; 262(11):1479–1484. [PubMed: 2769898]
- Ford J, Finch JF, Woodrow LK, Cutitta KE, Shea J, Fischer A, Sears SF. The Florida Shock Anxiety Scale (FSAS) for patients with implantable cardioverter defibrillators: Testing factor structure, reliability, and validity of a previously established measure. *Pacing and Clinical Electrophysiology*. 2012; 35(9):1146–1153.10.1111/j.1540-8159.2012.03455.x [PubMed: 22758923]
- Fries R, Bauer D, Heisel A, Juhasz J, Fichter J, Schieffer H, Sybrecht GW. Clinical significance of sleep-related breathing disorders in patients with implantable cardioverter defibrillators. *Pacing and Clinical Electrophysiology*. 1999; 22(1):223–227. [PubMed: 9990635]
- Go AS, Mozaffarian D, Roger VL, Benjamin EJ, Berry JD, Blaha MJ, Turner MB. Heart disease and stroke statistics - 2014 update: A report from the American Heart Association. *Circulation*. 2014; 129:28–292.10.1161/01.cir.0000441139.02102.80 [PubMed: 24323793]
- Grimm W, Apelt S, Timmesfeld N, Koehler U. Sleep-disordered breathing in patients with implantable cardioverter-defibrillator. *Europace*. 2013; 15(4):515–522. [PubMed: 23129543]
- Harvey A. A cognitive theory and therapy for chronic insomnia. *Journal of Cognitive Psychotherapy*. 2005; 19(1):41–59.
- Hayter AJ. The maximum familywise error rate of Fisher’s Least Significant Difference Test. *Journal of the American Statistical Association*. 1986; 81(396):1000–1004.10.1080/01621459.1986.10478364
- Iber, C.; Ancoli-Israel, S.; Chesson, A.; Quan, S. *The AASM manual for the scoring of sleep and associated events: Rules, terminology and technical specifications*. Westchester, IL: American Academy of Sleep Medicine; 2007.
- Johns M. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. *Sleep*. 1991; 14(6):540–545. [PubMed: 1798888]
- Johns M, Hocking B. Daytime sleepiness and sleep habits of Australian workers. *Sleep*. 1997; 20(10): 844–849. [PubMed: 9415943]

