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Pedersen, S.S.; Theuns, D.A.; Erdman, R.A.M.; Jordaens, L.

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Clustering of Device-Related Concerns and Type D Personality Predicts Increased Distress in ICD Patients Independent of Shocks¹

SUSANNE S PEDERSEN, PH.D.,*† DOMINIC AMJ THEUNS, PH.D.,†
RUUD AM ERDMAN, PH.D.,†‡ and LUC JORDAENS, M.D., PH.D.†

From *CoRPS-Center of Research on Psychology in Somatic diseases, Tilburg University, Tilburg, The Netherlands; †Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands; and ‡Department of Medical Psychology and Psychotherapy, Erasmus Medical Center, Rotterdam The Netherlands

Background: This study examined the impact of clustering of device-related concerns and Type D personality on anxiety and depressive symptoms during a six-month period and the clinical relevance of shocks, implantable cardioverter defibrillator (ICD) concerns, and Type D.

Methods: Consecutively implanted ICD patients ($n = 176$) completed questionnaires at baseline and six months and were divided into four risk groups: (1) No risk factors (neither ICD concerns nor Type D); (2) ICD concerns only; (3) Type D only; (4) Clustering (both ICD concerns and Type D).

Results: The prevalence of Type D and concerns were 21.6% and 34.7%. Analysis of variance for repeated measures showed a reduction in anxiety over time ($P < 0.001$), with the risk groups exerting a stable ($P = 0.14$) but differential effect ($P < 0.001$); the highest level was seen in the clustering group. Similar results were found for depression, although depressive symptoms did not decrease ($P = 0.08$) and the impact of clustering was less clear. These results were confirmed in adjusted analysis, with shocks ($P = 0.024$) also being associated with anxiety but not depression. The impact of ICD concerns and Type D personality on anxiety and depression at baseline and six months was large (≥ 0.8) compared to negligible to moderate for shocks (0.0–0.6).

Conclusions: ICD patients with psychosocial risk factor clustering had the highest level of anxiety, whereas the pattern for depression was less consistent. Shocks influenced outcomes, but the impact was smaller compared to ICD concerns and Type D personality. It may be timely to expand the focus beyond shocks when seeking to identify ICD patients at risk for adverse clinical outcome due to their psychological profile. (*PACE* 2008; 31:20–27)

anxiety, clustering, depressive symptoms, ICD concerns, implantable cardioverter defibrillator, Type D personality

Introduction

The superiority of the implantable cardioverter defibrillator (ICD) compared to antiarrhythmic medication to prevent sudden cardiac death is well established both for primary and secondary prevention.^{1–3} Hence, compared to patients with general cardiovascular disease psychosomatic research in ICD patients has primarily focused on patient-centered outcomes, such as anxiety and depression, with anxiety (24–87%) being more prevalent than depression (24–33%) in this patient group.⁴ The studying of these out-

comes and their determinants is important in order to be able to identify high-risk patients,⁵ as preliminary evidence suggests that ICD patients may benefit from psychological intervention and cardiac rehabilitation in terms of reduced anxiety and improved exercise capacity.⁶

Determinants of anxiety and depression in ICD patients identified to date include an amalgam of demographic, clinical (e.g., shocks), and psychosocial factors, although it should be noted that not all studies have been able to demonstrate a relationship between shocks and these outcomes.^{7–9} Previous studies have shown that device-related concerns, such as worrying about the ICD giving a shock,¹⁰ and Type D personality⁹ are determinants of anxiety and depression independently of shocks. However, the latter studies were based on a cross-sectional design and evaluated the influence of the two risk factors separately. Given that psychosocial risk factors tend to cluster together within individuals (e.g., those who have marital problems also tend to have higher levels of depression compared to those with no marital

Address for reprints: Susanne S Pedersen, Ph.D., CoRPS, Department of Medical Psychology, Tilburg University, Warandelaan 2, PO Box 90153, 5000 LE Tilburg, The Netherlands. Fax: +31-13-466-2067; e-mail: s.s.pedersen@uvt.nl

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problems),¹¹ patients with both Type D personality and device-related concerns may be at greater risk of adverse health outcomes, including anxiety and depression, compared to patients with single risk factors.

