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Validity of the newly developed 4-item ANXxiety-scale in patients with an implantable cardioverter defibrillator: A 12-month follow-up study

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ABSTRACT

Background: Subclinical anxiety symptoms are associated with risk of impaired mental and physical health status, ventricular tachyarrhythmias and mortality, in patients with an implantable cardioverter defibrillator (ICD). This study evaluates the validity of the brief and new 4-item Anxiety Scale (ANX4) and its predictive value in relation to health status 12-months post ICD implantation.

Methods: A total of 288 ICD patients completed the ANX4 questionnaire. Factor analysis was performed to assess the validity of the scale. In a subsample of $N = 212$ patients, regression analysis was performed to assess questionnaires' predictive value of health status at 12-months follow-up.

Results: Analyses of the ANX4 revealed a one-factor structure with a high internal consistency ($\alpha = 0.894$). The ANX4 correlated significantly with existing generic and disease specific measures of anxiety symptoms STAI-S ($r = 0.62$), GAD-7 ($r = 0.58$), HADS-A ($r = 0.66$) and ICD related concerns (ICDC) ($r = 0.44$). Baseline anxiety symptoms were associated with lower levels of physical ($\beta = -0.276$; $p < .001$) and mental ($\beta = -0.551$; $p < .001$) health status 12-months post ICD implantation, adjusting for demographic and clinical variables.

Conclusions: The 4-item ANX4 shows to be a valid measure of anxiety symptoms in ICD patients and predicts physical and mental health status up to 12 months follow-up. Further studies are warranted to replicate these findings, determine the cut-off score for clinical relevant symptoms, and whether the ANX4 can be used in other populations.

1. Introduction

Sudden cardiac arrest, generally caused by an arrhythmia, occurs when the heart suddenly and unexpectedly stops beating [1]. At least half of these events can be attributed to ventricular tachyarrhythmias (VTa's) [2]. The implantable cardioverter defibrillator (ICD) is the treatment of choice for patients at increased risk of ventricular tachyarrhythmias (VTa's) (primary prevention) and for patients who have survived life-threatening VTa's (secondary prevention). ICD therapy is superior to arrhythmic drugs, with a significant risk reduction [1,3]. An ICD constantly monitors the heart rhythm and is able to deliver a shock or other appropriate electrical therapy upon detection of potentially fatal VTa's [1].

For most patients, ICD implantation results in desirable health status and the majority (73–82%) of patients returns to their pre-implantation level of psychological functioning 12-months after implantation [4,5].

In a systematic review of 45 studies, with sample sizes between 12 and 260 ICD patients, 11–28% of patients had clinically relevant depressive levels and 11–26% had clinically relevant anxiety levels. Besides, 5–41% reported subclinical depressive symptoms and even more (8–63%) reported subclinical anxiety symptoms the first year post ICD implantation [6]. These prevalence rates are significantly higher as compared to the general Dutch population [7] and often stay underdiagnosed and undertreated [8,9].

Identifying those ICD patients experiencing anxiety symptoms is especially important given the evidence that anxiety is associated with increased risk of VTa's [10–12] and mortality [10,11], one year post ICD implantation. Besides, psychiatric symptoms, such as anxiety, measured by existing anxiety questionnaires, reveal to be the most important factor to predict health status on the long-term in ICD patients [13]. Routine screening and systematic assessment of anxiety symptoms in the clinical practice is therefore strongly recommended

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[14]. However, the selection of the appropriate tool to screen for anxiety might be problematic as our recent study shows that these scales cannot be used interchangeably because they produce different prevalence rates and possibly tap into different types of anxiety [15,16]. A careful consideration of the pro's and con's of the assessment tools is therefore of utmost importance for the clinical practice.

