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CLINICAL RESEARCH

Course of anxiety and device-related concerns in implantable cardioverter defibrillator patients the first year post implantation

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Aims Implantable cardioverter defibrillators (ICDs) are well accepted by most patients, but 25–33% of patients are anxious and report device-related concerns. Previous studies focused on prevalence rates and mean scores, whereas the course of anxiety over time is unknown in individual patients. We examined the trajectory of anxiety in ICD patients during a 1-year period and determinants of these trajectories.

Methods and results Consecutive patients (N = 348) implanted with an ICD completed standardized measures of general anxiety and device-related concerns at five assessment occasions and the Type D Scale at baseline. Type D personality is defined by increased negative emotions and the inhibition of these emotions in social interactions. Seven trajectories were identified for state and trait anxiety and eight for device-related concerns. The course of the trajectories for general anxiety was stable over time, whereas device-related concerns showed more fluctuation, with a decrease in concerns generally spread out during the 1 year. Type D personality and social support were determinants of trajectory membership for general anxiety (all $P \leq 0.002$), whereas Type D ($P = 0.001$), social support ($P = 0.02$), and ICD shock ($P < 0.001$) determined trajectory membership for device-related concerns.

Conclusion The course of general anxiety in ICD patients was stable the first year post implantation, whereas device-related concerns fluctuated more. Type D personality and social support were determinants of trajectory membership for all outcomes, whereas ICD shock was related to device-related concerns only. A simple pre-implant screening may help identify patients at risk for high-distress trajectory membership.

Keywords Anxiety • Device-related concerns • Implantable cardioverter defibrillator • Trajectories

Introduction

Implantable cardioverter defibrillator (ICD) therapy is now the treatment of choice in patients at high risk for sudden cardiac death and has been shown to be superior to anti-arrhythmic drugs as both primary and secondary prevention.[1] Nevertheless, ICD therapy is associated with a number of complications, including inappropriate shocks, device advisories due to potential hardware malfunctioning of the device, or the associated leads, which in turn may have an adverse impact on patients' well-being and quality of life and also on prognosis.[2,3]

Anxiety and device-related concerns are the most studied patient-centred outcomes in ICD patients,[4,5] likely due to the ICD being able to provide a shock to terminate life-threatening ventricular arrhythmias, which is a distinguishing feature of ICD therapy compared with any other medical intervention available to treat heart disease. Although the majority of patients tend to adjust well to living with an ICD, with distress usually decreasing during the first year after implantation,[4,6] 25% of patients have difficulty with adjustment and experience probable levels of clinical anxiety and depression.[4] Anxiety and general psychological distress in ICD patients may have adverse effects on health outcomes, with distress precipitating arrhythmic events.[7–9]

In the context of ICD therapy, anxiety is generally studied by means of prevalence rates or changes in mean scores over time. However, such an approach may mask subgroups of patients

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with different courses of anxiety over time, who may have a differential risk of adverse health outcomes, which has been shown in post-myocardial infarction (MI) patients[10] and patients treated with percutaneous coronary intervention (PCI).[11] The demographic, clinical, and psychological determinants of the courses of distress may also differ,[11] with knowledge of these determinants being helpful in risk stratification and allocation of adjunctive psychological treatment to those patients who may need it the most. Therefore, the objectives of the current study were to examine the trajectories of anxiety in ICD patients during a 1-year period and the determinants of these trajectories, using a prospective study design.

Methods

Patients and study design

A consecutive series of patients implanted with an ICD (N = 348) between August 2003 and May 2008 at the Erasmus Medical Center, Rotterdam, The Netherlands, comprised the sample for the current study. All patients participated in the ongoing *M*ood and Personality as Precipitants of Arrhythmia in Patients with an *I*mplantable Cardioverter *D*efibrillator: *A* Prospective *S*tudy (MIDAS), which was primarily designed to investigate the impact of mood and personality on arrhythmias in ICD patients. Patients with a life expectancy of <1 year, on the waiting list for heart transplantation, with a history of psychiatric illness other than affective/anxiety disorders, or with insufficient knowledge of the Dutch language were excluded from the study.

