



# Sleep disturbance in patients with an implantable cardioverter defibrillator: Prevalence, predictors and impact on health status

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## Abstract

**Background:** Sleep disturbances are highly prevalent in patients with cardiac diseases and associated with poor health outcomes. However, little is known about sleep disturbance in patients with an implantable cardioverter defibrillator.

**Aims:** We examined the prevalence and predictors of sleep disturbance and the impact on perceived health status in a Dutch cohort of implantable cardioverter defibrillator patients.

**Methods:** Patients ( $n=195$ ) enrolled in the Web-based distress program for implantable cardioverter defibrillator patients (WEBCARE) trial completed questionnaires at the time of implantable cardioverter defibrillator implantation, three, six and 12 months afterwards. Sleep disturbance was assessed with the corresponding item #3 of the Patient Health Questionnaire 9.

**Results:** At baseline, 67% ( $n=130$ ) reported sleep disturbance (cut off  $\geq 1$ ). One year later, the prevalence was 57% ( $n=112$ ). Younger age (odds ratio=0.96, 95% confidence interval 0.92–0.99;  $p=0.012$ ) and high negative affectivity/low social inhibition (odds ratio=4.47, 95% confidence interval 1.52–13.17;  $p=0.007$ ) were associated with sleep disturbance at 12 months in adjusted analyses. Sleep disturbance was not associated with health status at 12 months. Charlson Comorbidity Index, anxiety, Type D personality and high negative affectivity/low social inhibition were associated with impaired health status at follow-up.

**Conclusions:** Sleep disturbance was highly prevalent in patients with an implantable cardioverter defibrillator. Younger age and high negative affectivity predicted sleep disturbance 12 months post-implantation independent of other demographic, clinical, intervention and psychological covariates. Sleep disturbance was not associated with impaired health status at the 12-month follow-up.

## Keywords

Sleep disturbance, implantable cardioverter defibrillator, health status, negative affectivity

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## Introduction

Sleep disorders (e.g. insomnia, obstructive sleep apnoea) have been associated with increased risk for cardiovascular and cerebrovascular diseases and metabolic disorders.<sup>1</sup> In addition, patients experiencing sleep problems report lower self-perceived physical health,<sup>2</sup> and impaired quality of life (QoL).<sup>3</sup> Hence, in their recent scientific statement the American Heart Association called for more

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research and implementation of evidence-based sleep recommendations by healthcare organizations.<sup>1</sup>

The implantable cardioverter defibrillator (ICD) is a device that monitors the heart rhythm and in the event of a potentially life threatening arrhythmia intervenes with cardioversion and an electric shock of up to 840 volts.<sup>4</sup> Despite the unequivocal medical benefits of the ICD,<sup>4</sup> a subgroup of ICD patients is at risk of experiencing adjustment problems post-implantation that include anxiety, depression and even posttraumatic stress.<sup>5,6</sup> In turn, this may lead to impaired QoL, adverse cardiovascular outcomes and perhaps sleep disturbances.<sup>7–9</sup> Particularly, patients with a Type D (distressed) personality (combination of high negative affectivity and high social inhibition) are prone to experience adverse health outcomes post-implantation.<sup>10,11</sup>

To date, only a few studies have focused on sleep disturbances in patients with an ICD. A Danish study found clinically significant sleep problems in up to 67% of patients.<sup>12</sup> One American study found that patients with ICD and co-morbid sleep problems reported increased fatigue, decreased mood and poorer device acceptance,<sup>8</sup> while a small study using actigraphy that measures sleep efficiency by means of sleep/wake cycles found that ICD patients had better sleep efficiency than cardiac patients without an ICD.<sup>13</sup> This is somewhat in line with a recent meta-analysis revealing that sleep disordered breathing is associated with an increased incidence of appropriate ICD therapy only in patients with heart failure and reduced ejection fraction.<sup>14</sup> This might indicate that the underlying disease (e.g. heart failure) is of importance when assessing patient-reported outcomes (PROs) and sleep disturbances in ICD patients.<sup>15</sup>

