# Comparison of Actigraphic and Subjective Measures of Sleep in Implantable Cardioverter Defibrillator and Coronary Artery Disease Patients

Address for correspondence: Natalie J. Cross, PhD Department of Veterans Affairs Greenville Community Based Outpatient Clinic 800 Moye Boulevard Greenville, NC 27858 natalie.cross@va.gov

Natalie J. Cross, PhD; Christina S. McCrae, PhD; Karen M. Smith, MD; Jamie B. Conti, MD; Samuel F. Sears, PhD

Department of Veterans Affairs (Cross), Greenville Community Based Outpatient Clinic, Greenville, North Carolina; Department of Clinical and Health Psychology (McCrae), University of Florida, Gainesville, Florida; Division of Cardiovascular Medicine (Smith, Conti), University of Florida, Gainesville, Florida; Department of Psychology (Sears), East Carolina University, Greenville, North Carolina

*Background:* Cardiac patients frequently have insomnia symptoms that may pose risk for future cardiac events. Poor sleep relates to hyperarousal, anxiety and depression, and the incidence of hypertension and myocardial infarction.

*Hypothesis:* The authors hypothesized that implantable cardioverter defibrillator (ICD) patients would have poorer sleep than coronary artery disease (CAD) patients related to hypervigilance for device functioning and shock discharge.

*Methods:* Authors investigated sleep efficiency and sleep latency in a sample of 60 patients (n = 30 CAD and n = 30 ICD) without obstructive sleep apnea at the University of Florida & Shands Hospital. For 14 days, participants completed a sleep diary. Additionally, half of the total sample also used actigraphy to objectively measure their sleep. Measures of somatic hypervigilance and psychosocial distress were administered.

*Results:* Using actigraphy, mean sleep efficiency was poorer (69.76%) in CAD patients compared with ICD patients (82.80%). This difference was highly significant,  $F_{1,27} = 16.840$ , P < 0.001. CAD patients also had shorter mean total sleep times per sleep diaries compared with ICD patients (336.19 minutes or 5.60 hours, 430.65 minutes or 7.18 hours, respectively),  $F_{1,27} = 15.908$ , P < 0.001.

*Conclusions:* The finding that ICD patients slept more efficiently than CAD patients is surprising given that CAD patients had higher ejection fractions and no concerns about ICD shocks. This difference cannot be accounted for by differences in hypervigilance, depression, anxiety, or physical activity. Results suggest that CAD patients may have more sleep problems and may warrant increased research attention.

# Introduction

In the management of cardiac disease, primary to tertiary care has endeavored to intervene in all key areas of the disease. Although an array of behavioral risk factors has been spotlighted previously, sleep patterns may represent a valuable and underinvestigated variable in the prevention and maintenance of cardiac disease. National Health and Nutrition Examination Survey I researchers<sup>1</sup> found that patients who sleep  $\leq 5$  hours or  $\geq 9$  hours per night are more likely to develop hypertension than those who sleep 7-8 hours. Ayas and colleagues<sup>2</sup> found that women who sleep <5 hours or  $\geq 9$  hours per night had a relative risk of 1.45 and 1.36, respectively, for future myocardial infarction (MI). Similarly, Chien and colleagues<sup>3</sup> followed 3430 adults and found that the relative risks for all-cause death for participants sleeping <5, 6, 8, and >9 hours per night were 1.15, 1.02, 1.05, and 1.43, respectively. Taken together, these trials highlight the importance of an optimal sleep time of 7–8 hours per night for cardiac and overall health. It is well known that cardiac patients commonly experience depression and anxiety. Although many patients with an implantable cardioverter defibrillator (ICD) experience depressive symptoms, the rates are not higher than those found in other cardiac populations.<sup>4–7</sup> Clinically significant anxiety, however, is more common in ICD patients and occurs in 13%-38% as related to hypervigilance, shock anxiety, and fears of device malfunction and death.8-11 Such anxiety and hypervigilance are risk factors for poor sleep.