An ICD nurse approached all patients for participation in the study and asked them to complete a set of standardized and validated psychological questionnaires and purpose-designed questions at five time points: (a) 1 day prior to ICD implantation (baseline), (b) 10 days post implantation, (3) 3 months post implantation, (4) 6 months post implantation, and (5) 1 year post implantation. The MIDAS study protocol was approved by the Medical Ethics Committee of the Erasmus Medical Center. The study was conducted to conform to the ethical tenets developed by the World Medical Association, as espoused in the Declaration of Helsinki. All patients provided written informed consent.

Measures

Baseline demographic and clinical variables

Demographic and clinical variables were obtained at baseline. Demographic variables included sex, age, marital status, education, smoking, and previous traumatic event, which were obtained from the patients' medical records or through purpose-designed questions. Information on clinical variables was obtained from the patients' medical records and included aetiology of cardiac disease, coronary artery disease (CAD), previous MI, congestive heart failure (CHF), previous PCI, previous coronary artery bypass graft surgery, New York Heart Association (NYHA) functional class, left ventricular ejection fraction (LVEF), ICD type, cardiac resynchronization therapy, indication for ICD therapy (primary vs. secondary), diabetes mellitus, QRS duration, and cardiac medication. Information on the use of psychotropic medication was obtained through a purpose-designed question.

Delivered implantable cardioverter defibrillator therapy during follow-up

Follow-up started at the time of ICD implantation. All patients were regularly followed at 3-month intervals and were advised to contact our outpatient clinic after a symptomatic event as soon as possible. All spontaneous episodes with stored electrograms that resulted in ventricular therapies were reviewed and classified by two experienced electrophysiologists from the EP staff of the Erasmus Medical Center. In the case of disagreement between the two reviewers about the stored electrograms, a third one was consulted and a consensus was reached. For each episode, the date, type, the mean cycle length of the tachyarrhythmia, and the type and outcome of delivered ICD therapy were recorded. The arrhythmias were classified as ventricular tachyarrhythmia (VT) or atrial tachyarrhythmia without a coexistent ventricular arrhythmia. Therapy triggered by VTs was considered appropriate, whereas therapy delivered for atrial tachyarrhythmias (including atrial fibrillation, atrial flutter, atrial tachycardia, and sinus tachycardia) or T-wave oversensing and noise was defined inappropriate.

Psychological measures

State Trait Anxiety Inventory

Anxiety was assessed with the 40-item State Trait Anxiety Inventory (STAI), with 20 items contributing to the state and trait scale, respectively.[12,13] State anxiety is assumed to fluctuate over time, whereas trait anxiety is considered to be more stable. All items are rated on a 4-point Likert scale from 1 (not at all) to 4 (very much so), with a score range of 20–80. A high score indicates high levels of anxiety, with a score ≥40 indicating probable levels of clinical anxiety.[12,13] The STAI is a valid and reliable scale, with Cronbach's α ranging from 0.87 to 0.92.[12] The STAI was administered at baseline, 10 days, 3 months, 6 months, and 1 year.

ICD Patient Concerns Questionnaire

Device-related concerns were measured with the eight-item ICD Patient Concerns (ICDC) questionnaire.[14] The ICDC was originally developed in the UK[15] and later adapted and abbreviated for the Dutch setting.[14] The eight items (e.g. *'I am worried about my ICD firing'* and *'I am worried about symptoms/pain associated with my ICD firing'*) are rated on a 5-point Likert scale from 0 (not at all) to 4 (very much so), with a score range of 0–32 and a higher score indicating more device-related concerns.[14] The internal consistency of the eight-item ICDC is good, with Cronbach's $\alpha = 0.91$.[14] The ICDC was administered at baseline, 10 days, 3 months, 6 months, and 1 year.

