Published in final edited form as:
Pacing Clin Electrophysiol. 2012 April ; 35(4): 431–443. doi:10.1111/j.1540-8159.2011.03328.x.

Sleep Quality and Sleepiness in Persons with Implantable Cardioverter Defibrillators: Outcome from a Clinical Randomized Longitudinal Trial

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Abstract

Background—Patients receiving an implantable cardioverter defibrillator (ICD) report various types and degree of sleep disruptions, but little is known regarding their characteristics, duration, and associated factors. The purposes of this study were: (1) to describe the effect of a psychoeducational intervention on sleep quality and daytime sleepiness, (2) to describe patterns of sleep over time, and (3) to identify predictors of poor sleep in an ICD population.

Methods—A randomized longitudinal intervention trial was designed to test the effects of a psychoeducational intervention, which included a sleep education and counseling session in patients receiving their initial ICD. Patients (n = 236; 75% men; mean age 58.4 [±11.2] from the PsychoEducationAl Intervention for ICD PatiEnts (PEACE) trial comprised the study population. Variables related to sleep were measured by the Pittsburgh Sleep Quality Inventory (PSQI) and Epworth Sleepiness Scale (ESS).

Results—No psychoeducational intervention effects on sleep outcomes were observed. However, 67.2% of the patients reported poor sleep quality at baseline, and 56.8% had low sleep quality at 6 months based on PSQI scores >5; one-third (32.6%) were excessively sleepy based on ESS scores =10 at 6 months. Anxiety, depression, physical function, pain intensity, and pain severity were all highly correlated to each other across time. Female gender was a significant covariate for the PSQI. New York Heart Association (NYHA) class was a significant covariate for sleepiness (Epworth).

Conclusions—Low sleep quality and daytime sleepiness are found at time of insertion and over time in patients with ICD. Female gender, higher NYHA class, as well as two latent factors encompassing increased anxiety, depressive symptoms, and decreased physical function and increased pain, were significant predictors of poor sleep quality and sleepiness over time. These data help identify those at higher risk for sleep problems after ICD.

Keywords

defibrillation-ICD; clinical trials

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Background

Research findings have contributed to the increasing awareness that sleep and sleep disorders are linked to cardiovascular disease. Sleep disorders contribute to the development of chronic cardiovascular conditions such as hypertension and heart failure (HF) as well as increased morbidity and mortality.[1–3] As many as 70% of patients with heart disease report disturbed sleep.[4] The sleep-wake cycle is influenced by a host of environmental, personal, social, psychological, disease-related, and treatment-related factors,[5] and greater understanding of the relationships between these factors and sleep disruptions is important to improve sleep outcomes in cardiac patients. The consequences of sleep deprivation on everyday life are excessive daytime sleepiness, fatigue, cognitive dysfunction, decreased alertness and reaction time, and mood disturbance.[4] Poor sleep also has a negative effect on quality of life (QoL) and daytime functioning.[6,7]

The implantable cardioverter defibrillator (ICD) is an implanted device that detects and treats life-threatening ventricular arrhythmias through antitachycardia pacing and internal defibrillation, and has been associated with sleep disturbance in varying degrees.[8,9] Although ICD use has reduced mortality remarkably in the past 20 years,[10] studies have shown that living with an ICD can lead to anxiety, fear of shocks, and avoidance of situations, places, and objects that the ICD recipient associates with shocks. These responses may lead to social isolation, avoidance of physical activity, and mood disturbances,[11–14] all of which may contribute to or may be aggravated by sleep problems.[5]

Sleep disturbances have also been studied in ICD recipients and reported to varying degrees by patients receiving ICDs. In a mixed population of 105 pacemaker and ICD recipients, 44% had poor sleep quality.[8] QoL is a construct that often includes symptoms such as sleep and sleep disturbance as a part of the overall definition.[9,15] A study assessing QoL in patients with life-threatening arrhythmias revealed that ICD patients had greater sleep disturbance compared with a cardiac control group.[9] In early studies when the ICD was originally implanted in the abdomen, sleep disturbance was regarded as one of the most troublesome responses compared to social isolation, reduced energy, emotions, physical mobility, and pain.[15] This outcome was explained by hypervigilance, due to fear of ICD discharge, which is a frequent cause of disruptions in sleep patterns. Also, side effects of antiarrhythmic medication were suggested as contributory.[15] In more recent studies and in the context of improved technology, sleep disturbance is still an area of concern. A higher degree of sleep disturbance (34% vs 22%) was reported by patients who experienced an ICD shock,[16] and lower sleep quality was found in women at the time of implant.[17]

Undiagnosed sleep disorders were reported in 40%–70% of ICD patients with 46%–56% having central sleep apnea[18,19] and 18% having obstructive sleep apnea (OSA).[19] Sleep-disordered breathing has also been related to ICD shock.[20,21] Even though sleep problems are found more frequently in cardiac patients with coronary heart disease than in patients with an ICD,[22] sleep remains an important and little studied area of concern.

Although the literature has descriptive studies reporting sleep disturbances in ICD patients, little study of related factors or clinical interventions has been carried out. No intervention studies measuring subjective sleep quality or daytime sleepiness have been reported for patients with ICDs.

