Shock and Patient Preimplantation Type D Personality Are Associated With Poor Health Status in Patients With Implantable Cardioverter-Defibrillator

Susanne S. Pedersen, PhD; Fetene B. Tekle, PhD; Madelein T. Hoogwegt, MSc; Luc Jordaens, MD, PhD; Dominic A.M.J. Theuns, PhD

- *Background*—Implantable cardioverter-defibrillator (ICD) shock is a critical event to patients associated with well-being after implantation, although other factors may play an equally important role. We compared the association of shock and the patient's preimplantation personality with health status, using a prospective study design.
- *Methods and Results*—Consecutively implanted ICD patients (n=383; 79% men) completed the Type D Scale at baseline and the Short-Form Health Survey 36 (SF-36) at baseline and 3, 6, and 12 months. Of all patients, 23.5% had a Type D personality and 13.8% received a shock during follow-up. Shocked patients reported significantly poorer health status, as did Type D patients. Health status patterns were poorest in patients with combined Type D personality and shock during follow-up. Shock during follow-up was a significant independent associate of poorer health status for 4 of 8 subscales of the SF-36 and the Mental Component Summary (all P < .05), with shocked patients scoring between 2.60 to 13.30 points lower than nonshocked patients. Type D personality was an independent associate of poor postimplantation health status for 6 of 8 of the SF-36 subscales and the Mental Component Summary, with Type D patients scoring between 2.12 to 8.02 points lower, adjusting for demographic and clinical characteristics.
- *Conclusions*—ICD shock and the patient's preimplantation personality disposition were equally important associates of health status 12 months after implantation. Identification of the patient's personality profile before ICD implantation may help identify subsets of patients who may need additional care, for example, with a psychosocial component. (*Circ Cardiovasc Qual Outcomes.* 2012;5:373-380.)

Key Words: arrhythmias ■ implantable cardioverter-defibrillator ■ Type D personality ■ health status ■ shock ■ quality of life

I mplantable cardioverter-defibrillator (ICD) shocks may be associated with poor patient-rated health status and quality of life, although the patient's response to shock may vary considerably from relief that the ICD works to severe distress including posttraumatic stress^{1–3} and in extreme cases, a wish to have the ICD explanted.⁴ It is generally accepted that an ICD shock is a critical event to individual patients, although empirical results on the association between shock and patient-reported outcomes (PROs; ie, anxiety, depression, and quality of life) are inconsistent.^{1–2} These mixed results may in part be attributed to smaller sample sizes in some of the observational studies² but they also suggest that the relationship between ICD shock(s) and PROs may be neither linear nor straightforward.^{5,6}

The psychological response to a shock is likely to be associated with a complex interplay of factors and not with shocks alone. In addition, patients may become distressed in the absence of shocks. Factors associated with poor PROs include symptomatic heart failure,^{7–9} the number of shocks received,¹⁰ the appropriateness of the shock and associated pain,⁴ the patient's preimplant personality disposition, and concerns about the device.^{2,11} Although results with respect to the relationship between sex and PROs are mixed,¹² indication for ICD implantation seems to play less of a role in explaining the variability in PROs.¹³

Knowledge of the subsets of ICD patients at risk of poor PROs is important for the optimal treatment and care of these patients, as anxiety and high levels of ICD concerns alone and in combination with personality factors,^{14,15} depression,¹⁶ and posttraumatic stress¹⁷ are associated with the occurrence of ventricular tachyarrhythmia's and survival in ICD patients. Preliminary evidence also indicates that poor health status may be related to morbidity and mortality in ICD patients.¹⁸

In the current study, we focused on health status as the PRO rather than on anxiety and depression, as less attention

Received November 11, 2011; accepted March 30, 2012.

From CoRPS, Center of Research on Psychology in Somatic diseases, Tilburg University, Tilburg, The Netherlands (S.S.P., M.T.H.); the Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands (S.S.P., L.J., D.A.M.J.T.); and the Department of Methodology and Statistics, Tilburg University, Tilburg, The Netherlands (F.B.T.).

Correspondence to Susanne S. Pedersen, PhD, CoRPS, Department of Medical Psychology, Room P506, Tilburg University, Warandelaan 2, PO Box 90153, 5000 LE Tilburg, The Netherlands. E-mail s.s.pedersen@uvt.nl

^{© 2012} American Heart Association, Inc.

has been given to health status and particularly the associates of poor health status in this patient cohort. To disentangle the association between ICD shocks and health status versus other potentially competing factors, we made a head-to-head comparison between shocks and the patient's preimplantation personality as associates of health status, using a prospective study design with health status assessed at baseline and 3, 6, and 12 months postimplantation. We had specifically chosen to single out the distressed (Type D) personality as the primary competing associate for a head-to-head comparison, because the role of preimplantation factors, such as personality, tend to be neglected in arrhythmia research despite their potential significant contribution to variability in PROs and clinical outcome.^{14,15,19}

WHAT IS KNOWN

• Although anxiety and poor health status have been attributed to ICD shocks, little is known about the association between ICD shocks, patient health status, and the patient's preimplantation psychological profile and personality type.