Type D Scale (DS14)

The 14-item Type D Scale (DS14) was administered to assess the *distressed* (Type D) personality.[16] The DS14 comprised two seven-item subscales: negative affectivity (e.g. *'I often feel unhappy'*; seven items) and social inhibition (e.g. *'I am a closed kind of person'*; seven items). Items are answered on a 5-point Likert scale ranging from 0 (false) to 4 (true), with a score range of 0–28 for both subscales.[16] The DS14 is a valid and reliable measure, as shown by its high internal consistency (i.e. Cronbach's α of 0.88/0.86) and 3-month test–retest reliability (i.e. $r = 0.72/0.82$) for the negative affectivity and social inhibition subscales, respectively.[16] Type D caseness is determined by means of a standardized cut-off ≥10 on both subscales.[16,17] The DS14 was originally developed in cardiac patients, with the prevalence of Type D personality in cardiac patients ranging from 25 to 33%.[18] Type D patients have a higher risk of morbidity and mortality, with the risk being four-fold independent of biomedical risk factors and mood states such as anxiety and depression.[18] The DS14 is a stable measure over an 18-month period[19] and is not confounded by cardiac disease severity and measures of anxiety and depression.[19,20] It is the combination of the two traits, negative affectivity and social inhibition, rather than the single traits that is associated with adverse health outcomes.[21] The DS14 was administered at baseline.

Multidimensional Scale of Perceived Social Support

Social support was assessed with the 12-item Multidimensional Scale of Perceived Social Support (MSPSS), with the items contributing to three subscale scores for *family*, *friends*, and *significant others*, and a total score.[22,23] Each item is answered on a 7-point Likert scale from 1 (very strongly disagree) to 7 (very strongly agree). The psychometric properties of the scale are adequate, with test–retest reliability (2–3 months) for the subscales and the total scale ranging from 0.72 to 0.85 and Cronbach's α ranging from 0.81 to 0.98 in non-clinical samples.[22,23] In a recent study of a mixed Dutch and Danish sample of ICD patients, partners of ICD patients, and patients with CHF, we confirmed the factor structure of the MSPSS and found a Cronbach's α for the total scale of 0.94.[24]

Statistical analysis

A number of hierarchical, latent class regression models using Latent GOLD 4.0[25] were fit to examine the course of anxiety around and following ICD implantation and to determine how many latent classes (i.e. anxiety trajectories) may be identified. As the distributions of STAI-state, STAI-trait, and ICD concern scores were all left censored normal distributions, they were treated as continuous, censored dependent variables. Time was entered as a predictor. We compared eight models with an increasing number of trajectories (1–8). When a stable model was identified, values of the Bayesian Information Criterion (BIC)[26] of each model was compared, and the model with the lowest BIC was preferred, as this then is the most parsimonious solution.

In a next step, potential determinants of trajectory membership were added as predictors. These were Type D personality, social support, indication for ICD (primary or secondary), ICD shock (either appropriate or inappropriate), diabetes, and CHF. Because depression and anxiety are highly co-morbid with a general prevalence of co-morbid depression and anxiety of 50–60%[27] and because of the large amount of shared genetic aetiology of depression and anxiety,[28,29] we decided to exclude depression as a potential determinant of anxiety trajectories. In all tests described earlier, the Wald test (equivalent to a likelihood ratio test) was used to evaluate the statistical significance of each regression coefficient in the model. The Wald test compares the Wald statistic to a normal χ^2 distribution, resulting in an indication of the significance of an effect (*P*-value).

Finally, we examined the determinants of each individual trajectory by multinomial regression analysis in SPSS 17.0. To this end, we first exported trajectory membership data for each participant and each variable from Latent GOLD to SPSS. Then, we re-organized trajectories for each anxiety outcome, so that the lowest trajectory number represented the lowest anxiety level and the highest cluster number represented the highest anxiety level at baseline. The lowest two anxiety trajectories were used as reference category, because of the limited number of patients in these two trajectories. Descriptive statistics were obtained with SPSS 17.0.