The purpose of this study was to: (1) to describe the sleep outcome of a psychoeducational intervention designed to promote improved psychological outcomes after ICD including symptoms related to sleep, (2) to describe patterns of sleep over time, and (3) to identify predictors of poor sleep in first time recipients of the ICD. The data are from the PEACE

Trial (Psycho-EducationAl Intervention for ICD Patients) which was designed to develop and test a nurse-managed psychoeducational intervention to reduce the psychological consequences attributed to the ICD through provision of education, counseling, symptom management, and coping skill training.[23] A clinical randomized design was used to test an intervention designed to alleviate distress in ICD recipients by addressing factors that have been previously associated with reduced outcomes in the ICD population: avoidant coping, threat illness appraisal, inadequate preparation for symptoms, and ICD shock and ICD concerns.[11,14] Sleep quality and daytime sleepiness were important outcomes of the intervention, and one specific component of the symptom management training intervention was directed at sleep problems. More details about the study design and the consort chart for reporting clinical trials have been published elsewhere.[23] The psychoeducational intervention was found to reduce anxiety and depressive symptoms early after ICD implant, lowered probability of depressive symptoms at one year, and decreased disability days/calls to providers.[23]

Methods

Design

A randomized longitudinal intervention trial was designed to test the effects of a psychoeducational intervention on persons receiving their initial ICD.[23] Participants were recruited in the hospital setting at the time of ICD implant, and randomized to one of three groups to receive either usual care (UC), telephone counseling (TC), or support group (GRP) interventions after baseline data collection. Follow-up study time points were at 1, 3, and 6 months after implantation. All procedures were reviewed and approved by the Institutional Review Board of enrolling hospitals and the academic setting, and all participants gave written informed consent.

Patient Population

Participants were selected if they were recipients of their first ICD for primary or secondary prevention in one of the five enrolling hospitals. All devices were standard ICDs with transvenous leads and a subcutaneous positioning of the device. Additional inclusion criteria were 21–75 years of age, English fluency, nonthoracotomy insertion of the ICD, living within 100 miles of the enrolling center, and phone accessibility. To reduce variability in the outcome measures and to reduce conditions that would interfere with ability to participate, patients were excluded if they were being evaluated for heart transplant or had any of the following conditions: congenital heart disease, genetic etiology of arrhythmia, psychiatric disorder requiring psychotropic medication, schizophrenia or bipolar disease, progressively debilitating musculoskeletal comorbidity, cognitive problems amounting to ≥3 incorrect responses on the Short Portable Mental Status Inventory, or hospital discharge to another health care facility as opposed to home.

Intervention

For those randomized to the TC or GRP study groups, the intervention was provided in both the acute care setting and at 2–3 months after implant by trained cardiovascular and mental health nurses. The overall intervention included education about the ICD and self-care, and training for active coping strategies. The component of the intervention that was directed at sleep consisted of individual education and counseling sessions with the nurse before hospital discharge regarding guidelines to improve sleep and prevent sleep disturbances. Further, written material describing self-managed interventions to improve sleep was discussed and an audiotape with the same information, as well as relaxation exercises, was provided. The intervention was designed to prospectively educate ICD patients on improving sleep early in the recovery process before and regardless of shock, and content

included sleep hygiene, sleep-promoting behaviors, pain and anxiety management to promote sleep, and ICD-specific self-care such as positioning and support during sleep. Because the intervention content was based on data from prior studies and reported patient experiences with the ICD, other sensory information such as "phantom shocks" during sleep, and dreams related to the ICD were discussed as possible and previously reported patient experiences. The standardization of the intervention was safeguarded by means of training and retraining the research nurses, standard use of an audiotape to deliver the content, and documentation of the provision of the counseling and taped session. Patients could take the audiotape and tape player home, and they kept a log of the number of times they listened to the tape. The UC group received routine education and support from their providers and unstructured follow-up phone calls from the research staff at the same time as the intervention and intervention booster sessions. This approach provided the UC group with the same attention as intervention but not the content. Participants were recruited from five participating hospitals in the greater Atlanta area in the United States.[23]

Measures

Demographic and clinical data including history of cardiovascular disease, arrhythmias, and reason for ICD placement and comorbidities were obtained from the participants and their medical records during their index hospitalization. The clinical history variables of cardiovascular disease, arrhythmias, and other comorbidities were obtained from chart review. Appropriate and inappropriate shocks were defined based on the interrogation of the ICD and electrocardiologist determination as to the triggering event and appropriateness of device-related therapy. Baseline measures before intervention were completed in the acute care setting. The follow-up data collection occurred by mailing the questionnaires and a return stamped addressed envelope to participants at the appropriate study time points.

Participants completed the following questionnaires to obtain information about: anxiety (State-Trait Anxiety Inventory-State, STAI-S), depressive symptoms (Beck Depressive Inventory II, BDI-II), physical function (Duke Activity Status Inventory, DASI), and pain (Brief Pain Inventory; BPI).[23] The outcome variables related to sleep were assessed by patient completion of standard self-report questionnaires on sleep and several study specific ancillary questions.