Type D personality refers to the tendency to experience increased negative emotions paired with nonexpression of these emotions.¹² Type D is an emerging risk factor in cardiovascular disease that has been associated with multiple adverse health outcomes, including mortality, morbidity, impaired quality of life, and emotional distress, despite appropriate medical treatment.¹³ The risk incurred by Type D personality on mortality and major adverse clinical events range from 4- to 8-fold, with the risk being independent of demographic and clinical risk factors including disease severity.¹³ Type D reflects a normal personality disposition rather than psychopathology and is more than negative affect, such as anxiety and depression, because the construct also stipulates how patients deal with their high levels of negative emotions, that is, showing a general preference for nonexpression due to fears of how others may react.^{12,13} To date, the cross-cultural validity of the construct has been confirmed in Belgian, Danish, German, and Italian samples.¹³

The objectives of this prospective study were to (1) examine the impact of risk factor clustering (i.e., device-related concerns and Type D personality) on anxiety and depressive symptoms during a period of six months in ICD patients, and (2) evaluate the clinical relevance of shocks versus ICD concerns and Type D personality as determinants of anxiety and depressive symptoms.

Methods

Patients and Study Design

Consecutive patients receiving an ICD implantation between August 2003 and July 2006 at the Erasmus Medical Center, Rotterdam, The Netherlands, participating in the ongoing *Mood and personality as precipitants of arrhythmia in patients with an Implantable cardioverter Defibrillator: A prospective Study* (MIDAS) comprised the patient sample for this study. MIDAS was designed to examine the impact of mood and personality on arrhythmias. Recently, in a smaller sample of patients from the MIDAS study ($n = 154$) Type D personality but not ICD indication was shown to influence health-related quality of life adversely three months postimplantation.¹⁴

Patients were excluded if they had a life expectancy less than one year, a history of psychiatric illness other than affective/anxiety disorders, were on the waiting list for heart transplantation, or had insufficient knowledge of the Dutch language. Pa-

tients were asked to complete a set of psychological questionnaires at baseline (i.e., one day prior to ICD implantation) and at six months. These assessment times coincided with clinical follow-up visits to the hospital, with the ICD nurse asking patients to fill out the questionnaires. Of 219 consecutive patients fulfilling the inclusion criteria, 211 (96.3% response rate) agreed to participate in the study. However, analyses are based on 176 patients, since some patients died during follow-up or did not complete questionnaires at six months. A flow chart of the patient selection is presented in Figure 1.

The MIDAS study protocol was approved by the medical ethics committee of the hospital. The study that was conducted to conform to the ethical tenets developed by the World Medical Association, as espoused in the Declaration of Helsinki.

Measures

Demographic and Clinical Variables

All demographic and clinical variables were obtained at baseline. Demographic variables included sex, age, marital status, and education. Information on clinical variables, including indication for ICD implantation, cardiac resynchronization therapy (CRT), coronary artery disease (CAD) etiology, chronic heart failure (CHF), previous myocardial infarction (MI), previous percutaneous coronary intervention (PCI), previous coronary artery bypass graft surgery (CABG), diabetes, left ventricular ejection fraction (LVEF), ventricular tachyarrhythmias and shocks during the six-month follow-up period, and cardiac medication were obtained from the medical records. Information on the use of psychotropic medication