Results

Patient characteristics

Table 1 summarizes the baseline characteristics of the 348 patients. Patients who refused to participate did not differ systematically from those who participated with respect to age, sex, indication for ICD implantation, and number of shocks received. Depending on the analysis, two to four participants were excluded because of too many missing values. Type D personality prevalence was 23%. Mean levels of anxiety and device-related concerns are presented in *Table 2*. The mean difference between the highest and lowest scores during the 1-year follow-up period was 4.5 for state anxiety, 2.7 for trait anxiety, and 4.5 for device-related concerns.

Table 1 Baseline patient characteristics

N (at implantation)	348
Demographics	
Sex (% male)	79
Age	57.7 (12.1)
Marital status (% w/o partner)	6.6
Higher educational level (%)	39.1
Smoking (%)	11.7
Traumatic event (%)	45.3
Disease characteristics	
Aetiology (idiopathic/ischaemic/hypertrophic) (%)	23.7/32.9/6.1
ICD type (% dual chamber)	53.2
CRT (%)	26.7
Indication (% primary)	60.1
Comorbidity	
Diabetes mellitus (%)	10.3
Cardiac history	
CAD (%)	58.5
Previous MI (%)	50.4
CHF (%)	38.3
Interventions	
PCI (%)	21.3
CAGB (%)	18.8
Cardiac function	
NYHA III–IV (%)	31.5
LVEF	28.5 (10.9)
QRS duration (ms)	130.3 (37.0)
Medication	
Amiodarone (%)	20.5
Beta-blockers (%)	77.5
Digitalis (%)	15.6
Statins (%)	55.7
ACE inhibitors (%)	71.6
Calcium antagonists (%)	2.4
Class I anti-arrhythmic drugs (%)	0.3
Psychotropic medication (%)	18.1

ACE inhibitors, angiotensin-converting enzyme inhibitor; CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; CHF, congestive heart failure; CRT, cardiac resynchronization therapy; MI, myocardial infarction; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association functional class; PCI, percutaneous coronary intervention.

At baseline, trait and state anxiety were highly correlated ($r = 0.73$, $P < 0.001$), whereas scores on trait anxiety ($r = 0.45$, $P < 0.001$) and state anxiety ($r = 0.56$, $P < 0.001$) were less strongly correlated with scores on device-related concerns. There was a high concurrence between average levels of state anxiety scores (Cronbach's $\alpha = 0.90$), trait anxiety (Cronbach's $\alpha = 0.92$), and device-related concerns (Cronbach's $\alpha = 0.89$) over time. Spearman correlations showed a significant relation of 0.26 ($P <$

Table 2 Mean (SD) anxiety levels at all measurement occasions for the total patient group

	Baseline	10 days post implant	3 months post implant	6 months post implant	1 year post implant
Generic anxiety					
STAI state	39.3 (10.8)	35.8 (10.0)	35.3 (10.8)	34.8 (10.3)	34.8 (10.7)
STAI trait	36.9 (11.4)	34.9 (11.4)	34.5 (11.9)	34.2 (11.5)	34.4 (12.1)
Disease-specific anxiety					
Device-related concerns	10.3 (7.7)	8.3 (7.6)	6.8 (7.2)	5.9 (6.5)	5.8 (6.9)

0.001) between patient trajectory membership for state and trait anxiety. In 21% of the patients, state anxiety reached the level of probable clinical anxiety, whereas in 39%, trait anxiety reached probable clinical levels.

During the 1-year follow-up period, 18.4% ($n = 64$) of the patients experienced appropriate ICD therapy delivered for a VT. Of these, 24 had 1 VT episode terminated with ICD therapy during the follow-up period, whereas 10 had 2 VT episodes and 16 had between 3 and 10 VT episodes treated by the device. The remaining 14 patients had 11–145 VT episodes followed by appropriate therapy. In 32 cases, between 1 and 8 VT episodes were followed by inappropriate therapy. Appropriate shocks were delivered in 35 patients (10%), of which 30 occurred during the first 6 months post implantation. Inappropriate shocks were delivered 16 times (4.6%) over the 1-year period.