The Pittsburgh Sleep Quality Index—The Pittsburgh Sleep Quality Index (PSQI) was used to measure sleep quality. The index consists of 19 self-rated questions to which the participant responds based on their assessment of sleep during the past month to items such as "How often have you had trouble sleeping because you wake up in the middle of the night or early morning?" Five additional questions are rated by the bed partner or roommate for clinical use only. The 19 items are grouped into seven component scores (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction due to sleepiness) with each weighted equally on a 0–3 scale. The seven component scores are then added up to yield a global PSQI score, which ranges from 0 to 21; higher scores indicate worse sleep quality. A cutoff score of >5 indicates poor sleep quality.[24] The PSQI items and subscales are developed based on clinical experience and not by factor analysis. In prior studies, the PSQI has demonstrated internal consistency reliability (Cronbach's alpha 0.83) and validity in that it was able to distinguish sleep-disordered patients from controls.[25] Its stability has been studied and it has been concluded that it is a stable measure but also well suited to detect change over time.[26] In this study, the Cronbach's alpha was acceptable at 0.85.

The Epworth Sleepiness Scale—The Epworth Sleepiness Scale (ESS) was used to measure daytime sleepiness and reflects the participant's perception of how likely they are

to fall asleep inadvertently while engaged in activities that involve low levels of stimulation. Subjects rated eight items on a 4-point scale from 0 to 3 to indicate how likely they would be to doze off or fall asleep while engaged in such activities as sitting, sitting and reading, and riding as a passenger in a car for one hour without a break. The items are added up to obtain a score ranging between 0 and 24, with a higher score indicating more daytime sleepiness. A cut-off score of 10 or more reflects excessive sleepiness.[27] The instrument has been tested for reliability and significantly distinguishes between healthy subjects and patients in various diagnostic groups, for example, OSA syndrome, narcolepsy, and idiopathic hypersomnia.[28] In this study the internal consistency reliability was acceptable with a Cronbach's alpha of 0.84.

The two sleep scales do not measure the same construct, and they are not considered useful as screening measures for polysomnographic sleep abnormalities.[25] In addition, a series of eight ancillary questions were developed for this study and completed by participants. The yes/no questions were asked to obtain participant perceptions of sleep during and after hospitalization, and perceived relationships between sleep and ICD concerns.

Anxiety—The "state" component of the significant anxiety (STAI)[29] consists of 20 statements to which the participant rates how they feel about that item on a 4-point scale. Higher scores indicate higher levels of anxiety. The scale is considered a sensitive indicator of changes in transitory anxiety and has been used extensively in cardiovascular and ICD patient studies, and the internal reliability consistency measured by Cronbach's alpha was 0.95.

Depressive Symptoms—BDI-II[30] is a 21-item instrument used to measure self-report of depressive symptoms. The statements were rated on a 0 to 3 scale indicating how participants felt over the previous 2 weeks and higher scores represent greater acknowledgement of depressive symptoms. Cronbach's alpha was 0.90.

Physical Function—DASI[24] was used to measure participants' perception of physical abilities as affected by their cardiac illness. The DASI has 12 items that reflect common daily activities, and participants rate the amount of difficulty they experience in performing these activities on a 1 to 4 scale, which are then summed. Higher scores indicate better-perceived physical function. The DASI has been used with multiple types of cardiac patients, including ICD recipients and the obtained Cronbach's alpha was 0.86.

Pain—The BPI is a 10-item instrument addressing pain history, etiology, intensity, location, quality, and interference with activities. Two subscales from the 10-item BPI[31] were used to indicate participants perceptions of pain severity (BPI-S) and pain interference with usual activities (BPI-I). Reading level is 5^{th}–6^{th} grade level, and the BPI demonstrated good internal consistency (alpha of 0.89) for both the pain severity and interference subscales.

Social Support—The EnrichD social support scale (ESSI) was used to measure perceived social support, defined as degree of perceived emotional, informational, and affirmational support. The instrument has six items rated on a 7-point Likert format scale. The scale total scores range from 8 to 34, and a higher score indicates higher perceived support. ESSI provides a measure of social support based on the presence of support regardless of the source. Internal reliability (Cronbach's) alpha has been reported at 0.86.

Randomization

After providing written informed consent according to the guidelines of the Institutional Review Board, participants meeting the inclusion criteria were randomized using a

computer-generated randomization table in blocks of six, with an allocation ratio 1:1:1 to one of the three groups to receive either UC, TC, or GRP intervention. A minimization program was used to equally distribute participants into study groups by gender and race to keep the groups equivalent throughout the study.

Data Analysis

Descriptive statistics were assessed for all measures, and group means and standard deviations were examined across time. Intention to treat analysis was used. All measures were reviewed for missing data, skewness, and outliers before analysis. The only measure with significant skewness was the BDI-II scores, which were transformed (square root) before subsequent analyses. To adjust for missing data across time, include time-varying predictors, and to assess the variance components within time and between subjects, multilevel mixed (MLM) models were used instead of repeated measures analysis of variance. These MLM models tested for time, group, group by time effects, time-varying predictors, and any other interactions over time after adjusting for significant demographic or clinical covariates.[32] In addition to assessing each key predictor individually, significant correlations among the predictors were also assessed. Upon finding significant correlations (multicollinearity), which were consistent across time, factor analysis was performed on these predictors across all time points to extract independent latent factors. A final MLM model was then run using these latent factors as predictors of sleep quality and daytime sleepiness, thus avoiding multicollinearity issues when including the individual predictors.