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Few studies have examined sleep patterns in ICD patients (see Serber et al),<sup>12</sup> and no studies to date have used actigraphy to objectively measure sleep in this population. Actigraphy is a method of measuring sleep based on movement data, which is used to infer time spent asleep and wake time.<sup>13–14</sup> An actigraph is a watch-like device containing an accelerometer with ample memory to sample movement across several days or weeks. Concordance rates for distinguishing sleep from wake time using actigraphy vs polysomnography have been high, at 82%-95%.<sup>15–17</sup>

The purpose of this study was to examine objective and subjective measures of sleep in ICD patients using coronary artery disease (CAD) patients as a control group. The authors hypothesized that ICD patients would have poorer sleep compared with CAD patients due to hypervigilance for device functioning and shock anxiety. Increasing our understanding of how ICD patients sleep could present appropriate targets for greatly needed sleeprelated interventions for cardiac patients.

# Methods

Participants were recruited with institutional review board approval during an outpatient consultation visit at the University of Florida & Shands Hospital Cardiovascular Medicine Clinics. Participants were currently undergoing ICD therapy and/or carried a diagnosis of CAD. Sleepdisordered breathing is prevalent among ICD recipients as well as CAD patients.<sup>18-20</sup> Therefore, patients with obstructive sleep apnea (OSA) or restless legs syndrome were excluded from study participation per medical-record review. CAD patients were chosen as a control group per convenience sampling. Patients taking hypnotic medications such as benzodiazepines were included during the recruitment process. Information on demographics, cardiac diagnoses, ejection fraction (EF), current medications, time since ICD implantation, and shock frequency was gathered via medical-record review. A 2-year period of shock history was used as a proxy to total lifetime history of shock.

# Actigraphy

The current study employed the Actiwatch-64 (Mini Mitter/Respironics Co., Bend, OR). This type of device records gross motor movements to measure sleep/wake cycles using the digital integration method. For every 30-second epoch, Actiwatch-64 samples data 32 times per second. Actiwatch-64 uses an omnidirectional, piezo-electric accelerometer with a sensitivity of  $\geq 0.05$  g force. A validated algorithm was used to identify each epoch of time as sleep or wake (Mini Mitter/Respironics.)<sup>21</sup> McCrae et al<sup>22</sup> provides a more detailed explanation of Actiwatch measurement as well as a description of the sleep variables under examination as defined by actigraphy.

#### **Sleep-Diary Data**

Participants completed a sleep diary<sup>23</sup> each morning for 14 days that contained standard sleep indices of bedtime, rise time, sleep-onset latency, number of awakenings, wake time after sleep onset, and a sleep quality rating. Time in bed, total sleep time, and sleep efficiency were derived from this information. Sleep efficiency was calculated using this formula: total amount of time spent sleeping / total amount of time spent in bed ×100.

## **Sleep Quality**

The Pittsburgh Sleep Quality Index<sup>24</sup> (PSQI) was used to measure sleep quality. Global scores range from 0 to 21, with higher scores indicating poorer sleep quality.

## **Mood and Anxiety**

The Hospital Anxiety and Depression Scale<sup>25</sup> (HADS) was used to measure anxiety and depression. A score  $\geq$ 11 was considered clinically significant for both the anxiety and depression subscales.

## Somatic Hypervigilance

The Body Vigilance Scale<sup>26</sup> (BVS) was used to measure attentional focus on interoceptive activity including heart palpitations, chest pain/discomfort, shortness of breath, and faintness. Higher scores on the BVS are associated with anxiety sensitivity and anxiety symptoms.

#### **Functional Status in Cardiac Disease**

The Duke Activity Status Index<sup>27</sup> (DASI) was used to assess self-reported functional capacity and some aspects of quality of life. Scores range from 0 to 58.2, with higher scores indicating healthier physical functioning.

## **Shock Anxiety**

The Florida Shock Anxiety Scale<sup>28</sup> (FSAS) was used to assess common worries and anxiety related to experiencing ICD shock discharge in these participants. It measures the cognitive, behavioral, emotional, and social impact of shock anxiety.

## Angina

The Seattle Questionnaire<sup>29</sup> (SAQ) was used to measure 5 clinically important dimensions of health in patients with CAD, including physical limitations, anginal stability and frequency, treatment satisfaction, and disease perception. Higher scores indicate less difficulty with chest pain.

Participants were assigned to either the Sleep Diary Only arm or the Sleep Diary+Actigraphy arm of the study. Assignment to group was partially based on resource accessibility (eg, availability of actigraphs when needed). This method was necessary to assure the flow of incoming data, as some participants were unable to return their Actiwatches as soon as planned upon study completion. Participants completed their packet of psychological self-report questionnaires and returned the data on Day 1. Sleep diaries were completed during Days 1–14 and returned by mail.