To assist healthcare providers in identifying ICD patients who experience anxiety symptoms with the opportunity to treat and improve health outcomes, a brief, easy to administer and validated questionnaire would be most optimal. Anxiety questionnaires that have been used to assess anxiety in patients with an ICD, include the disease-specific measures – The Florida Shock Anxiety Scale (FSAS) [17], the Florida Patient Acceptance Survey (FPAS) [18], the ICD Patient Concerns Questionnaire (ICDC) [14,19], and generic measures such as: the Generalized Anxiety Disorder Scale (GAD-7) [5,20], the Hospital Anxiety and Depression Scale (HADS) [5,14], the Back Anxiety Inventory (BAI) [21,22] and the Hamilton Anxiety Scale (HAM-A) [22,23]. However, these questionnaires often contain items that are more related to / measure other constructs than anxiety (e.g. well-being, general distress) [24]. In addition, some of the currently available tools are relatively long and require some time investment from both patients and healthcare providers, which might be experienced as a burden in the clinical practice. Hence, a brief, specific measure for anxiety that can be used in various populations is warranted.

In order to address these issues, a new anxiety scale – the ANX4 was developed. As compared to the existing anxiety measures, the 4-item scale reflects specific symptoms of anxiety that are frequently reported by the general population and is not based on psychiatric diagnosis of generalized anxiety disorder. The scale is also free from somatic anxiety symptoms that might be confounded by underlying cardiac disease or other medical disorders and is easily administrable, taking less than two minutes of patients' and healthcare providers' time.

The aims of the current study are to (i) validate the newly developed ANX4 scale, and (ii) examine its association with health status 12-months post ICD implantation, adjusting for the potential effects of demographic and clinical variables.

2. Methods

2.1. Participants

First-time implanted ICD patients were approached for participation between April 2010 and February 2013 as part of the WEB-based distress management program for implantable cardioverter defibrillator patients (WEBCARE) trial, which has been described previously [5]. In brief, WEBCARE is a web-based randomized controlled trial, in which ICD patients were randomized to either the 'WEBCARE' or 'Care as usual' group. Patients in the WEBCARE group received six lessons on-line behavioural treatment for 12 weeks, with the aim to mitigate distress and enhance quality of life [5]. Patients were recruited from six Dutch hospitals: Amphia Hospital (Breda), Canisius-Wilhelmina Hospital (Nijmegen), Catharina Hospital (Eindhoven), Erasmus Medical Center (Rotterdam), Onze Lieve Vrouwe Gasthuis (Amsterdam) and Vlietland Hospital (Schiedam). Inclusion criteria were: first-time ICD implantation, age between 18 and 75 years, having Internet access and knowledge how to use it, and ability to speak and understand the Dutch language. Exclusion criteria were: being on the waiting list for heart transplantation, history of a psychiatric illness other than affective/anxiety disorders, life-threatening comorbidities (e.g. cancer), significant cognitive impairments (e.g. mental retardation and dementia), life expectancy less than one year, insufficient knowledge of the Dutch language and lack of internet or computer skills. For the current study, no distinction is made between patients in the 'WEBCARE' and 'Care as usual' group, as WEBCARE was a negative trial with no intervention effect observed [5,25].

2.2. Procedure

ICD nurses at the participating centers approached patients meeting the inclusion criteria and none of the exclusion criteria prior to or within ten days after ICD implantation. Patients were informed both orally and in writing about the study. If they were willing to participate they signed the informed consent and those who could not decide at that time were approached again while in hospital post ICD implantation. After signing the informed consent and before leaving the hospital, patients were asked to complete the first set of questionnaires (baseline) and return them within one week post discharge. Questionnaires were returned by mail (in a pre-stamped and addressed envelope) to Tilburg University, which served as the core-lab for the trial. If the questionnaires were not returned within one week, patients received up to three reminder telephone calls. For follow-up assessments at 3-, 6- and 12-months post ICD implantation, patients received the questionnaires per mail and were asked to return these to Tilburg University within one week. If patients did not return the questionnaires within the first week, they received up to three reminder telephone calls. For the current study, baseline and 12-months follow-up data will be used.

The study was performed in accordance with the Declaration of Helsinki, as amended in 2008 by the World Medical Association. The study protocol was approved by the Medical Ethics Committee (METC number MEC-2009-211 / NL25617.078.09) of the participating hospitals, and all patients have signed informed consent. The WEBCARE trial was registered on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00895700) NCT00895700.