WHAT THE STUDY ADDS

- This article demonstrates that although ICD shocks are generally associated with impaired health status, the patient's preimplantation psychological profile and personality disposition also help explain variability in health status among ICD patients.
- With new algorithms being introduced in ICD programming to reduce the incidence of shocks, it seems timely to focus on other factors, including psychological, that influence health status to optimize the outcomes of ICD patients.

Methods

Patients and Study Design

A consecutive cohort of patients implanted with a first-time ICD or ICD with cardiac resynchronization therapy (CRT-D) between August 2003 and May 2010 at the Erasmus Medical Center, Rotterdam, The Netherlands, comprised the study sample. All patients were enrolled in the Mood and personality as precipitants of arrhythmia in patients with an Implantable cardioverter-defibrillator: A prospective Study (MIDAS). Patients on the waiting list for heart transplantation, with a life expectancy of <1 year, with a history of psychiatric illness other than affective/anxiety disorders, or with insufficient knowledge of the Dutch language were excluded from the study. The MIDAS study protocol was approved by the medical ethics committee of the Erasmus Medical Center. The study was conducted according to the ethical guidelines of the Helsinki Declaration, as set out by the World Medical Association. All patients received written and oral information about the study and provided written informed consent.

Procedure

An ICD nurse approached all patients for study participation, provided they fulfilled the inclusion criteria. Patients completed a set of standardized and validated self-report questionnaires at baseline (ie, 1 day before ICD implantation) and at 3, 6, and 12 months postimplantation. Information on demographic and clinical characteristics was gathered at baseline from patients' medical records or obtained via purpose-designed questions. Information on device therapy was obtained by device interrogation.

Measures

Baseline Demographic and Clinical Variables

Information on demographic variables included sex, age, marital status, and education. Information on clinical variables included indication for ICD therapy (primary versus secondary), CRT, left ventricular ejection fraction $\leq 35\%$, QRS > 120 ms, coronary artery disease, symptomatic heart failure (defined as New York Heart Association (NYHA) functional classes III and IV), atrial fibrillation, diabetes mellitus, smoking, cardiac (ie, amiodarone, diuretics, angiotensin-converting enzyme inhibitors, β -blockers, digoxin, and statins) and psychotropic medication.

Health Status

Health status was assessed with the Short Form Health Survey (SF-36).²⁰ The SF-36 consists of 36 items that contribute to the following 8 subscales: physical functioning, role functioning–physical, bodily pain, social functioning, mental health, role functioning–emotional, vitality, and general health. Scores on the subscales are linearly converted into a score between 0 and 100, with a higher score indicating better health status. A high score on the bodily pain subscale reflects absence of pain. Based on the SF-36, it is also possible to derive a Physical Component Summary (PCS) and a Mental Component Summary (MCS) score, with all subscales contributing to both summary scores based on a priori determined weights. The SF-36 has been validated in several Dutch populations and has a good internal consistency, with a mean Cronbach α of 0.84 across all subscales.²¹ Patients were asked to complete the SF-36 at baseline and at 3, 6, and 12 months postimplantation.

Type D Personality

Type D personality was assessed at baseline with the 14-item Type D Scale (DS14), which is a self-report measure that patients complete within 5 minutes.²² Type D personality is a stable personality construct defined as a general propensity to psychological distress that typifies individuals who experience increased negative emotions while not wanting to share these emotions with others due to fear of rejection.^{19,22} Items are rated on a 5-point Likert scale from 0 to 4. The DS14 can be summed into a 7-item negative affectivity subscale (eg, "I often feel unhappy") and a 7-item social inhibition subscale (eg, "I am a closed kind of person"), both with a score range from 0 to 28. A standardized cutoff score of ≥ 10 was used to define Type D caseness,²² which has been shown to be the optimal cutoff using item response theory.²³ The DS14 is a valid and internally consistent measure (Cronbach α : negative affectivity=0.88; social inhibition=0.86) and is stable over time (3-month test-retest reliability: negative affectivity, r=0.72; social inhibition, r=0.82).²² Type D personality is not confounded by indicators of disease severity, such as left ventricular ejection fraction, which makes it an ideal measure to use in cardiac and other somatic disease populations.24

ICD Therapy During Follow-Up

Information on delivered ICD therapy was recorded in our institutional database from the time of implantation. All patients were seen at 3-month intervals at our outpatient electrophysiology clinic. In addition, patients were advised to contact our clinic as soon as possible after a symptomatic event. Two experienced electrophysiologists from the electrophysiology staff of the Erasmus Medical Center reviewed and categorized all spontaneous episodes with stored electrograms that resulted in ventricular therapies. In the event of disagreement, a third reviewer was consulted and a consensus was reached. Arrhythmias were classified as ventricular tachyarrhythmia or atrial tachyarrhythmia without a coexistent ventricular arrhythmia. Therapy triggered by ventricular tachyarrhythmias 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 were considered inappropriate.

Statistical Analysis

Patients with missing values either on demographic and clinical variables or on health status at baseline were excluded from analyses. Baseline characteristics were compared by means of the χ^2 test (Fisher exact test when appropriate) for nominal variables and Student t test for continuous variables. Differences between the averages of the categories of shock (either appropriate or inappropriate shock versus no shock) over time were statistically tested using generalized linear mixed modeling repeated-measures analysis of variance (ANOVA) with a split-plot-like design that considers interaction effects between shock and time. Similar analyses were performed to test the trends for differences on average between categories of Type D versus non-Type D personality and combinations of shock and Type D. For these separate analyses on the association between shock and health status and Type D personality and health status, respectively, we adjusted only for the baseline measurement of the outcome variable (ie, the specific health status domain at baseline) but not for clinical and demographic variables.