- Kaneko Y, Floras JS, Usui K, Plante J, Tkacova R, Kubo T, Bradley TD. Cardiovascular effects of continuous positive airway pressure in patients with heart failure and obstructive sleep apnea. *The New England Journal of Medicine*. 2003; 348(13):1233–1241.10.1056/NEJMoa022479 [PubMed: 12660387]
- Kasai T, Bradley TD. Obstructive sleep apnea and heart failure: Pathophysiologic and therapeutic implications. *Journal of the American College of Cardiology*. 2011; 57(2):119–127.10.1016/j.jacc.2010.08.627 [PubMed: 21211682]
- Katz DA, McHorney CA. The relationship between insomnia and health-related quality of life in patients with chronic illness. *J Fam Pract*. 2002; 51(3):229–235. [PubMed: 11978233]
- Krupp L, LaRocca NG, Muir-Nash J, Steinberg AD. The fatigue severity scale: Application to patients with multiple sclerosis and systemic lupus erythematosus. *Archives of Neurology*. 1989; 46(10):1121–1123.10.1001/archneur.1989.00520460115022 [PubMed: 2803071]
- Kuhl EA, Dixit NK, Walker RL, Conti JB, Sears SF. Measurement of patient fears about implantable cardioverter defibrillator shock: An initial evaluation of the Florida Shock Anxiety Scale. *Pacing and Clinical Electrophysiology*. 2006; 29(6):614–618.10.1111/j.1540-8159.2006.00408.x [PubMed: 16784427]
- Lichstein KL, Durrence H, Taylor D, Bush A, Riedel B. Quantitative criteria for insomnia. *Behaviour Research and Therapy*. 2003; 41(4):427–445. [PubMed: 12643966]
- Lichstein KL, Means MK, Noe SL, Aguillard RN. Fatigue and sleep disorders. *Behavioral Research and Therapy*. 1997; 35(8):733–740.
- Lichstein KL, Riedel BW, Means MK. Psychological treatment of late-life insomnia. *Annual review of gerontology and geriatrics*. 1999; 18:74–110.
- Magyar-Russell G, Thombs BD, Cai JX, Baveja T, Kuhl EA, Singh PP, Amin N. The prevalence of anxiety and depression in adults with implantable cardioverter defibrillators: a systematic review. *Journal of Psychosomatic Research*. 2011; 71(4):223–231. [PubMed: 21911099]
- Mehra R, Benjamin EJ, Shahar E, Gottlieb DJ, Nawabit R, Kirchner HL. Sleep Heart Health Study. Association of nocturnal arrhythmias with sleep-disordered breathing: The Sleep Heart Health Study. *American Journal of Respiratory and Critical Care Medicine*. 2006; 173(8):910–916.10.1164/rccm.200509-1442OC [PubMed: 16424443]
- Mendelson WB. Experiences of a sleep disorders center: 1700 patients later. *Cleveland Clinic Journal of Medicine*. 1997; 64(1):46–51. [PubMed: 9014384]
- Morken IM, Isaksen K, Karlsen B, Norekvål TM, Bru E, Larsen AI. Shock Anxiety among Implantable Cardioverter Defibrillator Recipients with Recent Tachyarrhythmia. *Pacing and Clinical Electrophysiology*. 2012; 35(11):1369–1376.10.1111/j.1540-8159.2012.03505.x [PubMed: 22946670]
- Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, Heo M. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia: Multicenter Automatic Defibrillator Implantation Trial Investigators. *The New England Journal of Medicine*. 1996; 335(26):1933–1940.10.1056/nejm199612263352601 [PubMed: 8960472]
- Ohayon MM. Prevalence of DSM-IV diagnostic criteria of insomnia: Distinguishing insomnia related to mental disorders from sleep disorders. *Journal of Psychiatric Research*. 1997; 31(3):333–346. doi: [http://dx.doi.org/10.1016/S0022-3956\(97\)00002-2](http://dx.doi.org/10.1016/S0022-3956(97)00002-2). [PubMed: 9306291]
- Ohayon MM. Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Med Rev*. 2002; 6(2):97–111. [PubMed: 12531146]
- Ohayon MM, Caulet M, Lemoine P. Comorbidity of mental and insomnia disorders in the general population. *Comprehensive Psychiatry*. 1998; 39(4):185–197. [PubMed: 9675502]
- Pedersen SS, Spindler H, Johansen JB, Mortensen PT, Sears SF. Correlates of patient acceptance of the cardioverter defibrillator: Cross-validation of the Florida Patient Acceptance Survey in Danish patients. *Pacing and Clinical Electrophysiology*. 2008; 31(9):1168–1177.10.1111/j.1540-8159.2008.01158.x [PubMed: 18834469]
- Quesnel C, Savard J, Simard S, Ivers H, Morin C. Efficacy of cognitivebehavioral therapy for insomnia in women treated for nonmetastatic breast cancer. *J Consult Clin Psychol*. 2003; 71(1):189–200. [PubMed: 12602439]