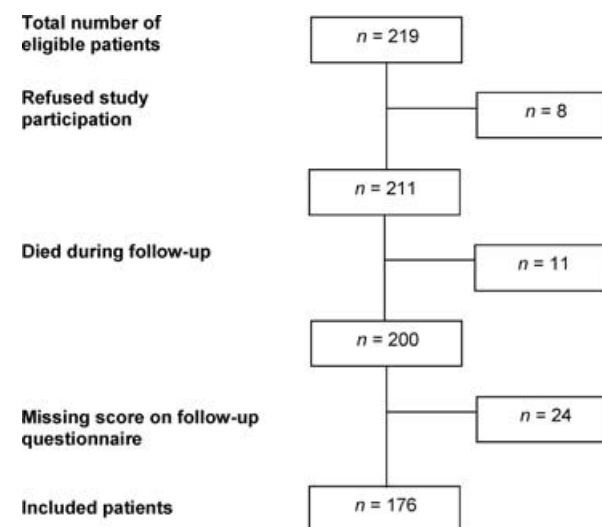


Figure 1. Flow chart of patient selection.

was obtained through a purpose-designed question.

Device-Related Concerns

Device-related concerns, as perceived by the patient, were assessed with the ICD Concerns (ICDC) questionnaire, which was originally developed in the UK,¹⁵ and later adapted and abbreviated for the Dutch setting.¹⁰ The ICDC consists of eight-items (e.g. “*I am worried about my ICD firing*” and “*I am worried about symptoms/pain associated with my ICD firing*”) that are rated on a 5-point Likert scale from 0 (not at all) to 4 (very much so). A higher score indicates a higher level of device-related concerns. The internal consistency of the eight-item ICDC is good, with Cronbach’s $\alpha = 0.91$.¹⁰ The ICDC was administered at baseline.

Type D Personality

Type D personality was assessed with the 14-item Type D Scale (DS14).¹² The DS14 comprises two normal and stable personality traits: negative affectivity (e.g. “*I often feel unhappy*”; 7 items) and social inhibition (e.g. “*I am a closed kind of person*”; 7 items).¹¹ Items are answered on a 5-point Likert scale ranging from 0 (false) to 4 (true), with a score range from 0–28 for both subscales. Type D caseness is determined by means of a standardized cut-off ≥ 10 on both subscales.^{12,16} The DS14 was developed in cardiac patients and is a valid and reliable measure, with Cronbach’s alpha of 0.88/0.86 and three-month test-retest reliability $r = 0.72/0.82$ for the negative affectivity and social inhibition subscales, respectively.¹² A recent study showed that Type D is a stable measure over an 18-month period, and is not confounded by cardiac disease severity and measures of anxiety and depression.¹⁷ In addition, it is the combination of traits rather than the single trait that is associated with adverse health outcomes, with Type D exerting an effect on these outcomes independent of mood states, such as anxiety and depression.¹⁸ The DS14 was administered at baseline

Anxiety and Depression

Symptoms of anxiety and depression were evaluated with the Hospital Anxiety and Depression Scale (HADS).^{19,20} Items are answered on a 4-point Likert scale from 0–3 (score range 0–21), with seven items contributing to each subscale. Probable clinical levels of anxiety and depression are indicated by a cut-off score ≥ 8 for both subscales.²¹ The HADS is a valid and reliable instrument that has been used across the world in cardiac and non-cardiac populations.²¹ The HADS was administered both at baseline and at six months follow-up.