The American Heart Association has advocated the assessment of cardiovascular health by using PROs, which represent patients' subjective evaluation of their functioning.<sup>16</sup> Given the association of sleep disturbances and cardiac and metabolic diseases,<sup>1,14</sup> it is of utmost importance to examine which patients are at risk of experiencing self-reported sleep disturbance and whether this affects their perceived health status. The objective of the current study was therefore (a) to examine the prevalence of sleep disturbance in an ICD population followed over a 12-month period; (b) to longitudinally relate demographic, clinical and psychological variables (i.e. depression, anxiety, Type D personality) to sleep disturbance; and (c) examine whether sleep disturbance has a negative effect on perceived health status, using a prospective study design.

## Methods

### Study design

Data from the Web-based distress program for patients with an implantable cardioverter defibrillator (WEBCARE)

trial was used in the current study. The study was registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT00895700). A detailed description of the WEBCARE trial has been published elsewhere.<sup>17</sup> In brief, WEBCARE examined the effectiveness of a Web-based intervention based on the principles of cognitive behavioural therapy that targeted symptoms of anxiety and depression in a randomised controlled trial design. No statistically significant differences were found between the intervention versus usual care group on the pre-specified primary and secondary endpoints.<sup>18</sup>

### Participants

Patients implanted with a first-time ICD between April 2010–February 2013 in one of six medical centres in the Netherlands (Amphia Hospital, Breda; Canisius-Wilhelmina Hospital, Nijmegen; Catharina Hospital, Eindhoven; Erasmus Medical Center, Rotterdam; Onze Lieve Vrouwe Gasthuis Hospital, Amsterdam; Vlietland Hospital, Schiedam) comprised the study population. Participants were eligible for inclusion if it was their first-time ICD and they were between 18–75 years of age. Exclusion criteria were other life-threatening comorbidities (e.g. cancer), significant cognitive impairments (e.g. dementia), history of psychiatric illness other than affective or anxiety disorders, life expectancy less than one year, and being on the waiting list for a heart transplant. Participants lacking Internet or computer skills and participants with insufficient knowledge of the Dutch language were also excluded.

### Procedure

The ICD nurse or technician approached patients about study participation in the hospital, prior to, or shortly after, the ICD implantation. All patients were informed about the study both orally and in writing. Patients who met all of the inclusion criteria and none of the exclusion criteria and provided written informed consent were included in the study. Patients completed a set of standardised and validated questionnaires at baseline (prior to leaving the hospital) and at three-, six- and 12 months post-implantation, and these were sent to their home address together with a pre-addressed stamped envelope. Patients received up to three reminder phone calls if the questionnaires were not returned within two weeks. The study protocol was approved by the medical ethics committees of the participating hospitals. The study was performed in accordance to the Declaration of Helsinki principals.

### Measures

**Demographic and clinical variables.** Information on demographic (age, gender, marital status, education level, body

mass index) and clinical variables (ICD indication – primary: patients at risk of experiencing sudden cardiac arrest vs secondary: patients who have previously experienced a sudden cardiac arrest-, heart failure, New York Heart Association Functional Class, left ventricular ejection fraction, QRS-width, heart rate, diabetes, comorbidities, psychotropic and cardiac drugs) were captured from the patients' medical records or by self-report.

**Sleep disturbance.** Sleep disturbance was assessed with item #3 of the Patient Health Questionnaire 9 (PHQ-9): 'Trouble falling or staying asleep, or sleeping too much'.<sup>19</sup> This item is evaluated on a four-point Likert scale ranging from zero (not at all) to three (nearly every day) and indicates sleep problems in the last two weeks. Previous research has shown that a cut off of  $\geq 1$  on the PHQ item #3 provides the best balance between sensitivity (82.5%) and specificity (84.5%) and that it can be used as a valid indication of sleep disturbance.<sup>20</sup>

