

Type-D personality but not implantable cardioverter-defibrillator indication is associated with impaired health-related quality of life 3 months post-implantation

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Secondary prevention;
Type-D personality

Aims Little is known about the impact of ICD indication (primary vs. secondary) on health-related quality of life (HRQL). Indication may also interact with psychological factors, such as personality. Using a prospective design, we examined whether ICD indication and type-D personality (i.e. experiencing increased negative emotions paired with emotional non-expression) serve as modulators of HRQL at baseline and 3 months post-implantation.

Methods and results Consecutively implanted ICD patients ($n = 154$) completed the Type-D Scale (DS14) at baseline and the Short-Form Health Survey 36 (SF-36) at baseline and 3 months. Of all patients, 82 (53%) received an ICD due to prophylactic reasons; the prevalence of type-D was 23%. Indication had no influence on HRQL ($P = 0.75$). Further stratification by personality showed a main effect for type-D personality ($P < 0.001$), with type-D patients generally experiencing poorer HRQL; there was no main effect for indication ($P = 0.45$) nor was the interaction effect indication by type-D significant ($P = 0.22$). There was a significant improvement in HRQL over time ($P = 0.001$). Type-D remained an independent predictor of impaired HRQL, adjusting for clinical factors and shocks during follow-up ($P < 0.001$). However, in adjusted analysis there was no longer a significant change in HRQL over time ($P = 0.099$).

Conclusion Type-D personality but not ICD indication was associated with impaired HRQL at the time of implantation and at 3 months. In the quest for enhancing risk stratification in clinical practice, personality factors, such as type-D, should not be ignored, as both type-D and poor HRQL have been associated with increased risk of mortality in cardiac patients.

Introduction

Indications for the implantation of an implantable cardioverter-defibrillator (ICD) have expanded since the device was first introduced to prevent sudden cardiac death (SCD) in patients who had experienced a previous cardiac arrest (secondary prevention), with current guidelines now also advocating its use in patients at risk for life-threatening ventricular arrhythmias (primary prevention).¹ The superiority of device therapy compared with anti-arrhythmic drugs for the primary prevention of SCD in high-risk patients is well established.^{2–4}

However, little is known about the impact of ICD indication on health-related quality of life (HRQL). Health-related quality of life is an important patient-centered outcome that is receiving increasing attention in cardiovascular research together with the study of its determinants in order to facilitate implementation of research findings in clinical practice.⁵ In addition, impaired HRQL has been associated with increased risk of mortality and hospital readmissions in patients with cardiovascular disease (CVD) and chronic heart failure (CHF).^{6,7} To our knowledge, only one study has investigated the impact of primary vs. secondary prevention indication on HRQL. This study was based on a retrospective subgroup analysis of the Pacing Fast VT Reduces shock thErapies (PainFREE Rx II) trial.⁸ No

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differences were found on HRQL between patients who received an ICD due to primary or secondary prevention indication.

ICD indication (i.e. primary vs. secondary) *per se* may exert a main effect on HRQL, but indication may also interact with psychological factors, such as personality. In CVD, the distressed (type-D) personality (i.e. the tendency to experience increased negative emotions paired with emotional non-expression) is an emerging risk factor for mortality, impaired HRQL, and distress across CVD patient groups.⁹ Previously, type-D has also been associated with a seven-fold increased risk of anxiety and depressive symptoms in ICD patients, adjusting for baseline characteristics including shocks.¹⁰

In the current prospective study, which is part of an ongoing study, Mood and personality as precipitants of arrhythmia in patients with an implantable cardioverter defibrillator: a prospective study (MIDAS), we examined whether ICD indication and type-D personality serve as modulators of HRQL at baseline and at 3 months following ICD implantation.

Methods

Patients and study design

Consecutive patients receiving an ICD implantation between August 2003 and January 2006 at the Erasmus Medical Center, Rotterdam, the Netherlands, participating in the ongoing prospective MIDAS study, comprised the patient group for the current study. The MIDAS study was designed to evaluate the impact of mood and personality on arrhythmias. Patients with a life expectancy <1 year, with a history of psychiatric illness other than affective/anxiety disorders, on the waiting list for heart transplantation or with insufficient knowledge of the Dutch language were excluded. Of 187 consecutive patients fulfilling the inclusion criteria, 181 (97%) agreed to participate in the study. However, only patients ($n = 154$) with a HRQL score both at baseline (i.e. 1 day prior to implantation) and 3 months post-implantation qualified for inclusion in the current study. 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 Erasmus Medical Center. The study was conducted conform to the Helsinki Declaration and all patients provided written informed consent.