2.3. Measures and instruments

2.3.1. Demographic and clinical variables

Information on demographic variables, including age, gender, marital status, educational level, and employment were obtained by purpose-designed questions in the questionnaires or from patients' medical records. Information on clinical variables was collected from patients' medical records and include ICD indication (primary or secondary prevention), heart failure, cardiac (beta-blockers) and psychotropic medication use, disease severity (left ventricular ejection fraction (LVEF) and New York Heart Association (NYHA) functional class) and comorbidity (Charlson Comorbidity Index (CCI)).

2.3.2. Anxiety symptoms (ANX4) item pool

The anxiety scale (ANX4) was developed prior to the WEBCARE study with the aim to develop a brief measure to assess specific anxiety symptoms which are not based on psychiatric criteria of generalized anxiety, are reported by the general community, and are not confounded by underlying disease (somatic symptoms of anxiety). Based on the literature and expert opinion, an item-pool of 10 anxiety items were selected. Eight items were selected from existing questionnaires: Edinburgh Depression Scale [26] (item 4 and 5), Minnesota Multiphasic Personality Inventory [27] (item 43, 337, and 431), Hospital Anxiety and Depression Scale [28] (item 3; from this item 2 new items were created), and the Penn State Worry Questionnaire [29] (item 7). Additional two items were self-constructed. The 10 item scale was administered in a healthy volunteer sample of $N = 3118$. Factor analysis revealed that a one factor structure was observed, based on factor loadings and expert review 4 items were selected which now comprise the ANX4 scale with a Cronbach's α of 0.88, which represents a good internal consistency. The ANX4 is a self-report questionnaire, consisting of four statements (e.g. "I feel anxiety about something or someone almost all the time") that are answered on a 5-point Likert scale ranging from zero ("false") to four ("true"). The total score ranges from 0 to 16, with a high score indicating a high level of anxiety (see Appendix A for the complete version of the ANX4). The 4-item ANX4 was administered at baseline in the WEBCARE cohort.

2.3.3. Generic anxiety measures

Besides the newly developed ANX4, three generic questionnaires were administered at baseline and used to assess construct validity.

2.3.4. STAI-S

The State version of the State-Trait Anxiety Inventory (STAI-S) is used to assess general symptoms of anxiety, such as worries, concerns and tension [30]. The STAI-S is a self-report questionnaire, consisting of two 10-item subscales measuring the presence (e.g. "I am worried") and absence of anxiety (e.g. "I feel calm"). Items are answered on a 4-point Likert scale ranging from 1 ("not at all") to 4 ("very much so"), with total scores ranging from 20 to 80 and higher scores indicating higher anxiety levels. A predetermined cut-off score of ≥ 40 is used to indicate the presence of probable clinical levels of symptoms of anxiety [30]. The STAI-S has shown to be a reliable, valid measure of anxiety with Cronbach's α ranging from 0.87 to 0.92 [30] and has been previously used to assess anxiety in ICD patients [5,11,12,24].

2.3.5. GAD-7

The 7-item General Anxiety Disorder (GAD-7) scale is also used to assess symptoms of anxiety [31]. The GAD-7 is a 7-item self-report questionnaire, assessing anxiety symptoms in the past two weeks (e.g. "Feeling nervous, anxious, or on the edge"). Items are answered on a 4-point Likert scale ranging from 0 ("not at all") to 3 ("almost every day"). The total score ranges from 0 to 21 with higher scores indicating higher levels of anxiety. A cut-off score of ≥ 10 is used as an indication of probable clinical levels of anxiety [31]. The GAD-7 has shown to be a reliable, valid measure of anxiety, with a Cronbach's α of 0.92 and an intraclass correlation of 0.83 [31]. The GAD-7 has previously been used to assess anxiety in ICD patients [5,20].

2.3.6. HADS

2.3.6.1. Anxiety. The 7-item anxiety subscale (e.g. "I feel tense or wound up") from the Hospital Anxiety and Depression Scale (HADS-A) was also used to assess anxiety symptoms [28]. The HADS-A is a self-report questionnaire consisting of 7-items, which are answered on a 4-point Likert scale from 0 to 3. The total score ranges from 0 to 21 with a higher score indicating more symptoms of anxiety. A predefined cut-off score of ≥ 8 indicates probable clinical levels of symptoms of anxiety [28]. The HADS-A has shown to be a reliable, valid measure of anxiety, and has been previously used to assess anxiety in ICD patients [5,14].