#### Psychological variables

**Anxiety.** Symptoms of anxiety were assessed with the seven-item General Anxiety Disorder Scale (GAD-7).<sup>21</sup> Items of the GAD-7 are answered on a four-point Likert scale ranging from zero (not at all) to three (almost every day), with the total score ranging from 0–21. Higher scores indicate higher levels of anxiety. The GAD-7 has an excellent internal consistency with a Cronbach's  $\alpha$  of 0.92 and good test-retest reliability with an intraclass correlation of  $r=0.83$ .<sup>21</sup>

**Depressive symptoms.** Depressive symptoms were assessed with the two-item Patient Health Questionnaire (PHQ-2), as these two items represent the core symptoms of depression.<sup>19</sup> This was done in order to prevent overlap with the predictor variable (i.e. sleep) and outcome variable (i.e. depressive symptoms) in the analyses. The two items represent the frequency of depressed mood and anhedonia over the past two weeks and are answered on a four-point Likert scale ranging from zero (not at all) to three (nearly every day), with a score which can range from 0–6.<sup>22</sup> The PHQ-2 has a good validity and internal consistency with a Cronbach's  $\alpha$  of 0.83.<sup>22</sup>

**Type D personality.** Type D (distressed) personality was assessed with the 14-item Type D Scale-14 (DS14).<sup>23</sup> Items are rated on a five-point Likert scale ranging from zero (false) to four (true). The 14 items can be divided into two seven-item subscales, negative affectivity (NA; 0–28) and social inhibition (SI; 0–28). A cut-off score of 10 on both the NA and SI subscales is used to classify Type D personality. Both subscales show a high level of internal consistency with a Cronbach's  $\alpha$  of 0.88 for the NA subscale and 0.86 for the SI subscale and a high level of structural validity with test-retest correlations of  $r=0.72$  for the

NA subscale and an intraclass correlation of  $r=0.82$  for the SI subscale.<sup>23</sup>

**Health status.** Perceived health status was assessed with the 12-item Short-Form Health Survey (SF-12). This survey is a shorter version of the 36-item Short-Form Health Survey (SF-36) and is a good alternative to the SF-36 because of the high degree of correspondence between both measures ( $r=0.94$ – $0.97$ ).<sup>24</sup> The 12 items can be divided into two subscales, the Physical and the Mental Component Summary (PCS and MCS, respectively) scores. The scores range from 0–100 with a higher score indicating better perceived health status. The test-retest reliability is 0.89 and 0.76 for the PCS and MCS, respectively.<sup>24</sup>