Results

Participants Flow

Patients were recruited between March 2001 and August 2004. Over the time period of study, 940 patients were assessed for eligibility, and 694 (73%) were excluded due to not meeting the rigorous inclusion criteria (n = 454) or physician preferences that the patient not be enrolled (n = 12). Of the 474 approached to participate, a total of 246 (51.9% of those eligible) participants consented and were randomized to the three groups, and baseline measures were obtained from 235 patients. The 228 who declined participation were not significantly different based on the screening data of age, gender, New York Heart Association (NYHA) class, and left ventricular ejection fraction (LVEF) from those who enrolled. In addition, of the 246 who were randomized, 11 participants did not have baseline measures due to early discharge, increased illness severity, and one death after consent. However, one individual who did not have baseline PSQI and ESS measures did complete these at 1 and 3 months and, thus, were included in the complete MLM models, for 236 participants considered herein. The full consort chart and data are reported elsewhere.[23] Although the chart reflects the fact that the complete allocated intervention was not received by 27 participants, all participants randomized to intervention received the initial education and counseling in the acute care setting including the sleep information, and the missing component reflected lack of attendance at group or telephone sessions. The complete study attrition (n = 65) at 6 months was due to lost to follow-up (n = 32), withdrawal (n = 23), and death (n = 10) with no differences by group.

Baseline Data

The characteristics of the total sample in terms of clinical, demographic, and behavioral variables at baseline are presented in Table I. The mean age of the participants was 58.4 years; the majority were men (75%) and most (77.1%) were white. Around 20% had a biventricular pacemaker with ICD. The mean LVEF of 26.3% reflected compromised ventricular function. Approximately half of the sample (52.1%) had a history of sudden cardiac arrest (SCA); 74.6% had previous cardiac disease. Clinically STAI scores ≥40 was

present in 36.6%; mild or greater depressive symptoms (BDI-II > 13) were present in 23.4%. There were no differences by randomized group on any of the variables. Over time, 14 patients (5.9%) received at least one ICD shock within 1 month, 26 (11.0%) by 3 months, and 35 (14.9%) by 6 months. There were no differences by group in incidence of shock and the number of ICD shocks received by 6 months was not related to any of the sleep variable scores.

Interventional Effect

Both the mean PSQI total sleep quality and ESS scores declined slightly over time. For the PSQI, the intervention group exhibited lower scores over all time points. For the ESS, the intervention group was slightly higher at baseline, but had lower scores at 6 months when compared to the UC group (Table II). Table II reports the percentages of participants in each group at each time point whose scores reflect clinically relevant poor sleep quality (PSQI > 5), excessive daytime sleepiness (ESS ≥ 10), and extreme sleepiness (ESS > 18). These percentages reflect the same trend as seen within the average scores across time. No significant group differences were detected for these sleep measures over time. Therefore, all subsequent analyses considered all participants together without regard to their randomized treatment group designation.

Correlations Among Measures

Correlations among the demographic and clinical variables (gender, age, NYHA class, body mass index [BMI], race), time varying predictors (DASI, STAI-S, sqrt [BDI-II], BPI-S, BPI-I), and sleep measures were examined. No significant correlations were noted between the demographic and clinical variables with the time-varying predictors. However, there were significant correlations among the time-varying predictors (Table III). Given these significant correlations, to prevent multicollinearity, a factor analysis was performed on these five time-varying predictors using principal components analysis with varimax rotation to extract independent latent factors for use in a comprehensive MLM model. Two eigenvalues were >1 and explained 74% of the variance. The first factor loaded highly for physical function (DASI), mood (anxiety [STAI-S] and depression (sqrt [BDI-II], whereas the second factor loaded highly for pain [BPI-S, BPI-I]; Table III). Within the demographic and clinical variables, percentages of participants in NYHA classes varied by gender (129 males [72.9%] were NYHA class I and II vs 30 females [50.8%] NYHA class I and II), χ^2 = 9.773, df = 1, P = 0.002); thus, in the resulting models, either gender or NYHA was included as a covariate but not both. Summary statistics over time for the time varying predictors of DASI, STAI-S, sqrt (BDI-II), BPI-S, BPI-I, and the factor scores for the two latent factors are presented in Table IV.

Multilevel Model Approach

For each MLM model, the first level of the model was for the within subjects changes over time which included an intercept and a linear time (in months) term. The second level of the model included random effects for between subjects intercepts and slopes, predicted by the covariate(s) and time-varying latent factors predictors. Each MLM used variance components covariance type and maximum likelihood estimation. Age, gender, BMI, NYHA class, race, and social support at baseline as well as interactions between each of these and time were assessed individually to see which were significant and should be retained in the model. Then the two latent factors as well as possible factor by time interactions were assessed to create comprehensive MLM models for PSQI and Epworth scores over time. Table V provides the sequential progression of model results and includes coefficients for the fixed and random effects, deviance statistics (distributed as a χ^2 statistic equal to the difference between the –2 log likelihood (–2LL) values for the two models specified with degrees of freedom equal to the differences in the number of parameters for

the two models), associated P values, as well as percent variance changes within each random variance component.