A subset of participants (n = 14 CAD patients and n = 15 ICD patients) used actigraphy to obtain an objective index of their sleep patterns. Participants were instructed to wear their actigraph device throughout the 24-hour period for Days 1–14. Participants received 2 phone calls from the first author during Days 1–14 of data collection to encourage compliance with sleep-diary completion and actigraphy data collection. Data were analyzed using Actiware version  $5.0^{21}$  and SPSS version 15.0 (SPSS Inc., Chicago, IL). Standard mean sleep indices of sleep efficiency, sleep-onset latency, total sleep time, and waking after sleep onset were calculated for each participant across the 14-day data-collection period.

## Results

Of the final sample of 60 participants, 30 (50%) were ICD patients and 30 (50%) were CAD patients; 31 (52%) comprised the Sleep Diary Only arm and 29 (48%) comprised the Actigraphy+Sleep Diary arm (Table 1). There were no group differences found between the ICD and CAD groups for any demographic variables.

Descriptive data specific to ICD and CAD patients is presented in Table 2. Of the 30 ICD patients, 9 (30%) had experienced shock discharge in the past 2 years. Of these 9 shocked patients, all but 1 had received 1–7 shocks in the previous 2 years; 1 participant received 25 shocks during this time period. When the ICD and CAD groups were compared for medical variables, ICD patients (61.3%) were more likely than CAD patients (31.0%) to be taking diuretic medication,  $r_{\phi} = 0.019$ , and as expected, the mean EF for ICD patients (35.53%) was lower than that of CAD patients (48.69%).

## **Tests for Group Differences on Psychosocial Distress**

The ICD and CAD patients were compared on psychosocial variables. Analyses of covariance using EF as the control variable were performed for DASI and PSQI scores, as these distributions met the appropriate assumptions of normality, homogeneity of variance, linearity, and homogeneity of regression slopes. There were no differences for any of these measures. For HADS scores, the Wilks tests revealed non-normality in kurtosis. For BVS scores, Levene's test revealed a lack of homogeneity of variances. Therefore, Kruskal-Wallis ANOVAs were conducted for these 3 variables. No cardiac group differences were found for any of these measures.

Regarding HADS scores, 2 participants had outlying z scores of z > 3.00, and these data were excluded from

Table 1. Descriptive Statistics on Demographic, Medical, Sleep, and Psychosocial Variables for Overall Sample

Variable	Ν	Mean %	SD
Demographic variables			
Age, y	59	66.9	10.18
Male sex	59	61.5%	
Race			
Caucasian	53	81.5%	
African American	5	7.7%	
Asian/Pacific Islander	1	1.5%	
Married	42	64.6%	
Has children	55	93.2%	
No. of children	55	2.64	1.40
Protestant religion	42	64.6%	
Retired	32	49.2%	
Income of \$75,000–\$89,000	12	18.5%	
Sleep variables			
Actigraphy:			
Sleep efficiency	28	76.75%	10.56%
Sleep-onset latency	28	30.14	19.02
Waking after sleep onset	28	55.86	27.73
Total sleep time	28	386.80 min (6.45 hr)	77.87 min (1.30 hr)
Sleep diary:			
Sleep efficiency	29	83.09%	9.36%
Sleep-onset latency	29	32.66	29.51
Waking after sleep onset	29	30.54	26.83
No. of awakenings	29	1.86	0.89
Total sleep time	29	416.22 min (6.94 hr)	75.95 min (1.27 hr)
Sleep quality (diary)	29	3.47	0.66
Sleep quality (PSQI total score)	29	7.71	4.87

Clin. Cardiol. 33, 12, 753–759 (2010) N.J. Cross et al: Comparison of sleep in ICD and CAD patients Published online in Wiley Online Library (wileyonlinelibrary.com) DOI:10.1002/clc.20827 © 2010 Wiley Periodicals, Inc. Table 1. Descriptive Statistics on Demographic, Medical, Sleep, and Psychosocial Variables for Overall Sample (*Continued*)

Variable	Ν	Mean %	SD
Psychosocial variables			
Distress (HADS)	57	10.68	7.99
Hypervigilance (BVS)	52	21.17	9.41
Physical activity (DASI)	57	25.44	12.81
Shock anxiety (FSAS)	29	17.31	8.56

Abbreviations: BVS, Body Vigilance Scale; DASI, Duke Activity Status Index; FSAS, Florida Shock Anxiety Scale; HADS, Hospital Anxiety and Depression Scale; PQSI, Pittsburgh Sleep Quality Index; SD, standard deviation.