State anxiety

Trajectories

Analysis with Latent GOLD identified the presence of seven trajectories for state anxiety in the best-fitting model (*Table 3*; *Figure 1A*). Time had a significant effect on the trajectories (Wald statistic = 70.10, $P < 0.001$), which was equal for all trajectories when compared with a model in which the effect of time was free to differ between trajectories ($\Delta BIC = -13.65$), making the difference in intercept the most important characteristic of the seven classes. The largest trajectory contained 31% of the patient population and the smallest trajectory 3%, with the seven trajectories explaining 70% of the total variance (R^2).

Determinants

The latent class regression model showed that of the six potential predictors, Type D personality ($P < 0.001$) and social support ($P < 0.001$) were determinants of state anxiety trajectory membership (a combination of slope and intercept) (*Table 4*). When examining individual trajectories using multinomial regression analysis (SPSS), compared with the reference category, Type D patients had a 3.8 [95% confidence interval (CI) = 1.3–11.5; $P = 0.02$] greater risk of being in the highest state anxiety trajectory (trajectory 7). Type D personality also increased the risk of being in trajectory 6, albeit on the edge of significance [odds ratio (OR) = 3.5, 95% CI = 0.98–12.9; $P = 0.056$]. None of the other determinants placed patients at increased risk for a certain anxiety trajectory.

Table 3 Identification of the number of latent classes using LC regression models for STAI-state, STAI-trait, and device-related concerns

Model	LL	Npar	*n*	BIC
STAI-state				
1 cluster	−5369.55	3	344	10 774.14
2 clusters	−4988.46	7	344	10 029.48
3 clusters	−4885.42	11	344	9840.93
4 clusters	−4845.04	15	344	9777.69
5 clusters	−4826.35	19	344	9757.84
6 clusters	−4812.83	23	344	9748.31
7 clusters	*−4797.62*	*27*	*344*	*9735.41*
8 clusters	−4791.82	31	344	9741.34
STAI-trait				
1 cluster	−5466.11	3	345	10 949.76
2 clusters	−5021.38	7	345	10 083.66
3 clusters	−4887.21	11	345	9838.70
4 clusters	−4831.44	15	345	9750.54
5 clusters	−4800.85	19	345	9712.74
6 clusters	−4772.83	23	345	9679.86
7 clusters	*−4745.53*	*27*	*345*	*9648.84*
8 clusters	−4734.46	31	345	9650.07
Device-related concerns				
1 cluster	−4409.80	3	346	8837.14
2 clusters	−4132.61	7	346	8303.40
3 clusters	−4042.37	11	346	8149.06
4 clusters	−3982.52	15	346	8052.74
5 clusters	−3952.08	19	346	8015.25
6 clusters	−3929.60	23	346	7993.66
7 clusters	−3913.53	27	346	7984.92
8 clusters	*−3900.07*	*31*	*346*	*7981.39*
9 clusters	−3892.58	35	346	7989.78

LL, log likelihood; Npar, number of parameters; *n*, number of patients; BIC, Bayesian information criterion. Italicized rows denote the most parsimonious solution.

STAI-trait

Trajectories

Seven latent classes were identified for trait anxiety, as the seven-class solution fit the data best (*Table 3*; *Figure 1B*). Time had a significant effect on the trajectories (Wald statistic = 43.97, $P <$