2.3.6.2. Depression. Depression was assessed using the 7-items subscale (e.g. "I feel as if I am slowed down") of the above described HADS questionnaire. The items on this subscale are also answered on a 4-point Likert scale from 0 to 3, with the total score range from 0 to 21. A cut-off score of ≥ 8 indicates probable levels of depression symptomatology [28].

2.4. ICD concerns

The Dutch version of the ICD Patient Concerns questionnaire (ICDC) is used to measure patients' concerns about the ICD, which is associated with ICD patients' anxiety level [32]. The ICDC is a self-report questionnaire consisting of 8 items (e.g. "I'm worried that my ICD will fire") rated on a 5-point Likert scale ranging from 0 ("not at all") to 4 ("very much"). The total score ranges from 0 to 32 with higher scores indicating higher levels of concern, associated with higher levels of anxiety [32]. The ICDC has shown to be an internal consistent scale with a Cronbach's α of 0.94 [32] and has been previously used to assess patients' concerns related to the ICD [14,19]. The ICDC was also administered at baseline.

2.5. Health status

The Dutch version of the Short-Form Health Survey 12 (SF-12) is a

self-report questionnaire and is a generic measure of health status [33]. The SF-12 consists of 12 items measuring physical and mental quality of life, as indicated by the Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score. Scores on both scales range between 0 and 100, with a higher score indicating better physical or mental functioning [33]. The SF-12 has shown to be a valid and reliable measure [33,34]. The SF-12 was administered 12-months post ICD implantation.

3. Statistical analyses

Groups were compared on continuous variables with the Student's *t*-test and are presented as means with standard deviations (*SD*), while discrete variables were compared with the X^2 test and are presented as numbers and percentages. If a questionnaire had < 20% missings, data were imputed using the mean score of the patient.

Objective 1: To address the first objective of the study, only baseline data were used (sample 1). To examine the factor structure of the scale, principal component analysis (PCA) was used, after the assumptions were checked. The number of extracted principal components was based on the scree plot and Kaiser's criterion of eigenvalues greater than one. Subsequently, the internal consistency of the ANX4 was determined by means of Cronbach's α and the convergent validity was assessed by calculating Pearson correlations between the ANX4 and three existing generic measures of anxiety symptoms, STAI-S, GAD-7, HADS-A and one disease-specific measure, the ICDC. Divergent validity was assessed by calculating the Pearson correlation between the ANX4 and the HADS-D questionnaire.

Objective 2: For the second objective, univariable and multivariable linear regression analyses were used to examine the association between anxiety symptoms at baseline assessed by the ANX4, and physical (PCS) and mental (MCS) health status 12-months post ICD implantation (sample 2). In multivariable analyses, these associations were adjusted for demographic (age, gender, marital status, educational level, employment), clinical (ICD indication, heart failure, NYHA functional class, CCI) and medication (i.e., beta-blockers and psychotropic medication). Data analyses are performed with SPSS version 23.0. All tests are two-tailed and a *p*-value < .05 is used to indicate statistical significance.

4. Results

4.1. Patient characteristics

A total of 1024 consecutive ICD implanted patients were approached for participation. 492 (48%) were excluded for not meeting the inclusion criteria, while an additional 192 (36%) refused to participate (due to time constraints, not needing help, too much work/too sick, having to deal with other issues). Of the remaining 340 patients, 52 did not return their baseline measures or lacked information on demographic variables in order to be included in the current analysis. Hence, of all patients included in the WEBCARE trial, 84.7% (288/340) could be included as *sample 1* in the statistical analyses for the first objective. As compared to patients who were excluded from the current analyses, significant differences were only observed in the use of psychotropic medication, with less patients using psychotropic medication being included in the current analysis compared to being excluded (7% vs 25%; $p \leq .001$). To assess the second objective of the current study, 62.4% (212/340) of all patients included in the WEBCARE trial could be included as *sample 2* in the current analyses. The reason for excluding 125 patients (36.8%) was missing data on the SF-12 questionnaire administered 12-months after baseline. Of these 125, 52 patients (41.6%) were also excluded in sample one. The remaining three patients (0.9%) were excluded due to not representing the target population because of significant outliers. Patients who were excluded had a lower mean age ($M = 57$ vs 59; $p = .021$), more often had a job

Table 1
Baseline characteristics of *sample 1* and *sample 2*.

