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

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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

Implantable 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 stress1–3 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

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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 with a life expectancy of ≥1 year, with a history of psychiatric 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.

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 ≤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.

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.
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 $\chi^2$ 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-
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 MCS 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 (\(13.82 \pm 26.08\) to \(-1.55\)) lower on mental health status as compared with nonshocked patients and about 5 points (\(5.14 \pm 9.73\) 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 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 non-shocked 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-
Table 2. Independent Associates of Health Status at 12-Month Follow-Up*

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<tr>
<th>Predictors</th>
<th>PF</th>
<th>RF-P</th>
<th>BP</th>
<th>SF</th>
<th>MH</th>
<th>RF-E</th>
<th>VI</th>
<th>GH</th>
<th>PCS</th>
<th>MCS</th>
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</thead>
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<tr>
<td>Shock(s) during follow-up</td>
<td>NS</td>
<td>–13.30 (–22.78 to –3.82)‡</td>
<td>NS</td>
<td>–6.74 (–12.05 to –1.44)†</td>
<td>–5.27 (–8.84 to –0.71)‡</td>
<td>NS</td>
<td>–4.79 (–9.02 to –0.54)†</td>
<td>NS</td>
<td>NS</td>
<td>–2.60 (–4.71 to –0.48)†</td>
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<td>Type D personality</td>
<td>–4.42 (–8.65 to –0.19)†</td>
<td>–8.02 (–15.51 to –0.54)‡</td>
<td>–4.04 (–8.04 to –0.04)†</td>
<td>–6.21 (–10.40 to –2.01)‡</td>
<td>–3.10 (–6.02 to –0.19)‡</td>
<td>–6.75 (–13.16 to –0.39)‡</td>
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<td>Psychotropic medication</td>
<td>NS</td>
<td>–8.27 (–13.52 to –3.29)‡</td>
<td>–3.52 (–6.68 to –0.38)‡</td>
<td>–7.73 (–15.18 to –0.28)‡</td>
<td>NS</td>
<td>–4.80 (–8.79 to –0.83)‡</td>
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<td>NS</td>
<td>–2.13 (–4.10 to –0.17)†</td>
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<td>Baseline health status (SF-36)</td>
<td>0.57 (0.50–0.64)§</td>
<td>0.38 (0.30–0.46)§</td>
<td>0.33 (0.27–0.40)§</td>
<td>0.32 (0.26–0.38)§</td>
<td>0.54 (0.48–0.61)§</td>
<td>0.29 (0.22–0.35)§</td>
<td>0.57 (0.50–0.64)§</td>
<td>0.77 (0.70–0.84)§</td>
<td>0.59 (0.52–0.66)§</td>
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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.

†P<0.05; ‡P<0.01; §P<0.001.

NS indicates not statistically significant (P>0.05).
ated with poor health status. At 12 months after implanta-
tion, 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, adjust-
ing 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 Nonis-
chemic Cardiomyopathy Treatment Evaluation (DEFINITE),29
Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),30
and Multicenter Automatic Defibrillator Implantation Trial II
(MADIT-II),31 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 person-
ality of the patient than on shock(s), with an anxiety preva-
ence 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 pro-
spective 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 combi-
nation of ICD shock(s) and Type D personality was associ-
ated 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 preva-
ience 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 psycholog-
ical interventions that have been shown to reduce psycholog-
ical distress in ICD patients.35

The limitations of the current study should be acknowl-
dged. 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 poten-
tially 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 person-
ality 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 psycho-
logical functioning.2

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