We used generalized linear mixed modeling repeated measures analysis of covariance (ANCOVA) to assess the effects of shocks during the follow-up period and Type D personality on changes in health status controlling for the effects of demographic and clinical variables. Since a correlation between follow-up assessments on health status can be presumed, the usual regression analysis that assumes independent observations is not an appropriate method.25 In addition to taking care of the fact that measurements are correlated, the mixed modeling approach does not require that each of the subjects should have an equal number of follow-up measurements. As such, patients can be kept in the analysis even if they did not complete all assessments, thereby reducing potential bias that occurs when patients are lost to attrition during follow-up.25 The linear mixed model used in our analysis assumes a normal distribution for the random effect that accounts for the correlation between observations within a subject. Because the interest of the analysis is mainly on the fixed effects (comparison of groups), valid inferences can be obtained even when the random effects might have been incorrectly assumed to be normally distributed.26,27 For each of the SF-36 subscales and the PCS and the MCS, we fitted a separate model using linear mixed models advanced statistical option in SPSS. A priori based on the literature, we decided to enter the following covariates in adjusted analyses (in addition to shock and Type D personality and the interaction of Type D personality by shocks) in each of the random intercept models: sex, age, marital status, education, indication for ICD implantation, CRT, coronary artery disease, atrial fibrillation, diabetes mellitus, smoking, amiodarone, β -blockers, psychotropic medication, and baseline health status. If the interaction of Type D personality by shocks was not statistically significant, the model was run and results presented without the interaction. This approach was adopted to avoid the inclusion of covariates that may be statistically significant due to the specific sample under study, as also recommended by others.²⁸ All tests were 2-tailed, and a probability value <0.05 was used to indicate statistical significance. Estimates are reported with corresponding 95% confidence intervals (CI). All data were analyzed using PASW Statistics 17 statistical software (PASW IBM Corp, Armonk, NY).

Results

Participants Versus Nonparticipants on Baseline Characteristics

Of 448 patients eligible and approached for study participation, we had to exclude 67 (14.9%) from statistical analyses because of 1 of the following reasons: No score on the SF-36 or on the DS14 at baseline (n=29) or lack of information on demographic or clinical variables (n=38). Cases excluded from analyses did not differ systematically from included cases (n=383) on baseline characteristics, except for ex
 Table 1. Patient Baseline Characteristics for the Total Sample

 and Stratified by the Occurrence of Any Shock (Either Appropriate

 or Inappropriate) During the 12-Month Follow-Up Period*

	S	hocks (Any) Duri	ng Follow-Up	
Characteristics	Total (n=383)	Yes (n=53)	No (n=330)	P Value
Demographics				
Men	304 (79.4)	43 (81.1)	261 (79.1)	0.73
Age, y, mean \pm SD	57.7±12.0	57.8±13.8	57.7±11.7	0.97
Single/no partner	25 (6.5)	4 (7.5)	21 (6.4)	0.75
Lower education ⁺	95 (24.8)	14 (26.4)	81 (24.5)	0.77
Clinical				
Primary prevention indication	252 (65.8)	27 (50.9)	225 (68.2)	0.014
CRT	111 (29.0)	13 (24.5)	98 (29.7)	0.44
LVEF \leq 35%	284 (85.8)	38 (88.4)	246 (85.4)	0.61
QRS > 120 ms	190 (49.6)	32 (60.4)	158 (47.9)	0.09
CAD	224 (58.5)	28 (52.8)	196 (59.4)	0.37
Symptomatic heart failure‡	124 (32.4)	18 (34.0)	106 (32.1)	0.79
Atrial fibrillation	87 (22.7)	18 (34.0)	69 (20.9)	0.035
Diabetes mellitus	53 (13.8)	12 (22.6)	41 (12.4)	0.046
Smoking	45 (11.7)	9 (17.0)	36 (10.9)	0.20
Medication				
Amiodarone	69 (18.0)	8 (15.1)	61 (18.5)	0.55
Diuretics	218 (56.9)	27 (50.9)	191 (57.9)	0.34
ACE inhibitors	270 (70.5)	31 (58.5)	239 (72.4)	0.04
β -blockers	299 (78.1)	39 (73.6)	260 (78.8)	0.40
Digoxin	58 (15.1)	12 (22.6)	46 13.9)	0.10
Statins	217 (56.7)	26 (49.1)	191 (57.9)	0.23
Psychotropic medication	60 (15.7)	9 (17.0)	51 (15.5)	0.78
Psychological				
Type D personality	90 (23.5)	14 (26.4)	76 (23.0)	0.59
CRT indicates cardi	iac resynchron	ization therapy;	LVEF, left	ventricular

CRT indicates cardiac resynchronization therapy; LVEF, left ventricular ejection fraction; CAD, coronary artery disease; and ACE, angiotensinconverting enzyme.

*Results are presented as n (%) unless otherwise indicated.

†Education \leq 13 years.