Variable	Sample 1 (N = 288)	Sample 2 (N = 212)
	Mean ± SD; N (%)	Mean ± SD; N (%)
Demographics		
Age	58 ± 10.0	59 ± 9.8
Gender (male)	234 (81.3)	174 (82.1)
Partner (yes)	243 (84.4)	180 (84.9)
Education (high)	207 (71.9)	157 (74.1)
Employment (yes)	147 (51.0)	95 (44.8)
Clinical		
ICD indication (secondary)	90 (31.3)	70 (33.0)
Heart failure (yes)	156 (54.2)	118 (55.7)
NYHA functional class III or IV	45 (15.6) ^{N=231}	34 (16.0) ^{N=170}
LVEF ≤ 35%	183 (63.5) ^{N=242}	142 (67.0) ^{N=181}
CCI	1.69 ± 1.04	1.69 ± 1.08
Medication		
Beta-blockers	236 (81.9)	173 (81.6)
ACE-inhibitors	179 (62.2)	135 (63.7)
Statins	181 (62.8)	134 (63.2)
Diuretics	146 (50.7)	107 (50.5)
Psychotropic medication	20 (6.9)	11 (5.2)
Psychological		
Anxiety (ANX4)	2.1 ± 3.1	2.0 ± 3.1
Anxiety (STAI-S)	35.3 ± 10.3	34.3 ± 9.9
Anxiety (GAD-7)	4.3 ± 4.5	4.1 ± 4.4
Anxiety (HADS-A)	4.6 ± 3.3	4.4 ± 3.1
Depression (HADS-D)	3.5 ± 3.0	3.4 ± 2.9
ICD concerns (ICDC)	6.3 ± 6.5	6.3 ± 6.5
Physical health status (PCS)	–	45.7 ± 11.9
Mental health status (MCS)	–	49.1 ± 10.6

NYHA functional class = New York Heart Association; LVEF = Left ventricular ejection fraction; CCI = Charlson Comorbidity Index; PCS = Physical Component Score; MCS = Mental Component Score.

(60% vs 45%; $p = .027$) and more often used psychotropic medication (17% vs 5%; $p \leq .001$), compared to included patients.

The mean age of the two samples was 58 years ($SD = 10.0$; sample 1) and 59 years ($SD = 9.8$; sample 2) and 81.3% and 82.1% were men in sample 1 and 2, respectively. For a detailed description of the two samples see [Table 1](#).

4.2. ANX4

PCA was conducted on the 4-item ANX4. The suitability of PCA was assessed prior to the analysis. As such, inspection of the correlation matrix showed that all variables had at least one correlation coefficient greater than 0.3. Besides, the overall Kaiser-Meyer-Olkin (KMO) measure was 0.835 with individual KMO measures all > 0.8 , which is well above the limit of 0.5. The significance of Bartlett's test of sphericity $\chi^2(6) = 701.08$, $p < .001$ showed that correlations between items were sufficiently large for PCA. In sum, all indicators showed that it was appropriate to proceed with the analysis. PCA revealed one component having eigenvalues greater than one (3.077), suggesting a 1-factor structure, explaining 76.9% of the total variance. Additionally, visual inspection of the scree plot ([Fig. 1](#)) indicated a 1-factor structure. Second, the ANX4 with its 1-factor structure had a high level of internal consistency, as indicated by a Cronbach's α of 0.89. Factor 1 and its loadings are shown in [Table 2](#), together with the reliability coefficients. Third, [Table 3](#) presents the results of the convergent and divergent validity analyses, as the ANX4 was administered with four other scales measuring anxiety (i.e., STAI-S, GAD-7, HADS-A and ICDC) and depression (HADS-D) symptoms. Preliminary analyses showed the relationships to be linear with the ANX4 and the other scales. All were normally distributed and there were no outliers. The correlations between the total score of the ANX4 and the total scores of the STAI-S, GAD-7, HADS-A and ICDC were in the expected directions and all were statistically significant ($p < .001$). Besides, all correlations were large

($r = 0.62$, 0.58 and 0.66 , respectively), except for the moderate correlation ($r = 0.44$) between the ANX4 and the ICDC questionnaire. The correlations between the other anxiety measures (STAI-S: $r = 0.46$; GAD-7: $r = 0.47$; HADS-A: $r = 0.55$) and ICDC were slightly higher indicating that ANX4 shows less overlap with disease specific anxiety symptoms.