Measures

Demographic and clinical variables

Demographic variables included sex, age, marital status, employment status, and education. Information on clinical variables, including indication for ICD implantation, cardiac resynchronization therapy, coronary artery disease aetiology, CHF, previous myocardial infarction, previous percutaneous coronary intervention, previous coronary artery bypass graft surgery (CABG), diabetes, left ventricular ejection fraction (LVEF), shocks during the 3-month follow-up period, and cardiac medication were obtained from the medical records. Information on the use of psychotropic medication and participation in cardiac rehabilitation was obtained through purpose-designed questions. All demographic and clinical variables were obtained at baseline.

Type-D personality

Type-D personality was assessed with the 14-item Type-D Scale (DS14) that evaluates the presence of two stable traits, negative affectivity (e.g. 'I often feel unhappy'; seven items) and social inhibition (e.g. 'I am a closed kind of person'; seven items).¹¹ Items are

answered on a 5-point Likert scale ranging from 0 (false) to 4 (true), with a score range from 0 to 28 for both subscales. A standardized cut-off ≥ 10 on both subscales identifies type-D caseness.¹¹ The DS14 was developed in cardiac patients and is a valid and reliable measure, with Cronbach's alphas of 0.88/0.86 and test-retest reliability $r = 0.72/0.82$ for the negative affectivity and social inhibition subscales, respectively.¹¹ Previous studies have shown that it is the combination of traits rather than the single traits that is associated with deleterious effects on health.¹² In addition, the impact of type-D on morbidity and mortality in patients with established heart disease is independent of disease severity and mood states, such as symptoms of anxiety and depression.^{9,12,13} The DS14 was administered at baseline.

Health-related quality of life

The Short-Form Health Survey 36 (SF-36) was used to assess HRQL.^{14,15} The SF-36 is a generic measure consisting of 36 items that are divided into eight HRQL subdomains (i.e. physical functioning, role limitations due to physical functioning, role limitations due to emotional functioning, mental health, vitality, social functioning, bodily pain, and general health). The score range for each subdomain is converted into a score from 0 to 100; a high score indicates good HRQL, with a high score on the bodily pain subdomain representing the absence of pain. The SF-36 is a reliable measure, as indicated by Cronbach's alphas ranging from 0.65 to 0.96 for all subdomains.¹⁶ The SF-36 was administered at baseline and at 3 months.

Statistical analysis

Differences between groups stratified by ICD indication (primary vs. secondary) were examined with the χ^2 test (Fisher's exact test when appropriate) for nominal variables and are presented as n (%), whereas Student's *t*-test for independent samples was used for continuous variables with between group differences presented as mean (SD). Analysis of variance for repeated measures was

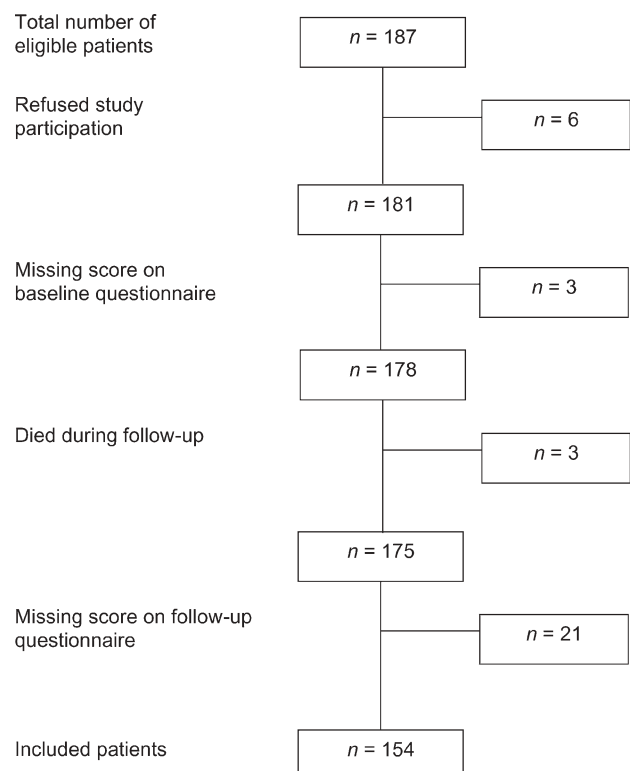


Figure 1 Overview of the patient selection for the current study.