PSQI Changes Over Time

When considering only a linear effect for time in months, time was significant and negative indicating that overall the PSQI scores were decreasing over time, however, unexplained variability remained in the random components for the residuals (within subjects), intercepts (baseline differences between subjects), and slopes (time effects between subjects) (Table V, PSQI Model A). For the demographic and clinical variables, only gender and NYHA class were significant. However, given the strong association between gender and NYHA class, only one was retained. Gender had the lower P value and was retained for all remaining MLM models for PSQI. The gender by time interaction term was not significant. After adjusting for a linear time effect, gender was significant, and only slightly changed the residual variance, but did reduce the intercept variance between subjects (subject differences at baseline) by 9.11% and reduced the variance between subjects slopes (subject differences across time) by 11.12% and the slope variance was no longer significant (PSQI Model B). After adjusting for a linear time effect and gender, both latent factors were then added to the model. Both were significant, with factor 1 (mood/physical function coefficient 1.82) weighted higher than factor 2 (pain, coefficient 0.89). Neither factor significantly interacted with time, and collectively reduced the residual variance by 6.60%, the intercept variance by 39.58%, and slopes variance by 77.64% (PSQI Model C). Thus, while female gender was significantly associated with increased PSQI scores, reflecting worse sleep quality over time, the combined factors representing physical function/mood and pain contributed significantly and accounted for about 78% of the variance over time.

ESS Changes over Time

When considering only a linear effect for time in months, time was significant and negative indicating that overall the ESS scores decreased over time; however, unexplained variability remained in the random components for the residuals (within subjects) and intercepts (baseline differences between subjects) (Table V, Epworth Model A). For the demographic and clinical variables, gender was not significant, but NYHA class was significant (with class III, IV having higher ESS scores) and reduced the intercept variance by 5.148% (Epworth Model B). After adjusting for a linear time effect and NYHA class, both latent factors were added to the model. Both were significant with factor 1 (mood/physical function coefficient 1.20) weighted higher than factor 2 (pain coefficient 0.33). Neither factor significantly interacted with time, and collectively reduced the residual variance by 0.487%, the intercept variance by 12.643%, and slopes variance by 31.564% (Epworth Model C).

Ancillary Questions Related to Sleep and the ICD

The percents of participants indicating sleep difficulty both in the hospital setting and at one week after discharge and perceived reasons for sleep difficulty are listed in Table VI. Although 28.0% indicated perceived trouble sleeping in the hospital setting, only 10.2% (n = 24) had concerns that they would have difficulties sleeping after hospital discharge. However, 33.9% actually reported trouble sleeping at home after discharge during the first week, and these participants had lower DASI scores (t = 2.219, df = 224, P = 0.03) and a lower percentage of coronary heart disease history (χ^2 = 4.156, df = 1, P = 0.04) than those who did not report trouble sleeping at home after discharge. Those reporting perceived difficulty sleeping due to worry or anxiety after hospital discharge (9.7%) were characterized by being female (χ^2 = 6.8, df = 1, P = 0.009) and had higher BDI-II (square root transformed) (t = 2.08, df = 202, P = 0.04), lower DASI (t = 2.19, df = 202, P = 0.03), higher BPI-I (t = 2.90, df = 202, P = 0.004), and higher BPI-S (t = 3.32, df = 202, P = 0.001)

scores. In-hospital, 8.1% reported difficulty sleeping due to worry or anxiety. These subjects were of younger age (t = 2.636, df = 211, P = 0.009) and had higher STAI-S scores (t = 3.04, df = 211, P = 0.003). Participants (8.9%) reporting that awareness of the ICD interfered with their sleep in-hospital were characterized by younger age (t = 2.15, df = 210, P = 0.03), less coronary heart disease history (χ^2 = 6.652, df = 1, P = 0.01), and higher BPI-I scores (t = 2.04, df = 210, P = 0.04). The number of participants who stated that awareness of the ICD interfered with their sleep after hospital discharge increased to 16.7% (n = 38) and was higher in those with lower DASI scores (t = 2.022, df = 214, P = 0.04). Thirty-three participants (13.8%) reported having problems with sleep disturbance (snoring, night-time sweating, morning headaches, or restless/jerking legs) one week after discharge and these symptoms tended to occur in those with lower DASI scores (t = 2.188, df = 144, P = 0.03; however, 86 participants did not respond to this question).