Statistical Analyses

Prior to statistical analyses, ICD concerns were dichotomized using the highest tertile to indicate high levels of device-related concerns. Subsequently, four risk groups were formed on the basis of the psychological factors ICD concerns and Type D personality in order to examine the impact of clustering versus single risk factors, as follows: (1) No risk factors (neither ICD concerns nor Type D); (2) ICD concerns only; (3) Type D only; (4) Clustering (both ICD concerns and Type D). Nominal variables were compared with the Chi-square test (Fisher’s exact test when appropriate) and continuous variables with analysis of variance (ANOVA) with a *post hoc* Bonferroni correction. ANOVA for repeated measures was used to evaluate changes in anxiety and depression over time, stratified by the risk groups. Analysis of covariance (ANCOVA) was used to rule out the potential confounding effect of demographic and clinical risk factors on anxiety and depression. A priori, sex, age, marital status (defined as single vs married/partner), education (defined as lower (i.e., ≤ 12 years) vs higher education (i.e., ≥ 13 years), ICD indication, CRT, CAD etiology, CHF, diabetes, and shocks, were selected as covariates for the ANCOVA. Cohen’s effect size index²² was used to evaluate the clinical relevance of shocks, ICD concerns, and Type D personality as determinants of anxiety and depression. Means and standard deviations for between-group differences on anxiety and depression, used as a basis for calculating Cohen’s *d*, were derived from multivariate analysis of variance (MANOVA). According to Cohen, an effect size of 0.2 is considered as small, 0.5 as moderate, and 0.8 as large.²² All tests were two-tailed. A P-value < 0.05 was used to indicate statistical significance. All analyses were performed using SPSS 14.0 for Windows (Chicago, IL, USA).

Results

Patients who participated in the study ($n = 211$) did not differ systematically on demographic and clinical characteristics, including on ventricular tachyarrhythmias and shocks, compared to nonparticipants ($n = 8$), except for participants being more likely to use β -blockers (80.8% vs 37.5%; $P = 0.011$) and to have a lower LVEF (mean = 27.7 ± 10.3 vs mean = 40.0 ± 13.1 ; $P = 0.022$) than nonparticipants. The latter analysis was based on 134 patients (participants: $n = 130$; nonparticipants: $n = 4$), given that echocardiography was not performed in all patients. No information on the use of psychopharmaca was available for nonparticipants, given that this was a purpose-designed question in the questionnaire.

Baseline Patient Characteristics Stratified by Risk Groups

No statistically significant differences were found on demographic and clinical baseline characteristics, including medication, between the four risk groups (Table I).

Of the 176 patients, 35 (19.9%) experienced a ventricular tachyarrhythmia during the six-month follow-up period, with 23 (13%) receiving a shock. There were no statistically significant differences between the four risk groups on ventricular arrhythmias (none: 17.8%; Type D only: 28.6%; concerns only: 24.3%; both: 16.7%; $P = 0.63$), nor on shocks (none: 13.9%; Type D only: 21.4%; concerns only: 8.1%; both: 12.5%; $P = 0.61$) during the follow-up period.

Type D Personality and ICD Concerns

The prevalence of Type D personality was 21.6%, whereas 34.7% scored high on ICD con-

cerns. Given that the primary objective of this study was to investigate the impact of the clustering of Type D personality and baseline ICD concerns, their interrelationship was first examined. As shown in Figure 2, Type D patients were more likely to report device-related concerns compared to non-Type D patients (63.2% vs 26.8%; $P < 0.001$).

Prevalence of Anxiety and Depression Stratified by Risk Groups

The prevalence of anxiety was higher in the clustering group compared to the other groups both at baseline and at six months. At baseline, the prevalence of anxiety was 83.3% in the clustering group followed by 40.5% in the ICD concerns group, with prevalences of 14.3% in the Type D and the 15.8% in the no risk groups being almost similar ($P < 0.001$). At six months, the prevalence in the clustering group was 50% versus 28.6% in