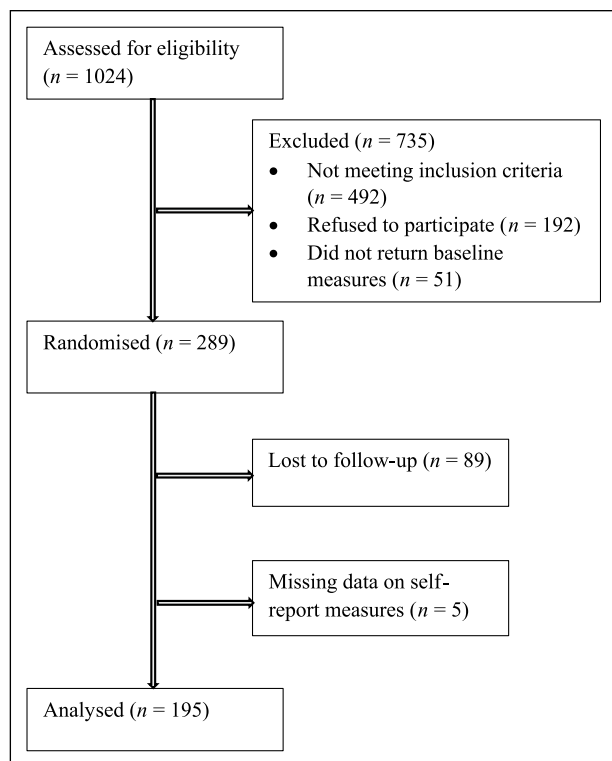
#### Statistical analyses

To compare patients with sleep disturbance to those without on baseline variables, Chi-square tests were performed to compare discrete variables and Student's *t*-tests were used to compare continuous variables. Univariate and multivariate (hierarchical) logistic regression analyses were used to identify the predictors of sleep disturbance at one year after implantation and to identify predictors of health status. Patients were classified as having a disturbed sleep if they had a  $\geq 1$  score on #3 item of the PHQ-9 (0=no sleep problems; 1=sleep problems). In multivariable analyses, we adjusted for age, gender, ICD indication, Charlson Comorbidity Index (CCI), use of psychotropic medication, depression and anxiety, and Type D personality. These variables were selected based on literature.<sup>25–28</sup> To assess the effects of Type D personality (high NA/high SI) on health status, three dummy variables were created: high NA/low SI, low NA/high SI, and low NA/low SI. Low NA/low SI served as the reference category. In the secondary analysis, (a) CCI and (b) psychotropic medication variable were replaced by heart failure (yes/no). If the questionnaire was missing  $\leq 20\%$ , the missing data were imputed using the mean score of the patient on the available completed items. For DS14, GAD-7, PHQ-2 and Health Status, two, three, two and six patients needed imputation respectively. All statistical tests were two-tailed, and  $p < 0.05$  was used to indicate statistical significance. IBM SPSS Statistics version 23 was used for all statistical analyses.

## Results

### Sample characteristics

A total of 195 patients were included in the current analysis (Figure 1). Patients who did not return the baseline questionnaires ( $n=51$ ) or were excluded from current analyses ( $n=94$ ) were younger ( $M=57.12$  vs  $59.94$ ;  $p=0.014$ )



**Figure 1.** Flow chart of patient recruitment.

and more likely to use psychotropic drugs (24 vs 15 patients;  $p=0.011$ ) compared to included patients. No other statistically significant differences were found between included and excluded patients on baseline demographic, clinical and psychological characteristics.

### Baseline characteristics

The mean age of the total sample was 59.9 years (standard deviation (SD)=10.00) and 82% of the participants were men. Patient baseline characteristics for the total sample and stratified by self-reported sleep disturbance are shown in Table 1. At baseline, 130 (67%) patients reported having a disturbed sleep at least several days per week. Patients with a disturbed sleep at baseline were more likely to have heart failure, symptoms of anxiety and depression and a Type D personality (Table 1). No other significant differences were found on demographic or clinical variables between patients with versus without reported sleep disturbance.

### Predictors of sleep disturbance

Figure 2 provides the prevalence of sleep disturbance at baseline and at three-, six- and 12-month follow-up.

Univariate logistic regression analyses showed that age (odds ratio (OR)=0.96; confidence interval (CI): 0.93–0.99;  $p=0.005$ ), anxiety symptoms (OR=1.11; CI:

1.03–1.19;  $p=0.007$ ), Type D personality (OR=2.99; CI: 1.24–7.23;  $p=0.015$ ) and high NA/low SI (OR=4.38; CI: 1.72–11.16;  $p=0.002$ ) were significant predictors of disturbed sleep 12 months after ICD implantation. None of the other baseline demographic or clinical variables were associated with sleep disturbance at the 12-month follow-up (results not shown).

Results of the multivariable analyses are presented in Table 2. Current findings show that younger age (OR=0.96; CI: 0.92–0.99;  $p=0.013$ ) and high NA/low SI (OR=4.47; CI: 1.52–13.7;  $p=0.007$ ) were independent predictors of disturbed sleep one year after implantation after adjusting for demographic, clinical, and psychological variables. Secondary analysis showed that replacing CCI or psychotropic drugs by heart failure in the model did not change the results. In the current sample, heart failure was not associated with disturbed sleep at 12 months (results not shown).

### Sleep disturbance and health status

After controlling for demographic (age, gender) and clinical (ICD indication, CCI, use of psychotropic medication) variables, sleep disturbance was a significant predictor of impaired physical and mental health status (Table 3). However, after adding the psychological variables (anxiety, depression, Type D personality, high NA/low SI) to the model, the effect of disturbed sleep on health status disappeared.