Table 2. Means and Standard Deviations/Frequencies for Medical, Sleep, and Psychosocial Variables by Cardiac Condition

Variable	ICD Patients	CAD Patients
Medical variables		
ICD type		
Single	40.0% (n = 12)	NA
Dual	36.7% (n = 11)	NA
Biventricular	23.3% (n = 7)	NA
No. of shocks, previous 2 y	1.84 ± 4.76	NA
No. receiving ≥1 shock, previous 2 years	9 (30%)	NA
Mo since ICD implantation	53.57 ± 45.47(4.5 y), min = 3; max = 168	NA
EF (%)	$35.53 \pm 13.12$	$48.69 \pm \textbf{12.58}$
CAD diagnosis (%)	58.1	100
History of MI, (%)	29.0	44.8
History of CABG, (%)	38.7	41.4
Angina (SAQ)		
Physical limitation	NA	$52.44 \pm 18.31$
Anginal stability	NA	63.79 ± 27.21
Anginal frequency	NA	$81.39 \pm 21.17$
Treatment satisfaction	NA	$89.45 \pm 19.15$
Disease perception	NA	60.06 ± 21.52

756 Clin. Cardiol. 33, 12, 753–759 (2010) N.J. Cross et al: Comparison of sleep in ICD and CAD patients Published online in Wiley Online Library (wileyonlinelibrary.com) DOI:10.1002/clc.20827 © 2010 Wiley Periodicals, Inc. Table 2. Means and Standard Deviations/Frequencies for Medical, Sleep, and Psychosocial Variables by Cardiac Condition (*Continued*)

Variable	ICD Patients	CAD Patients
Sleep variables		
Actigraphy		
Sleep efficiency (%)	$\textbf{82.80}\pm\textbf{6.39}$	$69.76 \pm 10.24$
Sleep-onset latency	$\textbf{25.25} \pm \textbf{16.04}$	35.79 $\pm$ 21.20
Waking after sleep onset	45.82 ± 22.50	67.43 ± 29.48
Total sleep time	414.03 ± 0.02 min (6.90 ± 0.00 hr)	418.64 $\pm$ 0.02 min (6.98 $\pm$ 0.00 hr)
Sleep Diary		
Sleep efficiency (%)	$\textbf{82.26}\pm\textbf{8.39}$	$83.95 \pm 10.35$
Sleep-onset latency	33.83 ± 27.65	31.40 ± 31.84
Waking after sleep onset	32.56 ± 26.38	$\textbf{28.46} \pm \textbf{27.62}$
No. of awakenings	$\textbf{2.07} \pm \textbf{0.84}$	1.63 $\pm$ 0.74
Total sleep time	430.65 $\pm$ 43.04 min (7.18 $\pm$ 0.72 hr)	336.19 ± 79.39 min (5.60 ± 1.32 hr)
Sleep quality (diary)	$3.47\pm0.33$	3.46 ± 0.67
Sleep quality (PSQI total scores)	8.06 ± 4.75	$7.32\pm5.06$
Psychosocial variables		
Distress (HADS)	10.72 $\pm$ 7.50	$\textbf{10.64} \pm \textbf{8.60}$
Hypervigilance (BVS)	19.24 $\pm$ 10.89	$\textbf{23.36} \pm \textbf{7.01}$
Physical activity (DASI)	23.62 ± 10.98	27.50 ± 14.56
Shock anxiety (FSAS)	17.31 ± 8.56	NA

Abbreviations: BVS, Body Vigilance Scale; CABG, coronary artery bypass graft; CAD, coronary artery disease; DASI, Duke Activity Status Index; EF, ejection fraction; FSAS, Florida Shock Anxiety Scale; HADS, Hospital Anxiety and Depression Scale; ICD, implantable cardioverter defibrillator; MI, myocardial infarction; NA, not applicable; PSQI, Pittsburgh Sleep Quality Index; SAQ, Seattle Questionnaire.

analyses (1 ICD participant and 1 CAD participant). HADS data were also analyzed for levels of anxiety and depression that would be considered clinically diagnostic. Whereas many patients reported symptoms of anxiety and depression suggesting mild levels of distress, only 1 ICD patient and 3 CAD patients reported moderate to severe levels of anxiety. Likewise, only 1 ICD and 2 CAD patients

reported moderate to severe levels of depression according to interpretive guidelines for the HADS. Shock anxiety (FSAS) scores in ICD patients were similar to those found in the initial validation study for this measure (M = 17.31, SD = 8.56).