‡Defined as New York Heart Association classes III and IV.

cluded cases being more likely to have a lower educational level (P < 0.05).

Patient Baseline Characteristics

Baseline characteristics for the total sample and stratified by shocks (both appropriate and inappropriate) are displayed in Table 1. The prevalence of atrial fibrillation (P=0.035) and diabetes mellitus (P=0.046) was higher among patients who received 1 or more shocks during follow-up, whereas shocked patients were less likely to have an ICD due to a primary prevention indication (P=0.014). In contrast, the prescription of angiotensin-converting enzyme inhibitors was lower among patients who received a shock during follow-up as compared with nonshocked patients (P=0.04). No other systematic differences were found on demographic and clin-

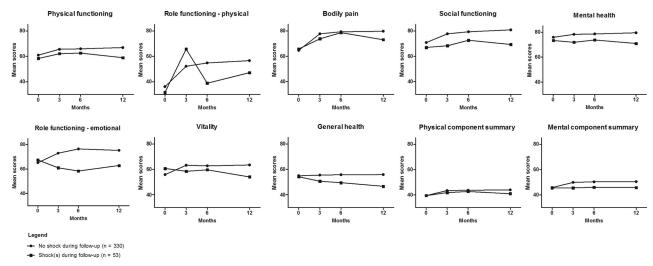


Figure 1. Mean scores on health status, stratified by the occurrence of shocks.

ical baseline characteristics between shocked and nonshocked patients.

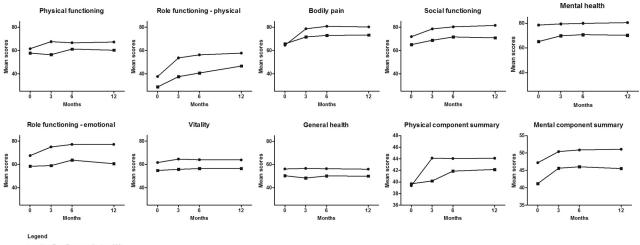
Health Status Stratified by Shocks and Type D Personality (Unadjusted Analysis)

Of all patients, 23.5% (90/383) had a Type D personality and 13.8% (53/383) received a shock during the 12-month follow-up period. Of all patients, 10.7% (41/383) had an appropriate shock and 3.9% (15/383) an inappropriate shock. Because of the low incidence of inappropriate shocks, further analyses were conducted with any shock (ie, whether appropriate or inappropriate).

Mean health status scores on the different SF-36 subscales and the PCS and the MSC during the follow-up period, stratified by the occurrence of shocks and Type D personality, are displayed in Figures 1 and 2, respectively. Patients receiving a shock during the follow-up period scored about 14 points (-13.82 [95% CI, -26.08 to -1.55]) lower on mental health status as compared with nonshocked patients and about 5 points (-5.14 [95% CI, -9.73 to -0.56]) lower on role functioning–physical. There were no significant differences between shocked and nonshocked patients on the other 6 of 8 SF-36 domains nor on the PCS and the MCS (all P>0.05) (Figure 1).

A similar pattern was visible for Type D patients as compared with non–Type D patients (Figure 2), although differences were significant for 5 of 8 health status domains (physical functioning: -5.40 [95% CI, -10.63 to -0.17]; role functioning–physical: -16.66 [95% CI, -26.23 to -7.08]; social functioning: -6.71 [95% CI, -11.65 to -1.77]; mental health: -4.44 [95% CI, -8.19 to -0.68]; role functioning–emotional: -12.04 [95% CI, -20.08 to -4.01]) and the PCS (-2.35 [95% CI, -4.57 to -0.13]) and the MCS (-3.48 [95% CI, -5.76 to -1.20]), with Type D patients scoring between about 4 to 12 points lower on specific health status domains and summary scores.

The probability values from repeated-measures analyses ANCOVAs that consider interaction effects between shock and time indicated significant interaction effects only for the subscales role functioning–emotional (P=0.023) and general health (P=0.024). Similar analyses among Type D categories showed that the differences on the averages for Type D and



Non-Type D personality (n = 293)
 Type D personality (n = 90)

Figure 2. Mean scores on health status, stratified by Type D personality.

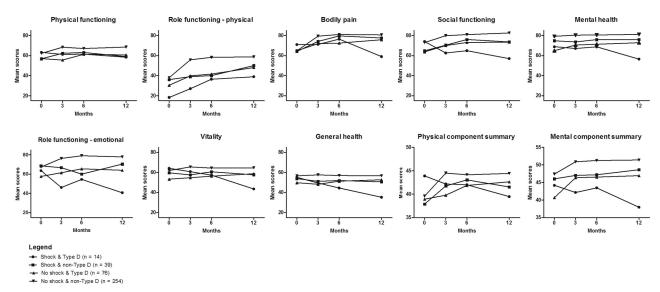


Figure 3. Mean scores on health status, stratified by the occurrence of shock and Type D personality.

non–Type D patients significantly change over time only for the subscales physical functioning (P=0.019) and bodily pain (P=0.017).