CCI (PCS:  $\beta=-0.220$ ;  $p=0.002$ ), anxiety (MCS:  $\beta=-0.270$ ;  $p=0.001$ ), and Type D personality (MCS:  $\beta=-0.169$ ;  $p=0.018$ ) were independent predictors of health status at 12 months post-ICD implantation. NA was the only significant predictor of both PCS and MCS, indicating that patients who with higher levels of NA at baseline, generally reported lower physical ( $\beta=-0.259$ ;  $p=0.001$ ) as well as mental ( $\beta=-0.276$ ;  $p\leq 0.001$ ) health status at the 12-month follow-up, after adjusting for demographic, clinical and other psychological variables. When heart failure was added to the model instead of psychotropic drugs, the results did not change significantly (not shown).

### Discussion

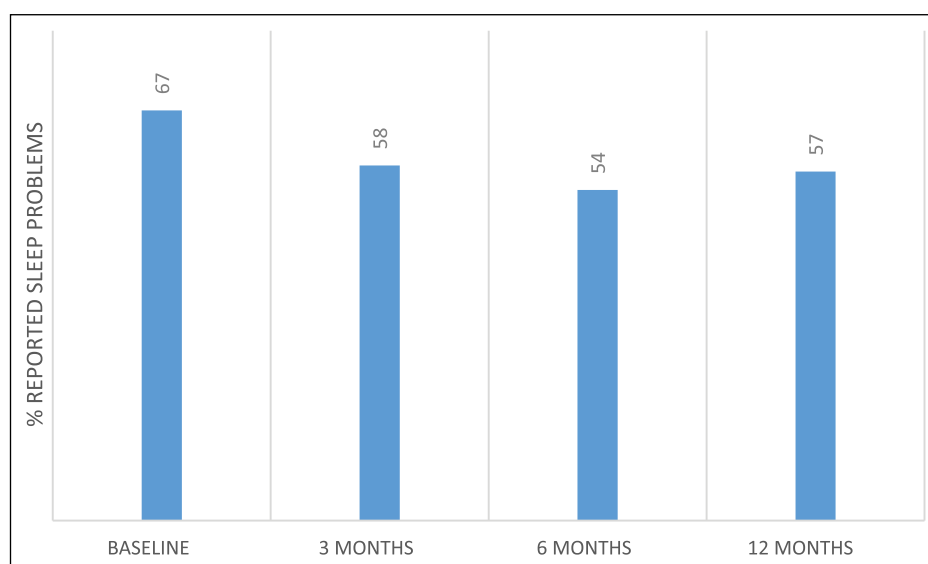
Current findings demonstrated that sleep disturbance is highly prevalent among patients with an ICD at the time of ICD implantation. Although sleep disturbance tended to abate somewhat over time, a significant number of patients still experienced disturbed sleep post-implantation. Multivariable analyses showed that, after adjusting for relevant demographic, clinical and psychological variables, younger age and high NA/low SI were independent predictors of sleep disturbances 12 months post-implantation. Patients with high NA/low SI scores had a 4.5-fold increased risk of having disturbed sleep at one-year follow-up. Sleep

**Table 1.** Baseline characteristics for the total sample and stratified by the presence of reported sleep problems at baseline.