4.3. Association between anxiety and health status 12-months post ICD implantation

Univariable regression analysis showed that anxiety (ANX4) at baseline was a significant correlate of *physical health status* 12-months post ICD implantation, $F(1,210) = 25.527$, $p < .001$. Anxiety at baseline was also significantly correlated with *mental health status* 12-months post ICD implantation ($F(1,210) = 82.792$, $p < .001$). Adjusting for age, gender, marital status, education level, employment, ICD indication, heart failure, NYHA functional class, LVEF $\leq 35\%$, beta-blockers, psychotropic medication and CCI in multivariable analysis, anxiety remained a significant correlate of *physical health status* ($\beta = -0.276$; $p < .001$) and *mental health status* ($\beta = -0.551$; $p < .001$) 12-months post ICD implantation. A more detailed description of the associations with physical and mental health status is displayed in [Table 4](#). In addition, a significant association between STAI-S, HADS-A, and GAD-7 with physical and mental health status at 12 months was observed, while ICDC was only associated with mental health status (data not shown). This further underlines that ANX4 taps into generic anxiety symptoms.

5. Discussion

The newly developed 4-item ANX4 appears to be a valid scale to measure anxiety symptoms in the ICD population. All four items in the ANX4 were related to the construct of anxiety and fitted into a one-factor model with a high internal consistency ($\alpha = 0.89$). The evidence for validity is supported by the finding of significant correlations of the ANX4 with already existing, generic measures of anxiety symptoms, the STAI-S [30], GAD-7 [31], HADS-A [28] and a low correlation with the disease-specific ICDC questionnaire [32] and the HADS-D questionnaire. The low correlation with the ICDC and the HADS-D questionnaire, reflects the divergent validity of the instrument and supports the purpose of developing the ANX4 as a generic measure for anxiety symptoms, instead of a disease-specific measure. Furthermore, results showed that the correlations between the other anxiety measures and the ICDC questionnaire were slightly higher as compared to the correlation between ANX4 and ICDC. These findings suggest that the ANX4 could be used in the ICD population but also in a wider medical population, although this needs to be confirmed in future studies.

Furthermore, our findings showed that the ANX4 can be used to identify ICD patients with poor health status at least up to 12 months' follow-up, as the experience of anxiety symptoms at time of ICD implantation was significantly associated with a lower physical and mental health status 12-months post implantation, even after adjustment for demographic and clinical variables. These findings are in line with previous literature that showed that anxiety symptoms assessed shortly after ICD implantation are associated with health status on the long-term [13]. Current findings add to existing literature by demonstrating that a specific anxiety questionnaire, without confounding psychiatric and/or somatic symptoms of anxiety is predictive of health status at 12 months follow-up.

Although existing questionnaires show good validity, the major shortcoming is that these questionnaires might measure different constructs of anxiety [15]. Hence, development of a specific anxiety measure with items that are only related to general anxiety symptoms as reported by the general community was of utmost importance. The ANX4 is not confounded by underlying disease symptoms hence, it can be used (although subject to more research) in various populations