## **Tests for Group Differences on Sleep Indices**

A series of 1-way ANCOVA were used to determine if group differences existed between ICD and CAD patients on sleep indices. EF was used as a covariate, as this measure differed significantly between cardiac groups. Prior to performing these analyses, data were tested for the assumptions necessary to perform these tests in order to refrain from biasing parametric tests. Data were analyzed for linearity and subjected to tests assessing normality and homogeneity of variance. One CAD participant was found to be an outlier in that the individual had scores of -3.00 >z > +3.00 from the mean for both waking after sleep onset (sleep diary) and sleep efficiency (sleep diary). Therefore, this participant's data were excluded from analyses. Data were also analyzed for homogeneity of regression slopes by measuring the interaction term between cardiac condition and EF. Four variables failed to meet the assumption of homogeneity of regression slopes, and therefore ANOVAs were used for these dependent measures (sleep efficiency [actigraphy], total sleep time [actigraphy], waking after sleep onset [actigraphy], and total sleep time [sleep diary]). For these variables, Levene's technique was used to test the assumption of homogeneity of variance, and all data satisfied this assumption.

As waking after sleep onset (sleep diary) and sleeponset latency (sleep diary) failed to meet the assumption of normality in kurtosis, nonparametric Kruskal-Wallis 1-way ANOVAs were conducted for these dependent measures. A Bonferroni-corrected level of P < 0.025 was employed for each pair of sleep indices (eg, sleep efficiency for sleep diaries and actigraphy; total sleep time for sleep diaries and actigraphy).

Results from ANCOVA indicated that CAD and ICD patients slept at a similar level of efficiency according to sleep-diary data, with CAD patients sleeping slightly more efficiently (83.95% vs 82.26%,  $F_{1,27} = 4.226$ , P = P 0.046). Results did not reveal significant differences between the groups for any other variables, including mean sleep-onset latency (actigraphy), mean number of awakenings (actigraphy), mean sleep efficiency (sleep diary), mean number of awakenings (sleep diary), and mean sleep quality (sleep diary).

The ANOVA results indicated significant differences for 1 actigraphy measure. The CAD patients had much lower mean sleep efficiencies than ICD patients (69.76% vs 82.80%;  $F_{1,27} = 16.840$ , P < 0.001). This finding cannot be accounted for by differences in psychological distress, somatic hypervigilance, or physical activity levels.

Significant group differences were also found for 1 sleep diary measure. CAD patients had shorter mean total sleep times per sleep diaries compared with ICD patients (336.19 minutes or 5.60 hours vs 430.65 minutes or 7.18 hours;  $F_{1,27} = 15.908, P < 0.001$ ). No significant differences were found for mean waking after sleep onset (actigraphy), mean number of awakenings (sleep diary), or mean total sleep time (sleep diary). An ANOVA using the Kruskal-Wallis test showed that sleep-onset latency (sleep diary) did not significantly differ between ICD and CAD patients ( $H_{1,57} = 0.79$ , P = 0.38). Similarly, no significant difference was found for waking after sleep onset (sleep diary),  $H_{1,56} = 0.76$ , P = 0.38.

# Discussion

The purpose of this study was to compare sleep patterns between CAD and ICD patients using both objective and subjective sleep data. It was hypothesized that ICD patients would have poorer sleep indices related to hypervigilance for device functioning and shock discharge. The primary and surprising finding was that CAD patients had poorer sleep compared with ICD patients in terms of sleep efficiency and total sleep time. This finding was surprising given that CAD patients had higher EFs compared with ICD patients. This finding cannot be attributed to group differences in anxiety/depression, physical activity levels, or somatic hypervigilance, as these differences were not statistically significant. Given the well-established high prevalence of depression and anxiety found in cardiac populations, the low rates of clinically significant depression and anxiety are surprising. The CAD patients had predictably higher EFs than the ICD patients, such that poor perfusion of blood to the body also cannot explain this finding. Although CAD patients reported poor sleep quality, it was also poor in the ICD sample, suggesting that sleep problems are widespread in cardiac disease. Therefore, sleep quality should be considered an increasingly important variable for clinical and research applications.