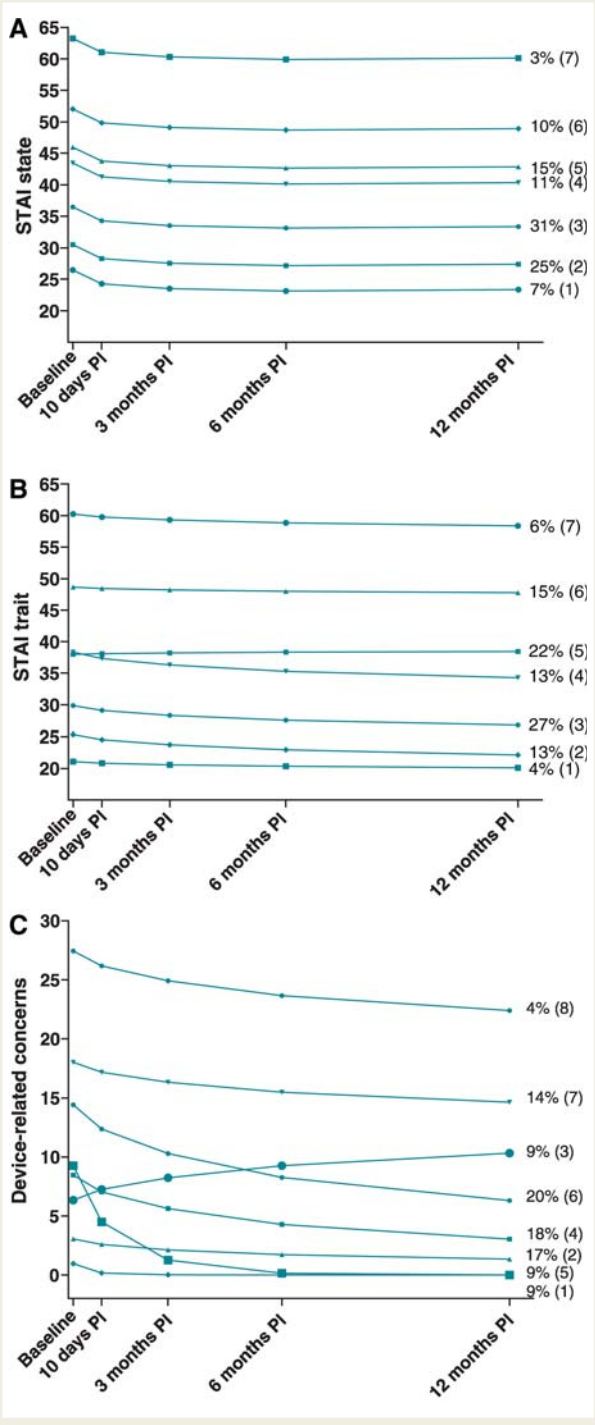

Figure 1 (*A*–*C*) Trajectories of general anxiety and device-related concerns. PI, post implant. Trajectories are counted bottom-up, so that trajectory 1 represents the trajectory with the lowest anxiety scores and 7 or 8 the trajectories with the highest anxiety scores.

0.001), which was equal for all trajectories ($\Delta BIC = -17.9$), making the difference in intercept the most important characteristic of the seven classes. The largest trajectory contained 27% of the patient population and the smallest trajectory 4%, with the overall R^2 being 76%.

Table 4 Determinants of trajectory membership for general anxiety (state and trait) and device-related concerns

Determinants	Wald statistic	*P*-value
STAI-state		
Type D personality	32.88	<0.001
Social support	21.24	0.002
Indication	7.63	0.27
ICD shock	8.86	0.18
CHF	4.32	0.63
Diabetes mellitus	5.44	0.49
STAI-trait		
Type D personality	26.49	<0.001
Social support	30.84	<0.001
Indication	3.26	0.78
ICD shock	6.20	0.40
CHF	3.84	0.70
Diabetes mellitus	2.77	0.84
Device-related concerns		
Type D personality	24.24	0.001
Social support	17.35	0.02
ICD shock	29.65	<0.001
Indication	11.48	0.12
CHF	7.90	0.34
Diabetes mellitus	9.84	0.20

CHF, congestive heart failure.