Figure 3 shows the trends for the SF-36 subscales and the PCS and the MCS separately for the 4 different combinations of shock and Type D categories: (1) shock and Type D; (2) shock and non-Type D; (3) no shock and Type D; and (4) no shock and non-Type D). Using (4) no shock and non-Type D as the reference group, there were no significant differences between this group and group (2) shock and non-Type D on any of the SF-36 subscales nor on the PCS and the MCS (all P > 0.05). Significant differences were found between the reference group and group (3) no shock and Type D on role functioning-physical (-15.90 [95% CI, -26.16 to -5.69]), social functioning (-6.94 [95% CI, -12.20 to -1.67], role functioning-emotional (-11.81 [95% CI, -20.42 to -3.20]) and the MSC (-3.18 [95% CI, -5.65 to -0.72]), with the no shock and Type D group scoring between 3 to about 16 points lower on these specific health status domains. Statistically significant differences were also found between group (4) no shock and non-Type D and group (1) shock and Type D on role functioning-physical (-30.46 [95% CI, -54.62 to -6.3]), mental health (-12.22 [95% CI, -21.33 to -3.11]), role functioning-emotional (-20.17 [95% CI, -40.15 to -0.20]) and the MSC (-6.53 [95% CI, -11.92 to -1.14]), with scores between 6 to 30 points lower on these domains in the shock and Type D group. Patterns for the 4 combinations of categories indicated the poorest health status in shocked patients with a Type D personality and the best health status in nonshocked non-Type D patients. The patterns for nonshocked Type D patients and shocked non-Type D patients showed similar trends, suggesting that generally shock and Type D personality may contribute almost equally to the variability in health status scores.

Health Status Stratified by Shocks and Type D Personality (Adjusted Analysis)

In Table 2, estimates with accompanying 95% CI for each of the predictor variables (ie, shock and Type D personality)

adjusted for other covariates for each subscale of the SF-36 and the PCS and the MCS are displayed. The occurrence of shock in the first year after implantation was a significant predictor of poorer health status during the follow-up period for 4 of 8 of the SF-36 subscales and the MCS (all P < 0.05). Type D personality was an independent predictor of postimplantation health status for 6 of 8 subscales and the MCS (all P < 0.05). Shocked patients scored between 2.60 to 13.30 points lower on these domains as compared with nonshocked patients. A similar pattern was found for Type D patients as compared with non-Type D patients, with Type D patients scoring 2.12 to 8.02 points lower. The interaction effect for Type D personality by shocks was not significant for any of the SF-36 domains nor the PCS and the MCS (results not shown). Hence, the models were run and are presented without the interaction effect. The interactions with time for either shock or Type D were not significant for any of the SF-36 domains nor the PCS and the MCS in all models shown in Table 2.

We also evaluated the separate effect of appropriate versus inappropriate shocks on all health status domains and the PCS and the MCS in multivariable models. We found no statistically significant influence of inappropriate shocks on outcomes (results not shown), which was probably due to the low incidence of inappropriate shocks during the follow-up period. For appropriate shocks, the impact on health status remained the same as presented in Table 2, with a trend toward the influence of appropriate shocks on health status being stronger as compared with examining the joint influence of any shock on health status outcomes (results not shown).

Discussion

In the current study, we sought to examine the relationship between ICD shock(s) and the patient's preimplantation personality as associates of health status, using a prospective study design with multiple assessments of health status up to 12 months after ICD implantation. We found that both ICD shock(s) and Type D personality were independently associ-

Particity Fig. Fig.						SF-36 Subscales	ales				
	Predictors	ΒF	RF-P	BP	SF	HM	RF-E	А	ВH	PCS	MCS
	Shock(s) during	NS	-13.30~(-22.78 to $-3.82)$ ‡	NS	-6.74 (-12.05 to -1.42)†	-5.27 (-8.84 to -0.71)‡	NS	-4.79(-9.02 to $-0.54)$ †	NS	NS	-2.60 (-4.71 to -0.48)†
	follow-up										
	Type D	-4.42 (-8.65 to -0.19)†	-8.02 (-15.51 to -0.54)†	-4.04 (-8.04 to -0.04)†	—6.21 (—10.40 to —2.01)‡	-3.10 (-6.02 to -0.19)†	-6.75 (-13.16 to -0.35)†	NS	NS	NS	-2.12 (-3.83 to -0.41)†
	personality										
	Sex	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	Age	NS	NS	NS	NS	NS	NS	NS	0.15 (0.01-0.28)†	NS	NS
	Single/ho	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	partner										
	Low	-4.37 (-8.51 to -0.23)†	NS	NS	NS	NS	NS	NS	NS	NS	NS
	education										
	Primary	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	prevention										
	indication										
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	CRT	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
	CAD	NS	NS	NS	NS	NS	-7.19 (-13.23 to -1.16)†	NS	NS	NS	-1.72 (-3.32 to -0.13)†
NS N	Atrial	NS	NS	-4.28 (-8.57 to 0.01)†	NS	NS	NS	NS	NS	NS	NS
NS N	fibrillation										
NS N	Diabetes	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
NS N	mellitus										
NS NS NS NS NS NS NS 375 (0.45–7.04)† 8.34 (0.89–15.79)† NS	Smoking	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
NS N	Amiodarone	NS	NS	NS	NS	3.75 (0.45–7.04)†	8.34 (0.89–15.79)†	NS	NS	NS	2.37 (0.41–4.33)†
NS NS	β -blockers	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
n 0.57 (0:50–0.64)\$ 0.38 (0:30–0.46)\$ 0.33 (0.27–0.40)\$ 0.32 (0.26–0.38)\$ 0.54 (0.48–0.61)\$ 0.29 (0.22–0.35)\$ 0.57 (0:50–0.64)\$ 0.77 (0.70–0.84)\$ 0.59 (0:52–0.66)\$	Psychotropic	NS	NS	NS	-8.27 (-13.25 to -3.29)‡	-3.52 (-6.86 to -0.18)†	-7.73 (-15.18 to -0.29)†	NS	-4.80 (-8.76 to -0.83)†	NS	-2.13 (-4.10 to -0.17)†
0.57 (0.50-0.64)§ 0.30-0.46)§ 0.33 (0.27-0.40)§ 0.32 (0.26-0.38)§ 0.54 (0.48-0.61)§ 0.29 (0.22-0.35)§ 0.57 (0.50-0.64)§ 0.77 (0.70-0.84)§ 0.59 (0.52-0.66)§	medication										
health status (5-36)	Baseline	0.57 (0.50–0.64)§	0.38 (0.30-0.46)§	0.33 (0.27–0.40)§	0.32 (0.26–0.38)§	0.54 (0.48-0.61)§	0.29 (0.22-0.35)§	0.57 (0.50–0.64)§	0.77 (0.70–0.84)§	0.59 (0.52-0.66)§	0.42 (0.35–0.48)§
status (SF-36)	health										
(SF-38)	status										
	(SF-36)										