	Total (n=195)	Sleep problems (n=130)	No sleep problems (n=65)	p
<b>Demographics</b>				
Age	59.9±10.0	59.2±9.8	61.4±10.4	0.16
Gender (male)	160 (82%)	104 (80%)	56 (86%)	0.29
Partner (yes)	166 (85%)	114 (88%)	52 (80%)	0.16
High education level, <sup>a</sup> n=194	138 (71%)	91 (71%)	47 (72%)	0.80
BMI, n=193	27.0±4.9	27.3±5.3	26.3±3.9	0.17
<b>Intervention (WEBCARE)</b>	91 (47%)	58 (45%)	33 (51%)	0.42
<b>Clinical variables</b>				
ICD indication (secondary)	67 (34%)	50 (38%)	17 (26%)	0.09
Heart failure	105 (54%)	61 (47%)	44 (68%)	<b>0.006</b>
NYHA III/IV, n=155	26 (13%)	21 (21%)	5 (9%)	0.06
LVEF≤35%, n=163	126 (65%)	80 (75%)	46 (81%)	0.45
QRS>120 ms, n=193	82 (42%)	53 (41%)	29 (45%)	0.58
Heart rate b/pm, n=190	72.5±15.4	72.5±15.9	72.5±14.5	0.99
Charlson Comorbidity Index	1.7±1.0	1.6±1.0	1.7±0.9	0.76
Diabetes	28 (14%)	19 (15%)	9 (14%)	0.89
<b>Medication</b>				
Psychotropic drugs (yes)	15 (8%)	13 (10%)	2 (3%)	0.09
Beta-blocker	161 (83%)	107 (82%)	54 (83%)	0.89
ACE inhibitor	124 (64%)	82 (63%)	42 (65%)	0.83
Statins	122 (63%)	79 (61%)	43 (66%)	0.46
<b>Psychological measures</b>				
Depressive symptoms	1.2±1.4	1.4±1.5	0.7±1.1	<b>&lt;0.001</b>
Anxiety	4.2±4.6	5.1±4.9	2.5±3.6	<b>&lt;0.001</b>
Type-D personality (yes)	31 (16%)	26 (20%)	5 (8%)	<b>0.027</b>
High NA/low SI	32 (16%)	26 (20%)	6 (9%)	0.06
Low NA/high SI	43 (22%)	27 (21%)	16 (25%)	0.54

ACE: angiotensin-converting enzyme; BMI: body mass index; ICD: implantable cardioverter defibrillator; LVEF: left ventricular ejection fraction; NA: negative affectivity; NYHA: New York Heart Association functional class; SI: social inhibition.

<sup>a</sup>≥10 years of education.



**Figure 2.** Prevalence of reported sleep problems during 12-month follow-up post implantable cardioverter defibrillator (ICD) implantation.

**Table 2.** Predictors of sleep problems 12 months after implantable cardioverter defibrillator (ICD) implantation.

Predictor variable	OR	95% CI	p
<b>Model 1</b>			
Age	0.96	0.93-0.99	<b>0.01</b>
Gender (female)	1.16	0.52-2.59	0.73
<b>Model 2</b>			
Age	0.95	0.92-0.99	<b>0.01</b>
Gender (female)	1.26	0.55-2.88	0.58
ICD indication (secondary)	1.21	0.64-2.28	0.56
Charlson Comorbidity Index	1.27	0.92-1.73	0.14
Psychotropic drugs (yes)	1.79	0.53-6.02	0.35
<b>Model 3</b>			
Age	0.96	0.92-0.99	<b>0.01</b>
Gender (female)	1.28	0.54-3.01	0.58
<b>Clinical variables</b>			
ICD indication (secondary)	1.26	0.65-2.43	0.50
Charlson Comorbidity Index	1.19	0.85-1.66	0.31
Psychotropic drugs (yes)	1.75	0.47-6.50	0.40
<b>Psychological measures</b>			
Depressive symptoms	0.90	0.68-1.19	0.47
Anxiety	1.04	0.94-1.15	0.46
Type D personality (yes)	2.32	0.85-6.32	0.10
High NA/low SI	4.47	1.52-13.17	<b>0.01</b>
Low NA/high SI	1.72	0.79-3.75	0.17

CI: confidence interval; NA: negative affectivity; OR: odds ratio; SI: social inhibition.

R<sup>2</sup>=0.06 for Model 1; 0.08 for Model 2; 0.17 for Model 3.

disturbance was predictive of impaired health status at the 12-month follow-up after adjusting for demographic and clinical variables. However, after adjusting for psychological variables, they were no longer associated with health status. In the final multivariable model, comorbidities were associated with impaired physical health status, while anxiety and Type D personality were associated with impaired mental health status. The combination of high NA/low SI was the only independent predictor of impairments in both mental and physical health status.