Determinants

Type D personality ($P < 0.001$) and social support ($P < 0.001$) were independent determinants of trait anxiety trajectory membership (*Table 4*). Multinomial regression analysis showed that patients with a Type D personality had a 2.9-fold (95% CI: 1.5–6.9, $P = 0.02$) increased risk of being in trajectory 5, a factor 3.2 (95% CI: 1.3–8.3, $P = 0.02$) of being in trajectory 6, and a factor 9.9 (95% CI: 3.2–30.3, $P < 0.001$) increased risk of being in trajectory 7 when compared with the reference category. None of the other determinants placed patients at increased risks for a certain anxiety trajectory.

Device-related concerns

Trajectories

The best-fitting solution identified the presence of eight latent classes for device-related concerns (*Table 3*; *Figure 1C*). Time had a significant and differential effect on the trajectories (Wald statistic = 181.02, $P < 0.001$; $\Delta BIC = 25.71$). The largest trajectory contained 20% of the patient population and the smallest trajectory 4%, with the overall R^2 being 0.76.

Determinants

Type D personality ($P = 0.001$), social support ($P = 0.02$), and ICD shock ($P < 0.001$) were identified as determinants of device-related concerns trajectory membership (*Table 4*). Multinomial regression analysis revealed that patients with a Type D

personality had a 6.1 (95% CI: 1.2–32.0, $P = 0.03$) greater risk of having the most device-related concerns (trajectory 8). When patients had received an ICD shock, the chance of being in trajectory 4 (OR = 0.12, 95% CI: 0.02–0.98, $P = 0.048$) was significantly reduced. Social support protected patients from belonging to trajectory 6, a trajectory characterized by relatively high and stable ICD concerns (OR = 0.96, 95% CI: 0.93–0.99, $P = 0.01$).

Trajectories 3 and 5 had the most interesting course, as patients in trajectory 3 showed increasing anxiety over the 1-year follow-up period, whereas those in trajectory 5 showed a relatively steep decline in anxiety. Although there were no significant determinants of these trajectories (potentially because of the limited group sizes), visual inspection of clinical and demographic characteristics of these two patient groups when compared with those in the other trajectories revealed some interesting observations. From the patients whose anxiety dissipated relatively quickly, none received shocks to treat VT/ventricular fibrillation, and fewer patients received appropriate therapy. In addition, these patients took less medication (specifically amiodarone, diuretics, and class I anti-arrhythmic drugs) and had undergone less previous revascularization procedures. Demographically, close to 95% of the patients lived together with a partner or were married, at least 15% more than in other trajectories.

Patients whose anxiety levels increased over the follow-up period (trajectory 3) had experienced the most appropriate shocks of all trajectories, had experienced a traumatic event as frequent as the highest anxiety trajectories, more frequently had a history of CAD, and had experienced an MI in the past as often as the patients in the highest anxiety trajectories.

Discussion

To our knowledge, this is the first study in patients at risk for life-threatening arrhythmias treated with cardioverter-defibrillator therapy to have examined the course of anxiety during a 1-year period and the determinants of these trajectories. In contrast to the traditional approach used in the arrhythmia research of studying changes in prevalence rates and mean scores, the derivation of trajectories is advantageous, as it allows for the identification of patients who may have a differential risk of adverse health outcomes, as shown in post-MI patients.[10]

The number of trajectories identified ranged from 7 for general anxiety (both state and trait) to 8 for device-related concerns. This relatively large number of identified trajectories indicates that there is considerable heterogeneity in terms of the level of anxiety and device-related concerns, with scores varying widely between patients. This heterogeneity would have been masked if we had used the standard approach in arrhythmia research of reporting mean anxiety scores at all measurement occasions during the 1-year follow-up. In previous studies on anxiety and depression trajectories in post-MI and PCI patients, the same heterogeneity has been found, although the number of trajectories ranged from 4 to 5.[10,11,30] Levels of state and trait anxiety reached probable clinical levels in 21 and 39% of the patients, respectively, which corresponds to the previous literature.[4]