Table I.
Baseline Patient Characteristics Stratified by Risk Groups*

	None (n = 101)	Type D (n = 14)	ICD Concerns (n = 37)	Clustering (n = 24)	P
Demographics					
Males	82.2	85.7	75.7	79.2	0.82
Age, mean (SD)	58.4 (13.2)	62.4 (9.6)	58.9 (9.8)	59.6 (10.5)	0.70
Single	6.9	0	5.4	12.5	0.62
Lower education ¹	62.4	71.4	63.9	56.5	0.84
Clinical variables					
Indication (secondary)	44.6	42.9	48.6	41.7	0.95
Resynchronization therapy	34.7	21.4	27.0	37.5	0.65
CAD etiology	58.4	50.0	59.5	66.7	0.79
Chronic heart failure	50.5	35.7	32.4	45.8	0.26
Previous MI	49.5	42.9	56.8	45.8	0.79
Previous PCI	14.0	15.4	19.4	39.1	0.06
Previous CABG	20.8	14.3	27.0	21.7	0.79
Diabetes	9.0	7.7	5.6	8.7	0.94
LVEF, mean (SD) ²	29.2 (11.2)	25.6 (6.4)	26.5 (11.8)	25.7 (9.8)	0.51
Medication					
Amiodarone	21.4	28.6	40.5	25.0	0.16
Beta-blockers	83.7	78.6	75.7	75.0	0.56
Diuretics	63.9	64.3	51.4	62.5	0.62
ACE-inhibitors	74.2	64.3	70.3	79.2	0.73
Statins	53.1	64.3	50.0	75.0	0.19
Digoxin	20.6	7.1	8.3	20.8	0.29
Psychopharmaca	16.8	14.3	22.2	29.2	0.51

* Presented as % unless otherwise indicated.

¹ Lower education ≤ 12 years.

² Echocardiography was only performed in a subsample of patients.

CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.

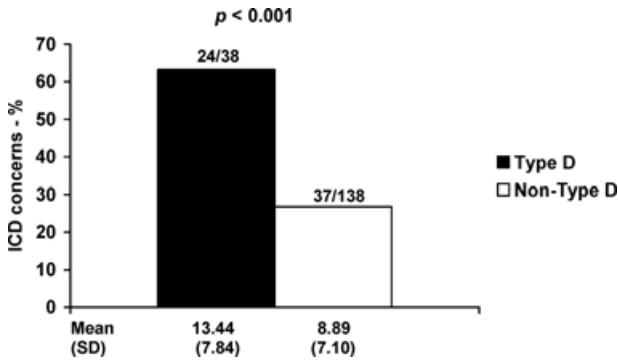


Figure 2. Prevalence of baseline ICD concerns stratified by Type D personality.* * Mean (SD) scores are presented below.

the Type D only, 27.0% in the ICD concerns only, and 14.9% in the no risk groups ($P < 0.003$).

Similarly, for depression at baseline the prevalence in the clustering group was 66.7% versus 50.0% in the Type D only, 27.0% in the concerns only, and 18.8% in the no risk groups ($P < 0.001$). At six months, the prevalence was 41.7% in the clustering group compared to 42.9% in the Type D only group, 24.3% in the ICD concerns only group, and 14.9% in the no risk group ($P = 0.008$).

Changes in Anxiety and Depression Stratified by Risk Groups (Unadjusted Analysis)

ANOVA for repeated measures showed that the within-subjects effect for time in relation to anxiety was significant ($F(1,172) = 17.719$; $P < 0.001$), indicating that patients experienced a general reduction in anxiety between baseline and six months follow-up (Fig. 3, top). The risk groups exerted a stable effect on anxiety over time, as indicated by the nonsignificant interaction effect for time by risk groups ($F(3,172) = 1.858$; $P = 0.14$), but the groups experienced different levels of anxiety ($F(3,172) = 26.019$; $P < 0.001$). The highest level of anxiety was seen in the clustering group, with all *post hoc* comparisons being significant ($ps < 0.05$), except between the no risk group and Type D only and Type D and ICD concerns only.

Similar results were found for depression, although the decrease in depressive symptoms over time was not statistically significant ($F(1,172) = 7.198$; $P = 0.08$) (Fig. 3, bottom). Again the interaction effect for time by risk groups was not significant ($F(3,172) = 1.429$; $P = 0.24$), indicating that the risk groups also exerted a stable effect on depression over the six-month period ($F(3,172) = 15.645$; $P < 0.001$). Nevertheless, the risk groups reported significantly different levels of depression, although the only significant *post hoc* comparisons were found between the no risk and Type