Discussion

Examination of the demographic and clinical variables suggests that the sample is comparable with ICD patient populations described in other studies of psychological and symptom variables.[33–39] Although the type of device changed as more biventricular ICDs were introduced toward the end of the inclusion period, no difference was found in the variables reported. Pedersen et al.[39] have reported that type of device does not seem to influence outcomes, and there is no evidence to suggest that patients receiving an ICD for primary prophylaxis have subsequently poorer QoL and greater distress than patients receiving an ICD for secondary prophylaxis. Half of the participants had experienced SCA before the insertion of the ICD. This is a fairly high number, which would likely not be observed if replicating the study today due to change of guidelines and increased primary ICD insertions.[32] The baseline anxiety level of approximately 37% is similar to findings in other studies.[33–36] Depression symptom rate of 24% was also similar to other studies,[38,41] even though one study found a higher rate.[12] The comorbidity score was lower compared to one other ICD study population.[37] The study was limited to those receiving their first ICD, and participation, at the time of implant, in the acute-care setting was required, limiting the overall generalizability of the study results. Because only 51.9% of approached participants were enrolled, concerns about generalizability to a broader population is acknowledged; however, the sample characteristics were similar to other ICD populations reported in studies of psychological assessment and interventions, reducing concern regarding this limitation. Another limitation of the study was the attrition due to severity of illness and loss to follow-up reflecting the inherent difficulties in implementing a behavioral intervention with a seriously ill patient population.

Effect of the Intervention

The results of the randomized intervention suggest that the in-hospital education and counseling intervention did not have an effect on the sleep quality and daytime sleepiness measures. A stronger intervention to ameliorate overall sleep problems and daytime sleepiness is needed. The intervention was an education and counseling intervention including aspects of sleep hygiene and symptom management, and although it included evidence-based approaches to enhancing sleep, it may not have been strong enough to counteract other interfering factors such as the effects of gender and poor physical function, pain, and mood. A large number of the patients had HF and had high BMI, both of which are associated with greater sleep problems. OSA is common in HF patients and may also be present in ICD patients. Thus, more serious sleep disorders might have been present which could not be treated by counseling alone. Future studies of the mechanisms of sleep difficulties and testing sleep interventions after ICD should account for these factors, especially OSA, depression, anxiety, physical function, and pain.

PSQI and ESS Scores

Although PSQI and ESS scores declined over time, more than half still had poor sleep quality at 6 months after ICD insertion. One-third were considered sleepy during the day, which is a higher number than the 21% found in persons with HF and no ICD.[42] The results provide an increased awareness that sleep assessments are necessary during hospitalization, especially in patients with pain, low physical function, and high depression and anxiety. Higher ESS scores were previously found to be related to limitation of activities or daily living[43] and were also reported to relate to poor QoL. At the time of ICD implantation, female gender, low physical function, high anxiety, and depression were factors that predicted poor sleep quality across time. This calls for early assessment and intervention directed at sleep hygiene, pain management, medication as needed, and addressing the anxiety and depression issues. It is interesting that poor sleep quality in women persists such that women consistently had higher PSQI scores and poorer sleep quality than men. The significant results related to gender are especially important because poor sleep quality has been found to be related to greater psychosocial distress, higher fasting insulin, fibrinogen, and inflammatory biomarkers, especially in women, and may be important in examining these gender differences in the association between symptoms of poor sleep and cardiovascular disease.[44] A low level of physical functioning also predicts daytime sleepiness, which may not be surprising but emphasizes the need to provide supportive interventions in everyday life. Exercise has been found to improve sleep quality[45]; therefore, exercise training may be appropriate as it has been found to be safe for ICD patients.[46] Because a percentage (4.7%) of participants was considered very sleepy (ESS > 18), further consideration should be given to individual driving recommendations and subsequent sleep evaluations/interventions. When considering all the MLM models for predicting poor sleep quality and daytime sleepiness across time, female gender, higher NYHA class, as well as the strong associations with depression, anxiety, and physical function, may direct clinical assessment and intervention development. Greater attention to pain management in the acute care setting is also a key approach to reducing sleep difficulty. These factors would be important to assess clinically to identify ICD patients who may be at risk of poor sleep quality and daytime sleepiness later in the recovery trajectory. Increased assessment of sleep during the first 6 months after ICD, and sleep promoting interventions that include sleep hygiene, pain and symptom management, and anxiety reduction, should be developed and tested. Such approaches may lead to improved sleep quality and QoL for both women and men who receive ICDs. Furthermore, screening for primary sleep disorders, for example, Obstructive and Central Sleep Apnea, would be beneficial to provide comprehensive sleep management for ICD patients.

Ancillary Questions Related to Sleep and the ICD

Disturbed sleep associated with hospitalization and recovery after treatment of cardiac conditions has a significant perceived impact on recovery, functional outcomes, and QoL. Hospitalized patients undergoing cardiovascular surgery have been reported to experience sleep disturbances, manifested as frequent awakenings, short sleep duration, perceptions of poor sleep quality, and daytime napping.[41,47,48] In this study, more than one of four patients had trouble sleeping while hospitalized. Evidence suggests that patients undergoing bypass surgery awaken after sleep onset for no identified reasons, and no clinical variables were found to be correlated to reported difficulty sleeping in the hospital.[49] This pattern has been reported before in cardiac patients,[50] suggesting the need to examine other variables that determine sleeping problems inhospital such as differences from usual sleeping patterns, noise, or emotional responses not detected by anxiety and depression instruments. Importantly, mood disturbances are linked to both ICD adjustment and to sleep deprivation.[4,14] Around 10% perceived that anxiety caused trouble sleeping when asked directly. The younger age, higher anxiety, depressive symptoms, and pain scores

characterizing those reporting anxiety as a cause of trouble sleeping provides direction for greater sleep assessment and attention to sleep issues in these ICD patients. As with other studies, sleep pattern disturbances seem to persist after discharge. Sleep problems have been reported in 39%–69% of cardiac surgery patients in the first weeks after discharge.[51,52] In this study the number of patients experiencing trouble sleeping one week after discharge increased from 28% (in hospital) to 33.9% (at home). Factors of lower sleep quality and lower DASI scores at baseline were observed in those experiencing trouble sleeping which is consistent with reports from Redeker et al.[53,54] studying patients after elective cardiac surgery and patients with HF. More participants reported trouble sleeping (15.7%) than expected to have trouble (10.2%). This finding suggests that clinical staff should address possible sleep difficulties in early recovery and develop interventional strategies before hospital discharge.