Table 2. Independent Associates of Health Status at 12-Month Follow-Up *

SF-36 indicates Short Form Health Survey 36; PF, physical functioning; RF-P, role functioning-physical; BP, bodily pain; SF, social functioning; MH, mental health; RF-E, role functioning-emotional; VI, vitality; GH, general health; PCS, Physical Component Summary score; MCS, Mental Component Summary score; CRT, cardiac resynchronization therapy; and CAD, coronary artery disease. *Results are based on mixed modeling repeated-measures ANCOVA analysis and presented as estimates with 95% confidence intervals only for statistically significant predictors.

NS indicates not statistically significant (P>0.05). *†P*<0.05; *‡P*<0.01; *§P*<0.001.

ated with poor health status. At 12 months after implantation, shock during follow-up was independently associated with 4 domains of the SF-36 (ie, role functioning–physical domain, social functioning, mental health, and vitality) and the MCS, whereas Type D personality was an independent associate of 6 domains of the SF-36 (ie, physical functioning, role functioning–physical, bodily pain, social functioning, mental health, and role functioning–emotional) and the MCS, adjusting for demographic and clinical characteristics and baseline health status. Patients receiving a shock or patients with a Type D personality scored between 2 to 13 points lower on some of the health status domains as compared with nonshocked or non–Type D patients. The combination of shock and Type D personality was generally associated with the poorest health status at 12 months.

Our mixed findings on the association between shock(s) and health status are in line with other studies, such as the large-scale primary prevention trials, Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE),29 Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),³⁰ and Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II),¹⁸ as they also found an association with some but not all health status domains using the SF-36 or the shortened SF-12 version. It is possible that ICD shock is only associated with specific health status domains, although this is speculative. Alternatively, the SF-36 and the SF-12 are not the most sensitive measures to evaluate the impact of shock(s) on patients, as they are generic rather than disease-specific, with some scales also only being composed of 2 items, which leaves room for little variability in scores. However, in a previous cross-sectional Danish study of 566 ICD patients, we also found no association between shock and scores on the Florida Patient Acceptance Survey (FPAS), which is a disease-specific measure of device acceptance and quality of life.31

In a previous cross-sectional study in a different cohort of ICD patients, we demonstrated that the risk of anxiety and depression may depend more on the preimplantation personality of the patient than on shock(s), with an anxiety prevalence of 61% in nonshocked Type D patients versus 32% in shocked non-Type D patients, and a depression prevalence of 57% in nonshocked Type D patients versus 19% in shocked non-Type D patients.³² Others have found that Type D but not shocks are associated both with interviewer-rated and patient self-report anxiety.33 The results of the current prospective study extend those findings, demonstrating that personality remains associated with health status over time and that Type D patients report poorer health status than non-Type D patients despite improvements during the course of the 12-month follow-up period. In particular, the combination of ICD shock(s) and Type D personality was associated with the poorest health status at 12 months on all health status domains. This is consistent with our findings on anxiety and depression, which also showed that the prevalence of psychological morbidity was highest in this subset of patients with 72% being anxious and 67% being depressed if patients had a Type D personality and received a shock.³²

Given that the patient's preimplantation personality is an important correlate of postimplant health status and that Type D personality has been associated with the occurrence of ventricular tachyarrhythmia, survival,^{14,15} and poor health status with an increased risk of mortality in ICD patients,¹⁸ it is important to identify this subset of high-risk patients in clinical practice. Information about the patient's personality profile may help to target nursing and psychosocial care to the needs of the individual patient, as Type D patients and in particular Type D patients who receive a shock after implant might benefit from adjunctive intervention, such as cardiac rehabilitation³⁴ in combination with behavioral or psychological interventions that have been shown to reduce psychological distress in ICD patients.³⁵

The limitations of the current study should be acknowledged. We had to exclude 67 patients from statistical analyses because some refused to participate and others had missing information on either demographic, clinical variables, or measures of health status at baseline. This despite the use of the latest statistical technique to analyze prospective data, which allows that patients be kept in the analysis even if they did not complete all follow-up assessments.25 However, patients excluded from analyses did not differ systematically from included patients on baseline characteristics, except for nonparticipants being more likely to have a lower educational level as compared with participants. We had no information on changes in comorbidity status nor changes in medication during the 12-month follow-up period, which might potentially have influenced the outcome. Finally, given the study design, it is not possible to infer causation and whether shocks lead to poor health status or vice versa.