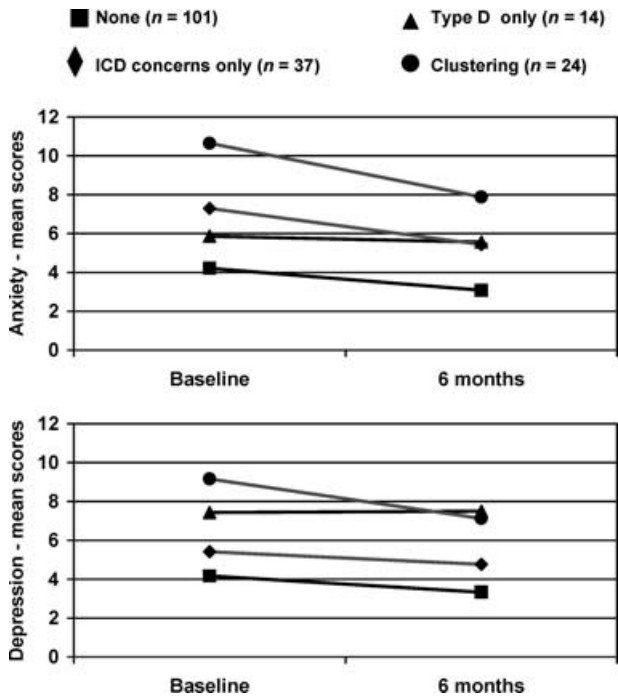


Figure 3. Mean anxiety and depression scores at baseline and six months stratified by risk groups.* * ANOVA for repeated measures (univariable analysis); a high score indicates more symptoms.

D only groups, no risk and the clustering groups, and ICD concerns only and the clustering groups ($ps < 0.05$).

Changes in Anxiety and Depression Stratified by Risk Groups (Adjusted Analysis)

In order to rule out that the influence of the risk groups on anxiety and depression could be attributed to potential confounding by shocks and other baseline characteristics, ANCOVAs for repeated measures were performed, adjusting for sex, age, marital status, education, ICD indication, CRT, CAD etiology, CHF, diabetes, and shocks.

For anxiety, the only within-subjects interaction effect for time by covariates that was significant was that for time by shock ($F(1,156) = 3.965$; $P = 0.048$). A view of the plot of the estimated marginal means showed that time had a differential influence on anxiety for shocked versus nonshocked patients, with those experiencing a shock reporting increased levels of anxiety at six months follow-up compared to nonshocked who reported a decrease in symptoms of anxiety. The between subjects effect for the four risk groups ($F(3,156) = 25.602$; $P < 0.001$), age ($F(1,156) = 4.075$; $P = 0.045$), lower education ($F(1,156) = 7.119$; $P = 0.008$), and shocks ($F(1,156) = 5.160$; $P = 0.024$)

were also statistically significant in adjusted analysis, whereas there was a trend for CAD etiology ($F(1,156) = 3.566$; $P = 0.061$). Taken together, the influence of the four risk groups on anxiety remained significant despite adjustment for demographic and clinical baseline characteristics including shocks.

For depression, there were no significant within-subjects interaction effects for time *by* covariates. The between subjects effect for the four risk groups ($F(3,156) = 15.158$; $P < 0.001$) and lower education ($F(1,156) = 5.725$; $P = 0.018$) were significant, whereas shocks ($F(1,156) = 2.583$; $P = 0.11$) were not related to depression in adjusted analysis. Similar to the results for anxiety, there was a trend for CAD etiology ($F(1,156) = 3.208$; $P = 0.075$). These results show that the four risk groups had a significant impact despite adjustment for demographic and clinical baseline characteristics including shocks.

The overall results did not change when adding LVEF as a covariate to the ANCOVAs, indicating that the impact of clustering on anxiety and depressive symptoms could not be attributed to cardiac disease severity.