Summary

This study examined an education and counseling intervention to reduce sleep problems after ICD insertion and when no effect on sleep outcomes was identified, the post hoc analysis examined changes in sleep over time as well as associated factors. Female gender, higher NYHA class, as well as two latent factors encompassing increased anxiety, depressive symptoms, and decreased physical function and increased pain were significant predictors of poor sleep quality and sleepiness over time. The high percentages of ICD patients with reduced sleep quality and significant daytime sleepiness, the role of psychological and physical function factors, and reduced sleep quality in women over time suggest the need for the development and testing of sleep enhancing interventions for ICD recipients to ultimately improve their QoL.

Acknowledgments

Supported in part by NIH NINR R01 5187 Psychoeducational Intervention for ICD Patients (PI-S. Dunbar).

Medtronic and Guidant (now Boston Scientific) are appreciated for their unrestricted educational grants to support participant refreshments at intervention group meetings. We thank the staff of the enrolling hospitals in the greater Atlanta area for their assistance and support: Emory University Hospital, Crawford Long Hospital of Emory University, Atlanta Veteran's Administration Medical Center, Piedmont Hospital, St. Joseph's Hospital.

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Table I

Demographic, Clinical, and Behavioral Variables

Variable	Total n = 236 (unless noted otherwise)
Demographic variables	
Age (years) (mean ± SD)	58.4 (±11.2)
Gender (n%)	
Male	177 (75.0%)
Female	59 (25.0%)
Married (n%)	
Single/divorced/widowed	61 (25.8%)
Married/domestic partner	175 (74.2%)
ESSI (mean ± SD) *	30.1 (±6.1)
Education (n%)	
≤High school	127 (53.8%)
High school	109 (46.2%)
Race (n%)	
White	182 (77.1%)
African American	48 (20.3%)
Other	6 (2.5%)
Clinical variables (n%)	
Type of device (n%) *	
ICD only	186 (79.1%)
Biventricular PM with ICD	49 (20.9%)
NYHA class (n%)	
I and II	159 (67.4%)
III and IV	77 (32.6%)
LVEF (%) (mean ± SD) *	26.3 (±11.3)
History of CAD n%	176 (74.6%)
History of SCA n%	
No	113 (47.9%)
Yes	123 (52.1%)
BMI (mean ± SD)	28.6 (±6.1)
Diabetes	69 (29.2%)
Antihypertensive meds BL *	143 (60.9%)
STAI-S ≥ 40 (clinical significant anxiety) *	86 (36.6%)
BDI-II >13 (at least mild depressive symptoms) *	55 (23.4%)
Charlson Comorbidity score (mean ± SD)	2.17 (±1.50)
Antidepressant/Antianxiety medications at BL (n%)	37 (15.7%)
Sleeping medications at BL (n%)	16 (6.8%)
Behavior variables n%	
Tobacco	36 (15.3%)

Variable	Total n = 236 (unless noted otherwise)
Alcohol >3 drinks/week	17 (7.2%)
Caffeine *	158 (67.2%)
Caffeine after 3 pm	74 (31.4%)

LVEF = left ventricular ejection fraction; CAD = coronary artery disease; SCA = sudden cardiac arrest; STAI = StateTrait Anxiety Inventory; BDI-II = The Beck Depression Inventory II; DASI = Duke Activity Status Inventory; BPI-I = Brief Pain Inventory-Interference; BPI-S = Brief Pain Inventory-Severity; ESSI = ENRICHD Social Support Inventory; SD = standard deviation; PM = pacemaker; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association; BMI = body mass index.

* Only 235 provided data for this item.

Table II

Unadjusted PSQI and Epworth Scores across Time

	Baseline			1 Month			3 Month			6 Month		
Time Point (n)	**ALL 235**	**UC 77**	**Int 158**	**All 212**	**UC 68**	**Int 144**	**ALL 194**	**UC 65**	**Int 129**	**ALL 190**	**UC 64**	**Int 126**
PSQI												
Mean (SD)	7.8(4.2)	8.3(4.3)	7.5(4.1)	7.4(3.9)	7.7(3.8)	7.2(4.0)	6.8(4.2)	7.7(4.7)	6.4(3.9)	7.0(4.3)	7.4(3.9)	6.8(4.4)
% score > 5	67.2%	70.1%	65.8%	64.9%	67.6%	63.9%	51.8%	58.5%	48.8%	56.8%	67.2%	51.6%
Epworth							*	**				
Mean (SD)	8.7(5.2)	8.2(5.0)	8.9(5.3)	8.2(5.0)	8.0(5.0)	8.3(5.0)	7.9(4.5)	7.7(4.6)	8.1(4.4)	7.8(4.9)	8.1(5.1)	7.6(4.8)
% score ≥10	40.4%	39.0%	41.1%	36.5%	35.3%	37.5%	29.2%	29.2%	29.7%	32.6%	34.4%	31.7%
% score >18	4.7%	3.9%	5.1%	3.8%	2.9%	4.9%	2.6%	3.1%	2.3%	3.2%	3.1%	3.2%

UC = usual care; INT = intervention groups combined; SD = standard deviation; PSQI = Pittsburgh Sleep Quality Inventory.