In conclusion, the results of the current study show that both ICD shock(s) and the patient's preimplantation personality disposition are important associates of health status 12 months after implantation, independent of demographic and clinical characteristics and baseline health status. Given that the incidence of shocks has decreased substantially with new programming algorithms and software,³⁶ it seems timely to focus on other factors in addition to shocks when identifying patients at high risk of poor health status and poor psychological functioning.²

Acknowledgments

We thank Agnes Muskens-Heemskerk for inclusion of the patients into the study and Simone Traa, Martha van den Berg, and Belinda de Lange for help with data management.

Sources of Funding

This research was supported with a VENI grant (451-05-001) from The Netherlands Organization for Scientific Research (NWO) and a VIDI grant (91710393) from The Netherlands Organization for Health Research and Development (ZonMw) to Dr Pedersen, The Hague, The Netherlands.

Disclosures

Dr Pedersen has received moderate consultancy and speaker's fees from St Jude Medical, Sanofi-Aventis, Medtronic, and Cameron Health in the past and is currently serving as a consultant for Cameron Health. Dr Jordaens has received research grants from Biotronik, Boston Scientific, St Jude Medical, Sorin, Cameron Health, and Medtronic. Dr Theuns has received research grants from St Jude Medical and Cameron Health and is currently serving as a consultant for Cameron Health.

References

- 1. Sears SF, Kirian K. Shock and patient-centered outcomes research: is an ICD shock still a critical event? *Pacing Clin Electrophysiol.* 2010;33: 1437–1441.
- Pedersen SS, van den Broek KC, van den Berg GM, Theuns DAMJ. Shock as a determinant of poor patient-centered outcomes in implantable cardioverter-defibrillator patients: is there more to it than meets the eye? *Pacing Clin Electrophysiol.* 2010;33:1430–1436.
- Versteeg H, Theuns DAMJ, Erdman RAM, Jordaens LJ, Pedersen SS. Posttraumatic stress in implantable cardioverter-defibrillator patients: the role of pre-implantation distress and shocks. *Int J Cardiol.* 2011;146: 438–439.
- Marcus GM, Chan DW, Redberg RF. Recollection of pain due to inappropriate versus appropriate implantable cardioverter-defbrillator shocks. *Pacing Clin Electrophysiol.* 2011;34:348–353.
- Pedersen SS, van den Broek KC. Implantable cardioverter-defibrillator shocks and their adverse impact on patient-centered outcomes: fact or fiction? J Am Coll Cardiol. 2008;52:1037–1038.
- Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. J Am Coll Cardiol. 2008;51:1357–1365.
- Suzuki T, Shiga T, Kuwahara K, Kobayashi S, Suzuki S, Nishimura K, Suzuki A, Ejima K, Manaka T, Shoda M, Ishigooka J, Kasanuki H, Hagiwara N. Prevalence and persistence of depression in patients with implantable cardioverter-defibrillator: a 2-year longitudinal study. *Pacing Clin Electrophysiol*. 2010;33:1455–1461.
- Pedersen SS, Hoogwegt MT, Jordaens L, Theuns DAMJ. Relation of symptomatic heart failure and psychological status to persistent depression in patients with implantable cardioverter-defibrillator. *Am J Cardiol.* 2011;108:69–74.
- Johansen JB, Pedersen SS, Spindler H, Andersen K, Nielsen JC, Mortensen PT. Symptomatic heart failure is the most important clinical correlate of impaired quality of life, anxiety, and depression in implantable cardioverter-defibrillator patients: a single-centre, crosssectional study in 610 patients. *Europace*. 2008;10:545–551.
- Braunschweig F, Boriani G, Bauer A, Hatala R, Herrmann-Lingen C, Kautzner J, Pedersen SS, Pehrson S, Ricci R, Schalij MJ. Management of patients receiving implantable cardiac defibrillator shocks: recommendations for acute and long-term patient management. *Europace*. 2010;12: 1673–1690.
- Pedersen SS, Theuns DAMJ, Erdman RAM, Jordaens L. Clustering of device-related concerns and type D personality predicts increased distress in ICD patients independent of shocks. *Pacing Clin Electrophysiol*. 2008; 31:20–27.
- Brouwers C, Denollet J, de Jonge N, Caliskan K, Kealy J, Pedersen SS. Patient-reported outcomes in left ventricular assist device therapy: a systematic review and recommendations for clinical research and practice. *Circ Heart Fail*. 2011;4:714–723.
- Pedersen SS, Sears SF, Burg MM, Van Den Broek KC. Does ICD indication affect quality of life and levels of distress? *Pacing Clin Electrophysiol.* 2009;32:153–156.
- van den Broek KC, Nyklicek I, van der Voort PH, Alings M, Meijer A, Denollet J. Risk of ventricular arrhythmia after implantable defibrillator treatment in anxious type D patients. J Am Coll Cardiol. 2009;54: 531–537.
- Pedersen SS, van den Broek KC, Erdman RAM, Jordaens L, Theuns DAMJ. Preimplantation ICD concerns and Type D personality increase the risk of mortality in patients with an implantable cardioverterdefibrillator. *Europace*. 2010;12:1446–1452.
- Whang W, Albert CM, Sears SF Jr, Lampert R, Conti JB, Wang PJ, Singh JP, Ruskin JN, Muller JE, Mittleman MA. Depression as a predictor for appropriate shocks among patients with implantable cardioverterdefibrillators: results from the Triggers of Ventricular Arrhythmias (TOVA) study. J Am Coll Cardiol. 2005;45:1090–1095.
- Ladwig KH, Baumert J, Marten-Mittag B, Kolb C, Zrenner B, Schmitt C. Posttraumatic stress symptoms and predicted mortality in patients with implantable cardioverter-defibrillators: results from the prospective living