The course of the trajectories found in the current study was relatively stable over time for general anxiety, indicating a slight decrease in anxiety between baseline and 10 days post implantation followed by a stable plateau that remained up till 1 year after implantation. For device-related concerns, there was more fluctuation, with decrease in concerns generally being spread out during the 1-year period. The same general stability of anxiety trajectories has been found in cardiac patients treated with PCI,[11] although relatively more fluctuation was seen in depression trajectories in one study of post-MI patients[10] but not in another.[30]

Type D personality and social support were determinants of trajectory membership both for state and trait anxiety and for device-related concerns. ICD shock was an additional determinant for trajectories of device-related concerns. Type D personality has previously been identified as a determinant of psychological distress, poor quality of life, and device acceptance in cardioverter-defibrillator patients and has been shown to cluster together with other psychosocial risk factors to enhance distress in this patient group.[6,31–34] ICD shock was associated with device-related concerns, which is not surprising given that the ICDC questionnaire measuring device-related concerns specifically taps fears related to the ICD giving a shock.[14,15] In an earlier study, we also found that ICD shock was associated with increased device-related concerns.[14] No relationship was found between general anxiety—neither state nor trait—and ICD shock in the current study. This is consistent with a number of studies and clinical trials, challenging the notion that ICD shock necessarily always leads to adverse psychological and quality of life outcomes.[33–36] Social support was protective for ICD concerns.

From a clinical perspective, the relative stability of the trajectories indicates that a simple pre-implantation screening procedure could be adopted in clinical practice as a means of risk stratification to help identify patients at risk for high-distress trajectory membership. This subgroup of patients could be offered an adjunctive psychological intervention either as standalone treatment or in combination with cardiac rehabilitation, which has been shown to be useful in reducing distress and increasing well being in ICD patients.[33,37] Such an approach would also be cost-effective, as the intervention would be offered to those patients who need it the most. Screening could be done with any measures used in the current study, including the 14-item Type D Scale, recommended by others as a valid and reliable instrument for screening for psychosocial risk factors in cardiac patients in clinical practice.[38] Irrespectively of the choice of instrument, it would be relevant to include a disease-specific measure, such as the ICDC[14,15] and the Florida Patient Acceptance Survey,[39] which taps concerns and symptoms that are relevant to ICD patients.

This study has some limitations. First, we did not have sufficient clinical events to be able to relate the trajectories to hard medical outcomes, as has been done by others in post-MI patients.[10] However, several studies in ICD patients indicate that psychological distress is related both to an increased risk of tachyarrhythmias[7–9] and to mortality.[40] Secondly, we were restricted by the sample size with respect to the number of covariates that we could include in the multivariable analyses. Thirdly, when examining determinants of the trajectories, we used a composite of appropriate and inappropriate ICD shocks, rather than examining their separate influence because of the relatively low number of inappropriate ICD shocks in the present sample. It is possible

that patients may react differently to an inappropriate shock than to an appropriate shock once this information is conveyed to them following device interrogation.

This study also has several advantages, including the novel statistical approach, which enabled us to delineate trajectories that might in the future prove helpful for the identification of patients who may have a differential risk of adverse health outcomes.[10] This statistical technique also allowed us to retain all patients in the analyses except for two to four patients, enhancing the generalizability of the results. The relatively large sample size and the prospective study design with multiple assessments of anxiety beginning at baseline, using both generic and disease-specific measures, comprise additional advantages.

In conclusion, seven trajectories were found for general anxiety (both state and trait) and eight for device-related concerns in this sample of cardioverter-defibrillator patients. This relatively large number of identified trajectories indicates that there is considerable heterogeneity in terms of the level of anxiety and device-related concerns, with scores varying widely between patients. The course of general anxiety in ICD patients was relatively stable during the first year post implantation, with more fluctuation found in device-related concerns. Type D personality was a determinant of trajectory membership for all outcomes, but ICD shock only for device-related concerns. The relative stability of the trajectories and the consistent finding that Type D personality is a predictor across the anxiety domains and trajectories indicate that a simple pre-implantation screening procedure, using either an anxiety measure or the 14-item Type D Scale, may help identify patients at risk for high-distress trajectory membership.

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