* 3 month Epworth, All n = 193,

** 3 month Epworth, Int n = 128.

Table III

Correlation Matrix among Predictors across All Time Points and Resulting Factor Analysis Loadings

	Correlation Matrix					Factor Loadings	
	BPI-S	**BPI-I**	**DASI**	**STAI-S**	**sqrt (BDI-II)**	**Factor1 (F1)**	**Factor 2 (F2)**
BPI-S	1					0.124	0.934
BPI-I	0.732**	1				0.303	0.869
DASI	−0.310**	−0.333**	1			−0.589	−0.287
STAI-S	0.269**	0.412**	−0.296**	1		0.833	0.156
sqrt (BDI-II)	0.256**	0.387**	−0.448**	0.651**	1	0.897	0.127

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

**Correlation is significant at the 0.01 level (two-tailed), n = 830.

Factor Analysis Extraction Method: Principal Component Analysis.

Factor Analysis Rotation Method: Varimax with Kaiser Normalization.

Table IV

Average Values for Anxiety, Depression, Physical Function, Pain, and Factor Analysis Scores across Time

Mean (SD)	Baseline	1 month	3 months	6 months
n	235	211	194	190
BPI-S	10.93 (8.23)	7.68 (8.18)	7.06 (8.47)	6.98 (8.33)
BPI-I	15.16 (17.00)	11.53 (15.34)	10.95 (15.01)	11.02 (15.99)
DASI	19.78 (16.45)	18.14 (13.71)	20.48 (15.71)	20.25 (15.89)
STAI-S	35.42 (12.26)	35.94 (13.18)	34.01 (12.86)	34.22 (12.42)
BDI-II	9.07 (7.48)	8.85 (7.31)	8.34 (7.65)	8.44 (7.22)
F1	−0.02 (0.97)	0.10 (0.99)	−0.06 (1.05)	−0.02 (1.00)
F2	0.27 (0.96)	−0.08 (0.99)	−0.11 (1.00)	−0.13 (1.00)

Table V

MLM Models for Sleep Quality (PSQI) and Daytime Sleepiness (Epworth)

Fixed Terms	PSQI-A	PSQI-B	PSQI-C	Epworth-A	Epworth-B	Epworth-C
Intercept	7.63**	7.10**	7.11**	8.53**	6.00**	6.81**
Time (mo)	−0.13**	−0.13**	−0.08	−0.11*	−0.11*	−0.50*
Gender						
0 = Male, 1 = Female		2.10**	1.34**			
NYHA						
Class I,II = 1, Class III,IV = 2					1.91**	1.23*
Time-Varying Predictor(s)						
Factor 1			1.82**			1.20**
Factor 2			0.89**			0.33*
Information criteria (−2LL)	4408.238	4391.646	4224.214	4633.627	4623.459	4580.872
Number of model parameters	5	6	8	5	6	8
Model compared to	na	Δ time (PSQI)	Δ time, gender (PSQI)	na	Δ time (Epworth)	Δ time, nyha (Epworth)
Deviance statistic (χ^2, df)	na	16.592, 1	167.432, 2	na	10.168, 1	42.587, 2
P value	na	<.001	<.001	na	0.001	<0.001
Random Components						
Residuals	6.773**	6.842** (−1.01%)	6.390** (6.60%)	8.402**	8.407** (−0.058%)	8.361** (0.544%)
Intercept	9.687**	8.805** (9.11%)	5.320** (39.58%)	15.844**	15.029** (5.148%)	13.128** (12.644%)
Slope (time)	0.078*	0.070 (11.12%)	0.016 (77.64%)	0.093	0.093 (0.267%)	0.065 (30.649%)

*P < 0.05,

**P < 0.01

−2LL = −2 Log Likelihood, (na) not applicable

PSQI: n = 236 participants, 830 data points total; Epworth: n = 236 participants, 829 data points total.

Table VI

Results of Ancillary Sleep Questions

	In Hospital n (% of 236)	1 Week after Hospital Discharge n (% of 236)
Perceived trouble sleeping	66 (28.0%)	80 (33.9%)
Concerned about being able to sleep after going home from the hospital	24 (10.2%)	NA
Perceived sleep difficulty due to anxiety or worry	19 (8.1%)%	23 (9.7)%
Perceived sleep difficulty due to awareness of the ICD	21 (8.9)%	38 (16.1%)
Perceived symptoms of sleep disturbance *	NA	33 (13.8%)

* Snoring, morning headaches, restless/jerking legs.