Clinical Relevance of Shocks, ICD Concerns, and Type D Personality as Determinants of Anxiety and Depression

Effect sizes for the impact of shocks, ICD concerns, and Type D personality on anxiety and depression at baseline and six months are shown in Figure 4. The influence of shocks on anxiety was negligible at baseline but moderate to large at six months. The negligible effect of shocks at baseline reflects that shocks occurred during the follow-up period (i.e., after the baseline assessment). By contrast, the impact of ICD concerns and Type D were large at both time points. For depression, the effect size for shocks was negligible at baseline but small to moderate at follow-up, whereas the effect sizes for ICD concerns and Type D personality were large at both time points.

Discussion

In this study, symptoms of anxiety but not depression abated over time. However, a differential pattern in the course of anxiety was seen in shocked versus nonshocked patients, with shocked patients experiencing increased levels of anxiety at six months follow-up compared to nonshocked who reported a decrease in anxiety. The clustering of device-related concerns and Type D personality was associated with the highest levels of anxiety at both baseline and six months compared to patients with no or one risk factor. The impact of clustering was less clear for depression, with higher depression scores in the clustering

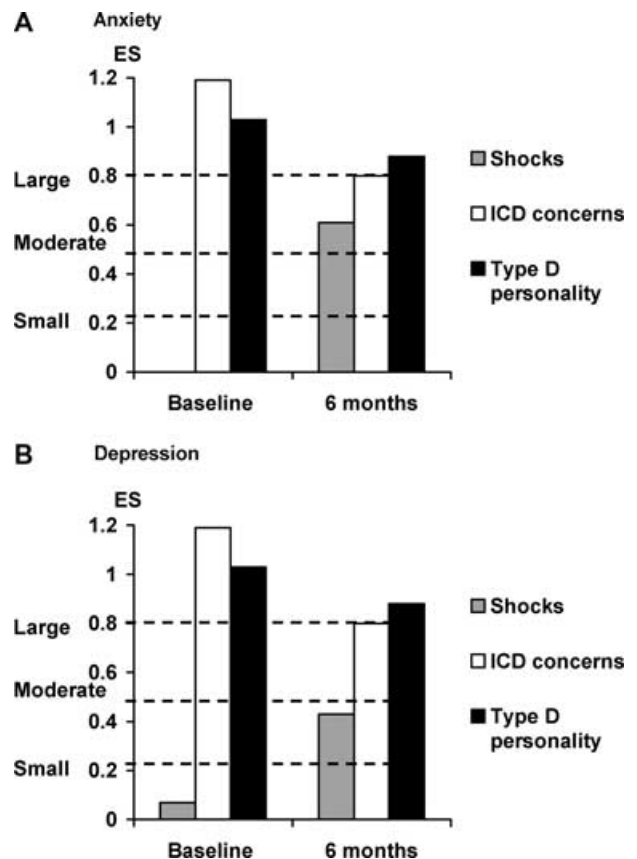


Figure 4. Clinical relevance of shocks, ICD concerns and Type D personality as determinants of anxiety and depression at baseline and six months post-ICD implantation. * * ES = Effect size.

group at baseline, whereas at follow-up depression levels were similar in patients with risk factor clustering and the single risk factor Type D personality. Shocks had a larger influence on anxiety than on depression, but generally the psychological risk factors ICD concerns and Type D personality had a greater influence on both anxiety and depression relative to shocks, as indicated by Cohen's effect size index.

A paucity of studies have investigated the impact of clustering of psychosocial risk factors in patients with cardiovascular disease, although these risk factors tend to cluster together within individuals and may incur a higher risk than single risk factors.¹¹ In this study, patients with clustering of device-related concerns and Type D personality, two factors that have previously been associated with increased anxiety and depression in ICD patients,^{9,10} experienced higher levels of anxiety compared to patients with no or one risk factor. The impact of clustering was less clear for depression, however. This finding supports the notion