- Redeker NS, Jeon S, Muench U, Campbell D, Walsleben J, Rapoport DM. Insomnia symptoms and daytime function in stable heart failure. *Sleep*. 2010; 33(9):1210–1216. [PubMed: 20857868]
- Redline S, Sanders MH, Lind BK, Quan SF, Iber C, Gottlieb DJ, Kiley JP. Methods for obtaining and analyzing unattended polysomnography data for a multicenter study. Sleep Heart Health Research Group. *Sleep*. 1998; 21(7):759–767. [PubMed: 11300121]
- Roth T, Ancoli-Israel S. Daytime consequences and correlates of insomnia in the United States: Results of the 1991 National Sleep Foundation Survey II. *Sleep*. 1999; 22(Suppl 2):S354–358. [PubMed: 10394607]
- Sears SF, Todaro JF, Lewis TS, Sotile W, Conti JB. Examining the psychosocial impact of implantable cardioverter defibrillators: A literature review. *Clinical Cardiology*. 1999; 22(7):481–489.10.1002/clc.4960220709 [PubMed: 10410293]
- Serber ER, Sears SF, Sotile RO, Burns JL, Schwartzman DS, Hoyt RH, Ujhelyi MR. Sleep quality among patients treated with implantable atrial defibrillation therapy: Effect of nocturnal shock delivery and psychological distress. *Journal of Cardiovascular Electrophysiology*. 2003; 14(9): 960–964. [PubMed: 12950541]
- Serizawa N, Yumino D, Kajimoto K, Tagawa Y, Takagi A, Shoda M, Hagiwara N. Impact of sleep-disordered breathing on life-threatening ventricular arrhythmia in heart failure patients with implantable cardioverter-defibrillator. *American Journal of Cardiology*. 2008; 102(8):1064–1068.10.1016/j.amjcard.2008.05.057 [PubMed: 18929710]
- Spielberger, CD.; Gorsuch, RL.; Lushene, R.; Vagg, PR.; Jacobs, GA. *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press; 1983.
- Taylor DJ, Lichstein KL, Durrence HH, Reidel BW, Bush AJ. Epidemiology of insomnia, depression, and anxiety. *Sleep*. 2005; 28(11):1457–1464. [PubMed: 16335332]
- Taylor DJ, Mallory LJ, Lichstein KL, Durrence HH, Riedel BW, Bush AJ. Comorbidity of chronic insomnia with medical problems. *Sleep*. 2007; 30(2):213–218. [PubMed: 17326547]
- Tomaello L, Zanolla L, Vassanelli C, LoCascio V, Ferrari M. Sleep disordered breathing is associated with appropriate implantable cardioverter defibrillator therapy in congestive heart failure patients. *Clinical Cardiology*. 2010; 33(2):E27–30.10.1002/clc.20602 [PubMed: 20043344]
- Ustinov Y, Lichstein KL, Wal GS, Taylor DJ, Riedel BW, Bush AJ. Association between report of insomnia and daytime functioning. *Sleep Medicine*. 2010; 11(1):65–68.10.1016/j.sleep.2009.07.009 [PubMed: 19783473]
- Verrier, RL.; Josephson, ME. Cardiac arrhythmogenesis during sleep: Mechanisms, diagnosis, and therapy. In: Kryger, MH.; Roth, T.; Dement, WC., editors. *Principles and Practice of Sleep Medicine*. 4. Philadelphia, PA: Elsevier Saunders; 2005. p. 1171-1179.
- Verrier, RL.; Mittleman, MA. Sleep-Related Cardiac Risk. In: Kryger, MH.; Roth, T.; Dement, WC., editors. *Principles and Practice of Sleep Medicine*. 4. Vol. 4. Philadelphia, PA: Elsevier Saunders; 2005. p. 1161-1170.
- Whang W, Albert CM, Sears JSF, Lampert R, Conti JB, Wang PJ, Mittleman MA. Depression as a predictor for appropriate shocks among patients with implantable cardioverter-defibrillators: Results from the Triggers of Ventricular Arrhythmias (TOVA) study. *Journal of the American College of Cardiology*. 2005; 45(7):1090–1095.10.1016/j.jacc.2004.12.053 [PubMed: 15808769]
- Whang W, Albert CM, Sears SF Jr, Lampert R, Conti JB, Wang PJ, Investigators TS. Depression as a predictor for appropriate shocks among patients with implantable cardioverter-defibrillators: results from the Triggers of Ventricular Arrhythmias (TOVA) study. *J Am Coll Cardiol*. 2005; 45(7):1090–1095.10.1016/j.jacc.2004.12.053 [PubMed: 15808769]

Table 1
Demographic and Health Related Characteristics for the Total Sample and by Sleep Disorder Diagnosis