The finding that ICD patients had more adaptive sleep patterns than CAD patients highlights the possibility of a perceived sense of safety and security from which many recipients may benefit. A positive psychosocial adjustment to having an ICD could help recipients feel less "vulnerable" and more "protected," thereby in turn potentially facilitating more adaptive sleep. The CAD patients reporting poorer sleep patterns than ICD patients also highlights the potential importance of potential chest pain as a variable that affects sleep. It is well known that rapid eye movement (REM) sleep is a time of autonomic instability marked by rapid fluctuations in sympathetic and parasympathetic influences causing sudden changes in heart rate and blood pressure.<sup>20,30,31</sup> It follows that REM sleep could relate to the occurrence of chest pain, especially in the latter half of the night. Nowlin and colleagues<sup>32</sup> found that nocturnal

angina occurred predominantly during REM sleep and was associated with increased heart rate. When dream content could be reported, it included awareness of chest pain and emotions of fear, anger, and frustration. In the current study, physical limitations due to chest pain (eg, activities of daily living and performing specific tasks), disease perception (degree to which chest pain interferes with life), and anginal stability over the previous 4 weeks were more problematic than the actual frequency of chest pain and treatment satisfaction.

In the ICD sample, 58.1% of participants had underlying coronary disease. Thus, 80% of the total sample had underlying coronary disease, which could lead to angina. Unfortunately, the SAQ was administered only to participants with CAD without an ICD. Future studies in this area could benefit from administering the SAQ to all participants in order to thoroughly measure and make comparisons for this construct. Although the medical severity of coronary disease may or may not correlate with the severity of complaints for physical symptoms such as chest pain, it is possible that ICD patients had greater coronary disease severity than CAD patients.

## **Study Limitations**

This study has methodological limitations that may require cautious interpretation of findings. Some study limitations relate to sample derivation. First, polysomnography was not used as a screening tool in the sample, leaving the possibility of undiagnosed OSA in the sample. Previous studies have found a high rate of comorbidity for OSA with ICD and CAD patients. Second, the psychological distress scores were lower than expected for this sample. We suggest that volunteering for a study that includes 2 weeks of diary work may have led to some unintended selection processes that preferred patients not experiencing emotional distress at this time. Third, alternate sampling procedures should be employed for future studies in this area. In the current study, 58% of ICD patients had underlying coronary disease, thus ICD status did not represent an entirely different group from the CAD group used for comparison. Fourth, results may not generalize to all ICD patients given that the current ICD sample included a large range of recipients, including those with newly implanted devices vs those who had had their device for several months or years. Another limitation is the inclusion of some participants with cardiac diagnoses or conditions in addition to those under study, CAD and ICDs. In this sample, there were participants with atrial fibrillation (13 participants, 22%), pacemakers (4 participants, 7%), congestive heart failure (2 participants, 3%), and cardiomyopathy (1 participant, 2%). Logistical constraints barred the derivation of a completely "pure" cardiac sample.

Other limitations relate to sample size and data collection. It would be useful to recruit a larger sample size, allowing for robust multivariate data analysis. The current study used actigraphy with one-half of the CAD participants and one-half of the ICD participants due to logistic constraints. Using actigraphy for the entire sample cohort would aid the interpretation of findings by increasing statistical power. A final limitation involves inaccurate memory and selective recall biases that may operate when self-report questionnaires are used. Some patients with insomnia have a tendency to focus on the worst experiences and to amplify their importance.

# Conclusion

This study furthers our understanding of how sleep patterns relate to 2 groups of patients living with cardiac disease. The current study is the first to date to use actigraphy in objectively measuring sleep patterns in electrophysiology patients. The finding that CAD patients have shorter total sleep times per sleep-diary data and poorer sleep efficiencies per actigraphy data highlights the potential importance of chest pain in factors that may influence sleep patterns in cardiac patients. Given the degree of poor sleep in both the ICD and CAD samples in this study, sleep should be considered a salient aspect of the disease process in cardiology. Cognitive Behavioral Therapy for Insomnia (CBT-I) is an empirically validated treatment that is currently being investigated for use with cardiac patients. Study results imply that both CAD and ICD patients could benefit from participation in CBT-I.

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