with an implanted cardioverter-defibrillator study. Arch Gen Psychiatry. 2008;65:1324–1330.

- Piotrowicz K, Noyes K, Lyness JM, McNitt S, Andrews ML, Dick A, Hall WJ, Moss AJ, Zareba W. Physical functioning and mental well-being in association with health outcome in patients enrolled in the Multicenter Automatic Defibrillator Implantation Trial II. *Eur Heart J.* 2007;28: 601–607.
- Denollet J, Schiffer A, Spek V. A general propensity to psychological distress affects cardiovascular outcomes: evidence from research on the Type D (distressed) personality profile. *Circ Cardiovasc Qual Outcomes*. 2010;3:546–557.
- Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey. Med Care. 1993;30:473–483.
- Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, Sprangers MA, te Velde A, Verrips E. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. *J Clin Epidemiol*. 1998; 51:1055–1068.
- Denollet J. DS14: standard assessment of negative affectivity, social inhibition, and Type D personality. *Psychosom Med.* 2005;67:89–97.
- Emons WH, Meijer RR, Denollet J. Negative affectivity and social inhibition in cardiovascular disease: evaluating type-D personality and its assessment using item response theory. J Psychosom Res. 2007;63:27–39.
- Martens EJ, Kupper N, Pedersen SS, Aquarius AE, Denollet J. Type-D personality is a stable taxonomy in post-MI patients over an 18-month period. J Psychosom Res. 2007;63:545–550.
- Cnaan A, Laid NM, Slasor P. Tutorial in Biostatistics: using the general linear mixed model to analyse unbalanced repeated measures and longitudinal data. *Stat Med.* 1997;16:2349–2380.
- Verbeke G, Molenberghs G. Linear Mixed Models for Longitudinal Data. New York: Springer; 2000:89.
- Verbeke G, Lesaffre E. The effect of misspecifying the random-effects distribution in linear mixed models for longitudinal data. *Comput Stat Data Analysis*. 1997;23:541–556.
- Babyak MA. What you see may not be what you get: a brief, nontechnical introduction to overfitting in regression-type models. *Psychosom Med.* 2004;66:411–421.
- Passman R, Subacius H, Ruo B, Schaechter A, Howard A, Sears SF, Kadish A. Implantable cardioverter-defibrillators and quality of life: results from the defibrillators in nonischemic cardiomyopathy treatment evaluation study. *Arch Intern Med.* 2007;167:2226–2232.
- Mark DB, Anstrom KJ, Sun JL, Clapp-Channing NE, Tsiatis AA, Davidson-Ray L, Lee KL, Bardy GH. Quality of life with defibrillator therapy or amiodarone in heart failure. *N Engl J Med.* 2008;359: 999–1008.
- Pedersen SS, Spindler H, Johansen JB, Mortensen PT, Sears SF. Correlates of patient acceptance of the cardioverter-defibrillator: crossvalidation of the Florida Patient Acceptance Survey in Danish patients. *Pacing Clin Electrophysiol.* 2008;31:1168–1177.
- 32. Pedersen SS, van Domburg RT, Theuns DAMJ, Jordaens L, Erdman RAM. Type D personality is associated with increased anxiety and depressive symptoms in patients with an implantable cardioverter-defibrillator and their partners. *Psychosom Med.* 2004;66:714–719.
- Van den Broek KC, Nyklicek I, Van der Voort PH, Alings M, Denollet J. Shocks, personality, and anxiety in patients with an implantable defibrillator. *Pacing Clin Electrophysiol.* 2008;31:850–857.
- 34. Lewin RJ, Coulton S, Frizelle DJ, Kaye G, Cox H. A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions. *Heart*. 2009;95:63–69.
- Salmoirago-Blotcher E, Ockene IS. Methodological limitations of psychosocial interventions in patients with an implantable cardioverterdefibrillator (ICD): a systematic review. *BMC Cardiovasc Disord*. 2009;9:56.
- Wathen M. Implantable cardioverter-defibrillator shock reduction using new antitachycardia pacing therapies. Am Heart J. 2007;153:44–52.