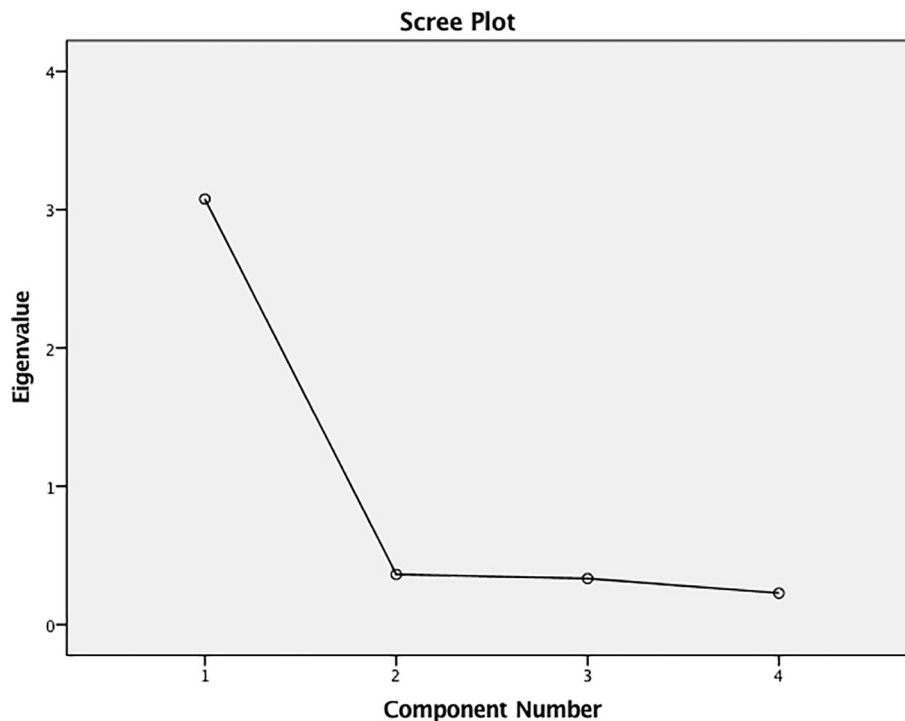


Fig. 1. Scree plot of eigenvalues for the ANX4.

which would increase the comparability between samples.

The importance of identifying anxiety symptoms in ICD patients at an early stage is highlighted by previous studies demonstrating the existence of a subgroup of ICD patients who experience (sub)clinical anxiety symptoms [6], and the knowledge that these symptoms are associated with an increased risk of VTa's [10–12] and even mortality [10,11]. The association between anxiety and, in particular, VTa's can be explained through the activation of the sympathetic arousal which can result in a cardiac event [35]. In the ICD population these results have to date been mixed which could partially be attributed to the use different measures, reflecting different constructs, to assess anxiety in the previous studies. Hence, this further underlines the need for a specific anxiety measure which taps into the core general construct of anxiety.

The majority of patients who experience psychosocial problems after ICD implantation seem to remain underdiagnosed and untreated [8], partly due to health care professional time constraints (e.g. time associated with identifying patients with anxiety) and the deficiency of skills in psychological matters [36]. The brief and valid ANX4 may fill this gap in the measurements that we have available in clinical practice to identify patients experiencing anxiety symptoms in order to offer this subgroup early specified treatment. A recent study showed that cognitive behavioural therapy might be the way forward in order to reduce anxiety levels in this population [22]. Future studies are warranted to replicate the validity of the ANX4 as a screening instrument for anxiety symptoms in other medical populations and to determine the cut-off

Table 2
Factor loadings and internal consistency of the ANX4.

Factor	Factor loadings	Cronbach's α if item deleted	Item-total correlation	Cronbach's α
Factor 1: Anxiety symptoms				0.894
1 I am often anxious or worried for no good reason.	0.852	0.880	0.741	
2 I am bothered by thoughts and images that frighten me.	0.872	0.863	0.766	
3 I feel anxiety about something or someone almost all the time.	0.899	0.855	0.807	
4 Sometimes, I feel jumpy or panicky for no good reason.	0.884	0.858	0.780	

ANX4 = 4-item Anxiety Scale.

Table 3
ANX4 convergent/divergent validity (n = 288).

	Pearson correlation (r)
Correlation among the ANX4 and:	
STAI-S	0.62**
GAD-7	0.58**
HADS-A	0.66**
ICDC	0.44**
HADS-D	0.50**

ANX4 = 4-item Anxiety Scale; STAI-S = State version of the State-Trait Anxiety Inventory; GAD-7 scale = General Anxiety Disorder scale; HADS-A = Hospital Anxiety and Depression Scale - Anxiety subscale; ICDC = ICD Patient Concerns questionnaire; HADS-D = Hospital Anxiety and Depression Scale -Depression subscale.

The significant of italics refers to correlations of questionnaires that were assessed to demonstrate divergent validity of the ANX4.