Current finding with respect to prevalence rates are comparable with a previous study reporting prevalence rates of up to 67% at baseline and 57% at the six-month follow-up within the ICD population.<sup>12</sup> Our findings extend current knowledge by providing prevalence rates over a prolonged period of 12 months post-ICD-implantation. These findings indicate that sleep disturbance is not merely caused by concerns associated with ICD implantation itself or other short-term adjustment issues. Moreover, as they remain relatively stable over time, this might suggest that there is an underlying, stable construct that accounts for these prevalences (e.g. psychological or medical profile). Hence, interventions that target sleep disturbances in this population should perhaps target more stable constructs that are associated with poor long-term adjustment.

**Table 3.** Predictors of quality of life 12 months after implantable cardioverter defibrillator (ICD) implantation.

Predictor variable	MCS		PCS	
	β	p	β	p
<b>Model 1</b>				
Sleep problems	-0.167	<b>0.02</b>	-0.174	<b>0.02</b>
<b>Model 2</b>				
Sleep problems	-0.154	<b>0.03</b>	-0.165	<b>0.02</b>
Age	0.113	0.13	-0.032	0.67
Gender (female)	-0.022	0.77	-0.131	0.08
<b>Model 3</b>				
Sleep problems	-0.149	<b>0.03</b>	-0.166	<b>0.02</b>
Age	0.133	0.07	0.003	0.96
Gender (female)	-0.020	0.78	-0.134	0.07
ICD indication (secondary)	0.102	0.15	0.093	0.19
Charlson Comorbidity Index	-0.197	<b>0.01</b>	-0.251	<b>&lt;0.001</b>
Psychotropic drugs (yes)	-0.157	<b>0.03</b>	-0.093	0.18
<b>Model 4</b>				
Sleep problems	-0.002	0.98	-0.073	0.29
Age	0.069	0.29	-0.019	0.79
Gender (female)	0.005	0.94	-0.118	0.09
ICD indication (secondary)	0.053	0.39	0.072	0.29
Charlson Comorbidity Index	-0.122	0.055	-0.220	<b>0.002</b>
Psychotropic drugs (yes)	-0.093	0.13	-0.071	0.30
Depressive symptoms	-0.113	0.13	-0.135	0.10
Anxiety	-0.270	<b>0.001</b>	-0.079	0.38
Type D personality (yes)	-0.169	<b>0.02</b>	-0.081	0.30
High NA/low SI	-0.276	<b>&lt;0.001</b>	-0.259	<b>0.001</b>
Low NA/high SI	-0.052	0.42	-0.064	0.37

MCS: Mental Component Score; NA: negative affectivity; PCS: Physical Component Score; SI: social inhibition.

MCS: R<sup>2</sup>=0.03 for Model 1; 0.04 for Model 2; 0.12 for Model 3; 0.38 for Model 4.

PCS: R<sup>2</sup>=0.03 for Model 1; 0.05 for Model 2; 0.13 for Model 3; 0.25 for Model 4.

With respect to predictors of sleep disturbances/lower sleep quality, others have shown that younger age, female gender, anxiety, depressive symptoms and underlying cardiac disease predict lower sleep quality over time.<sup>1,12-14</sup> Current findings are mostly in contrast to previous findings with the only similarity being that younger patients are identified as having a higher risk of experiencing disturbed sleep. No evidence was found that gender, anxiety, depression and underlying cardiac disease (heart failure) were associated with disturbed sleep. This difference could be attributed to the fact that the previous studies focused more on sleep quality as compared to sleep disturbances which were the focus of the current study. In addition, previous studies did not control for Type D personality or high NA/low SI. The relationship between psychological distress and sleep disturbances/quality could possibly be explained by the presence of a more stable construct such as NA.

A relationship between NA and impaired sleep has been demonstrated several times in previous research.<sup>29-31</sup> The

tendency to experience negative emotions across time and situations is associated with feelings of dysphoria, anxiety and a negative view of self.<sup>23,31</sup> This is partly also in line with the current findings, as high NA/low SI was an independent predictor of impaired health status. A possible explanation for the relation with sleep disturbance is that NA amplifies a person's reaction to, and perception of, stressful events. These individuals are likely to experience high levels of stress, tend to worry and often feel unhappy and irritated,<sup>23</sup> which may result in impaired sleep quality/sleep disturbances. In addition, impaired sleep quality may increase the patient's reaction to negative stimuli,<sup>32</sup> resulting in more distress and thus leading to a vicious cycle.