that it may be timely to shift focus from a “single-risk factor approach” to study the impact of psychosocial risk factor clustering in order to obtain the most accurate risk estimation for individual patients.¹¹ This is particularly important, given that mood states, such as anxiety and depression, have been shown to influence clinical outcome,²³ adherence,²⁴ and healthy lifestyle changes²⁵ in patients with cardiovascular disease. Hence, if the more deleterious influence of psychosocial risk factor clustering in ICD patients compared to single risk factors is confirmed in future studies, these high-risk patients should be identified in clinical practice and offered adjunctive psychological intervention. Preliminary evidence indicates that such patients may benefit from psychological intervention (e.g., cognitive behavioral therapy) in combination with cardiac rehabilitation in particular in terms of reducing anxiety.⁶ Of note, in this study risk factor clustering had the most profound and consistent effect on anxiety. Identification of these high-risk patients would likely also lead to a more optimal and cost-effective allocation of healthcare resources, as patients with a low-risk psychological profile are unlikely to derive any notable benefit from psychological intervention simply because they do not need it.

The influence of shocks on patient-centered outcomes, such as mood states and quality of life, in ICD patients is the subject of some debate, with some^{26–29} but not all studies^{7–10,14,30,31} confirming a relationship between shocks and these outcomes. The inconsistency in findings can in part be attributed to differences in study designs, including whether factors that may potentially compete with shocks as a determinant of outcome were studied, and the way that shocks was assessed (e.g., self-report vs objectively measured) and quantified (e.g., shocks/no shocks vs number of shocks). The results of the Canadian Implantable Defibrillator Study highlight how the quantification of shocks may influence the results, as only patients who had experienced ≥ 5 shocks were at risk for impaired quality of life.³¹ Although shocks were associated with anxiety in adjusted analysis but not with depression in this study, the importance of the risk factors device-related concerns and Type D personality was relatively larger than shocks, as indicated by Cohen’s effect size index. This finding is consistent with that of Sears and colleagues, who found that shocks contributed significantly to the explained variance in quality of life, but the contribution was relatively small compared to that of other factors, such as history of depression, trait anxiety, trait optimism, and social support.²⁷ With changes in the programming of the ICD and the use of new antitachycardia pacing therapies,³² which leads to a reduction in shocks and better quality of

life as shown in the PainFree RX II trial,³³ it may be timely to expand the focus beyond shocks when studying determinants of adverse health outcomes in ICD patients.

This study has some limitations. First, the baseline assessment (i.e., one day prior to implantation) is not optimal, as emotional distress at this time may reflect procedure-related distress. However, this time point was adapted to ensure standardization of assessment, as all patients were hospitalized one day prior to implantation. Second, the analyses were only adjusted for LVEF in a subsample of patients, given that echocardiography was not performed in all patients. Nevertheless, the overall results did not change when adding LVEF as a covariate to the analyses. Third, the follow-up period only extended to six months, with studies needing to confirm the findings of this study long term. Fourth, we had no information on lifestyle factors, such as smoking, extent of physical exercise, and adherence to dietary advice if given, which may have influenced outcome. Despite these limitations, this study also has several strengths, including the high response rate, the prospective study design, focus on risk factor clustering, use of a disease-specific measure (i.e., the ICDC questionnaire), and the inclusion of personality factors, which is a novel approach in arrhythmia research.⁹

In conclusion, ICD patients with risk factor clustering had higher anxiety scores compared to patients with single or no risk factors, although the pattern was less consistent for depression. Shocks were shown to influence outcomes, but the impact was generally smaller compared to that of ICD concerns and Type D personality. Patients with risk factor clustering should not be overlooked in clinical practice, as they may also be at higher risk of other adverse health outcomes, including poor prognosis. The Type D Scale (DS14) could be used as a screening tool in clinical practice in order to identify high-risk patients, as advocated by others.^{13,34} The scale is brief, comprises little burden to patients, is unconfounded by somatic symptoms¹² and disease severity,¹⁷ and reflects a normal personality construct rather than psychopathology. Finally, it may be timely to expand the focus beyond shocks when seeking to identify patients at risk for psychological maladjustment following ICD implantation.

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