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

score for the scale for patients who need referral to treatment.

The main limitation of this study is that the relatively small sample of patients may limit the generalizability of the findings, especially in the association between anxiety symptoms and health status 12-months post ICD implantation, given the high dropout rate. Second, the current data were collected as part of the WEBCARE trial, in which patients in the intervention group participated in an online behavioural treatment, implicating that there might have been a selection bias towards more

Table 4

Association between anxiety at baseline (ANX4) and physical and mental health status (SF-12) 12-months post ICD implantation, adjusted for demographic and clinical variables (multivariable analyses).

	Physical health status (SF-12-PCS)			Mental health status (SF-12-MCS)			
	β	SE_B	<i>p</i>	β	SE_B	<i>p</i>	<i>p</i>
ANX4	-0.276	0.33	< 0.001	-0.551	0.26	< 0.001	
Age	0.131	0.13	0.23	0.070	0.10	0.43	
Gender	-0.092	2.61	0.31	-0.047	2.09	0.53	
Marital status	-0.053	2.48	0.85	-0.049	1.98	0.47	
Education level	-0.039	2.13	0.87	-0.027	1.71	0.69	
Employment	0.216	2.35	0.024	0.067	1.88	0.44	
ICD indication	0.035	2.49	0.80	0.112	1.99	0.16	
Heart failure	0.012	2.39	0.86	0.137	1.91	0.10	
NYHA functional class	-0.204	2.34	0.013	-0.097	1.87	0.18	
LVEF \leq 35%	-0.027	2.87	0.98	-0.013	2.30	0.87	
Beta-blockers	0.013	2.52	0.94	0.009	2.02	0.89	
Psychotropic med.	-0.035	4.08	0.62	0.019	3.27	0.77	
CCI	-0.229	0.92	0.005	-0.223	0.74	0.002	

β = standardized regression coefficient; SE_B = standard error of the coefficient; NYHA functional class = New York Heart Association; LVEF = Left Ventricular Ejection Fraction; CCI = Charlson Comorbidity Index.

Bold refers to significant predictors of physical and mental health status.

motivated patients participating in the study. This may also result in reduced generalizability of the findings. Third, current database did not allow for a robust examination of divergent validity of the ANX4 as there was no information on constructs that were not related to anxiety, depression, and quality of life. Finally, the ANX4 validation was performed only at one point in time, hence, nothing can be said about the test-retest reliability of the scale in relation to the overall validity. This study also has several strengths, as it is the first study to investigate the validity and factor structure of a 4-item measure of anxiety symptoms in ICD-patients. The findings that the ANX4 has good psychometric properties and the correlation of the scale with health status on the long-term, are the first steps in introducing this scale in the medical population as a screening instrument for anxiety symptoms. Other strengths of the current study include the prospective study design, the relative long follow-up period of 12-months, and the inclusion of a considerable number of relevant demographic and clinical variables in the statistical analysis that may influence the association between anxiety and well-being.

In conclusion, the current findings indicate that the brief and novel 4-item ANX4 is a valid measure of anxiety symptoms in ICD patients. Due to its brevity, this scale could easily be used in clinical practice as a

screening instrument to assess patients' anxiety symptoms with the possibility of identifying patients who are in need of extra psychological care in order to prevent adverse outcomes and improve health status on the long-term. Future research needs to replicate the current findings, determine the cut-off score of the scale and the best moment to screen, examine the effect of earlier treatment on adverse outcomes and health status and investigate whether the use of the ANX4 as a screening instrument might also be usable in other medical populations.

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Declaration of Competing Interest

None declared.

Appendix A

A.1. ANX4

Below are a number of statements that people often use to describe themselves. Please read each statement and then **circle** the appropriate **number** next to that statement to indicate your answer.

	0 = false	1 = mostly false	2 = neutral	3 = mostly true	4 = true
¹ I am often anxious or worried for no good reason				0 1 2 3 4	
² I am bothered by thoughts and images that frighten me				0 1 2 3 4	
³ I feel anxiety about something or someone almost all the time				0 1 2 3 4	
⁴ Sometimes, I feel jumpy or panicky for no good reason				0 1 2 3 4	

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