Previous studies have shown that Type D personality is also significantly associated with impaired sleep.<sup>29</sup> In the current study, Type D personality (the combination of high NA and high SI) was also associated with sleep disturbance in univariate analyses, but not after adjusting for demographic, clinical and psychological variables. In accordance with our findings, a previous study which found an association between Type D personality and sleep problems also showed that NA was more strongly related to sleep problems in adolescents, as compared to SI.<sup>29</sup>

To date, none of the studies have focused on the effects of sleep disturbance on health status at 12 months post-ICD-implantation. Our findings showed that sleep disturbance was associated with impaired health status, but that this association was no longer significant after adjustment for psychological variables. Here again, high NA/low SI was the only predictor that was independently associated with both impaired mental and physical health status. These findings are in line with previous studies showing an association between NA and impaired health status.<sup>33</sup> In addition, comorbidities, anxiety and Type D personality were also associated with one of the components of health status, which is in line with previous findings.<sup>11,34</sup>

A number of limitations must be acknowledged. First, the WEBCARE trial was not designed to study sleep patterns in patients with an ICD and, hence, current findings should be interpreted with caution as the sample might not be representative for the general ICD population. Second, sleep disturbance was measured with one single item from the PHQ-9. Nevertheless, PHQ-9 item #3 has been shown to be an effective screener for identifying sleep disturbance and has been proven to significantly correlate with the Insomnia Severity Index, a measure that adequately assesses diagnostic criteria for insomnia.<sup>20</sup> Sleep disturbance measured by PHQ-9 item #3 has also been associated with an increased occurrence of cardiovascular risk factors and disease.<sup>2</sup> However, using a one-item measure might be associated with random measurement errors and interpretation biases. In addition, reliability statistics cannot be calculated with a one-item measure. Third, it was not possible to diagnose and distinguish between different kinds of sleep disorders like insomnia, obstructive sleep

apnoea and hypersomnia in this study. Fourth, due to the relatively small sample size and the risk of overfitting the regression models, it was not possible to adjust for all clinical variables that might be of interest. Finally, only 37% of the eligible patients were included in current analysis. This might have resulted in a bias in current findings. Hence, the results may not be representative for the general ICD population. However, this is the first study to determine the prevalence of sleep disturbance in patients with an ICD during the course of 12 months post-implantation, the predictors and the impact of sleep disturbance on health status at the 12-month follow-up. In addition, as advocated by the American Heart Association this study presents the subjective, PROs which are considered as a good measure of cardiovascular health.<sup>16</sup>

For clinical practice it would be recommended to identify younger patients with high levels of NA and offer them support as needed to improve their sleep quality and potentially their health status. Also patients with a Type D personality should be identified due to its impact on patients' health status. This could be done using the 14-item DS14 questionnaire<sup>23</sup> which could be administered within minutes. Patients could be identified at time of implantation and offered support as soon as possible in order to decrease long-term adjustment problems. Future studies should focus on examining the relationship between NA and disturbed sleep and also investigate whether the association between sleep disturbances and cardiovascular health is mediated by NA. In addition, larger studies with more objective measures (e.g. daily monitoring with wearables) are needed to replicate current findings and inform the clinical practice.

## Conclusions

Sleep disturbance is highly prevalent in patients with an ICD. Current findings show that particularly younger patients with high negative affectivity may experience disturbed sleep post-ICD implantation. Sleep disturbance was not associated with impaired health status at the 12-month follow-up.

## Implications for practice

- Sleep disturbance in patients with an implantable cardioverter defibrillator (ICD) should be addressed in clinical practice.
- Sleep disturbance remains relatively stable over time after ICD implantation.
- Younger age is associated with sleep disturbance.
- Negative affectivity is associated with sleep disturbance.

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### Declaration of conflicting interests

The authors declare that there is no conflict of interest.

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