	Total (n = 42)	Good Sleepers (n = 18)	Insomnia (n = 7)	Comorbid Insomnia & Apnea (n = 5)	Apnea (n = 12)
Age (years)	61.57 (12.60)	63.50 (11.38)	54.57 (20.42)	61.80 (7.76)	62.67 (10.20)
Gender (%female)	35.7%	33%	57%	40%	25%
Education					
No HS Diploma	2.4%	5.6%	0%	0%	0%
HS Diploma	14.3%	22.2%	14.3%	0%	8.3%
Some College	38.1%	38.9%	28.6%	80%	25%
Associate's	9.5%	0%	28.6%	0%	16.7%
Bachelor's	21.4%	11.1%	28.6%	20%	33.3%
Master's	2.4%	5.6%	0%	0%	0%
Ph.D.	11.9%	16.7%	0%	0%	16.7%
MMSE Total	27.68 (2.08)	27.76 (1.79)	27.14 (2.67)	28.00 (2.12)	27.75 (2.30)
Average Ejection Fraction %	35.88% (15.04)	30.28% (11.91)	53.13% (15.33)	39.50 (19.15)	37.25% (13.82)
Ischemia Diagnosis (%)	35.7%	50%	14.3%	40%	25%
Years Since ICD Implantation	3.55 (3.04)	4.00 (3.31)	1.40 (2.07)	4.40 (2.51)	3.42 (3.03)
# of Current Medications	10.90 (4.17)	10.67 (3.82)	11.25 (4.79)	12.80 (2.17)	10.92 (4.38)
Taking Sleep Medication (%)	19%	11%	17%	20%	17%
Psychiatric Diagnosis at Screening (%)	32%	30%	28.6%	20%	41.7%
Pre-Morbid Sleep Complaint (sleep difficulties pre-ICD Implantation)*	15.9%	5%	28.6%	40%	16.7%
Shock History (% experienced at least 1 shock)	38.1%	35%	40%	40%	41.7%

Note: Mean (Standard Deviation); MMSE = Mini Mental Status Exam

* There were 8 participants for whom we did not have adequate information regarding sleep complaint incidence and/or date of ICD implantation (Good Sleepers = 3 missing; Insomnia = 3 missing; Apnea = 2 missing; Comorbid = 0 missing).

Correlations Between Psychological Adjustment, Daytime Functioning, and ICD-Specific Variables

Table 2

	BDI-II	STAI	FSS	ESS	FPAS	FSAS
BDI-II	1	.848**	.634**	.353*	-.514**	.516**
STAI	.848**	1	.537**	.238	-.441**	.498**
FSS	.618**	.543**	1	.229*	-.401**	.351*
ESS	.353*	.238	.322*	1	-.268	.134
FPAS	-.514**	-.441**	-.403**	-.268	1	-.654**
FSAS	.516**	.498**	.286	.134	-.654**	1

Note: STAI = State-Trait Anxiety Inventory Y-2; BDI-II = Beck Depression Inventory-II; ESS = Epworth Sleepiness Scale; FSS = Fatigue Severity Scale; FPAS = Florida Patient Acceptance Survey; FSAS = Florida Shock

** Correlation is significant at the 0.01 level;

* Correlation is significant at the 0.05 level.

Table 3
Group Comparisons of Psychological Adjustment, Daytime Functioning, and ICD-Specific Adjustment

	Good Sleepers (n=18)	Apnea (n=12)	Insomnia (n=7)	Comorbid Insomnia & Apnea (n=5)	F (2, 38)	p	Partial η^2	Pairwise Comparisons
Psychological Adjustment								
STAI	29.83 (10.61)	34.17 (10.29)	45.57 (14.60)	43.80 (13.59)	2.92	.047*	.196	I & C > GS
BDI-II	4.72 (4.78)	11.42 (7.98)	19.86 (15.10)	17.60 (6.11)	5.88	.002*	.329	I & C > GS I > A
Daytime Functioning								
ESS	6.06 (3.24)	8.50 (5.32)	8.57 (5.80)	9.80 (8.70)	1.69	.186	.123	Non-Significant
FSS	3.10 (1.40)	4.22 (1.52)	4.84 (1.36)	5.84 (0.65)	5.84	.002*	.327	I, C, A > GS C > A
ICD-Specific Adjustment								
FPAS	88.98 (8.86)	79.58 (14.20)	64.46 (15.92)	65.33 (24.11)	6.21	.002*	.341	I & C < GS I < A
FSAS	14.50 (5.14)	16.67 (7.39)	22.57 (10.44)	22.60 (9.10)	2.56	.070	.176	Non-Significant

Note: Mean (Standard Deviation);

* $p < .05$;

STAI = State-Trait Anxiety Inventory Y-2; BDI-II = Beck Depression Inventory-II; ESS = Epworth Sleepiness Scale; FSS = Fatigue Severity Scale; FPAS = Florida Patient Acceptance Survey; FSAS = Florida Shock Anxiety Scale. GS = Good Sleepers; I = Insomnia; C = Comorbid Insomnia and Apnea; A = Apnea. Cohen's guidelines for interpretation of partial η^2 effect sizes: small = 0.01, moderate = 0.06, large = .14