performed to examine the main effects of ICD indication and personality and the interaction effect ICD indication by personality on HRQL at baseline and 3 months post-implantation. Adjunctive to the ANOVA, we conducted an analysis of covariance (ANCOVA) to rule out the potentially confounding influence of differences between ICD indication (primary vs. secondary)—as shown in Table 1—on the relationship between indication, personality and its interaction term on HRQL. Paired *t*-tests were used to determine changes in HRQL between baseline and 3-month follow-up within groups. A *P* value <0.05 was used to indicate statistical significance. All analyses were performed using SPSS for Windows, version 12.0.1.

Results

Patients who had complete questionnaire data did not differ systematically from those with incomplete data on any of the baseline characteristics, including on type-D personality (23 vs. 33%, *P* = 0.39).

ICD indication, personality, and baseline characteristics

Baseline characteristics stratified by ICD indication (primary vs. secondary) are shown in Table 1. Of the 154 patients, 82 (53%) received an ICD due to prophylactic reasons. Patients with a prophylactic indication were more likely to have a biventricular pacemaker, CHF, reduced LVEF, and to be prescribed digoxin (Table 1).

Table 1 Baseline patient characteristics stratified by ICD indication^a

	Primary (<i>n</i> = 82)	Secondary (<i>n</i> = 72)	<i>P</i> ^a
Demographics			
Females	18 (22)	11 (15)	0.4
Age, mean (SD)	58 (12)	59 (13)	0.59
Single	4 (5)	8 (11)	0.26
Not employed	52 (63)	48 (67)	0.8
Lower education	21 (26)	19 (27)	0.98
Clinical variables			
Resynchronization therapy	35 (43)	13 (18)	0.002
CAD aetiology	46 (56)	47 (65)	0.32
CHF	50 (61)	15 (21)	<0.001
Previous MI	41 (50)	40 (56)	0.6
Previous PCI	14 (17)	19 (26)	0.24
Previous CABG	16 (20)	19 (27)	0.38
Diabetes	9 (11)	5 (7)	0.54
LVEF, mean (SD) ^b	26 (10)	32 (11)	0.002
Attending cardiac rehabilitation	6 (7)	4 (6)	0.96
Medication			
Amiodarone	18 (23)	22 (31)	0.35
Beta-blockers	66 (83)	56 (78)	0.6
Diuretics	50 (63)	38 (54)	0.34
ACE-inhibitors	64 (80)	49 (69)	0.17
Statins	45 (56)	42 (60)	0.7
Digoxin	21 (26)	6 (9)	0.009
Psychotropic medication	15 (19)	12 (17)	0.93

^aPresented as *n* (%) unless otherwise indicated.

^bEchocardiography was only performed in a subsample of the patients: primary (*n* = 56) and secondary (*n* = 40) indication.

CAD, coronary artery disease; CHF, chronic heart failure; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft surgery; LVEF, left ventricular ejection fraction.

The prevalence of type-D personality in the current sample was 23%. The prevalence of type-D did not differ significantly according to primary vs. secondary indication (26 vs. 21%; *P* = 0.61).

During the 3-month follow-up period, 26 (17%) patients had experienced a shock. Patients with shocks were neither more likely to have a type-D personality (27 vs. 23%; *P* = 0.83) nor to have an ICD due to primary indication (39 vs. 56%; *P* = 0.15) compared with patients who had received no shocks during follow-up.

ICD indication and HRQL

Analysis of variance for repeated measures showed that patients with primary vs. secondary indication did not differ significantly on HRQL [*F* (1,152) = 0.103; *P* = 0.75] (Figure 2). ICD indication also exerted a stable effect on HRQL over time, as demonstrated by the non-significant interaction effect for time by indication [*F* (1,152) = 0.005; *P* = 0.94]. In other words, patients with primary prevention indication were not likely to improve or deteriorate more than patients with secondary prevention indication. However, patients generally experienced a significant overall change in HRQL between ICD implantation and 3-month follow-up [*F* (1,152) = 20.217; *P* < 0.001].

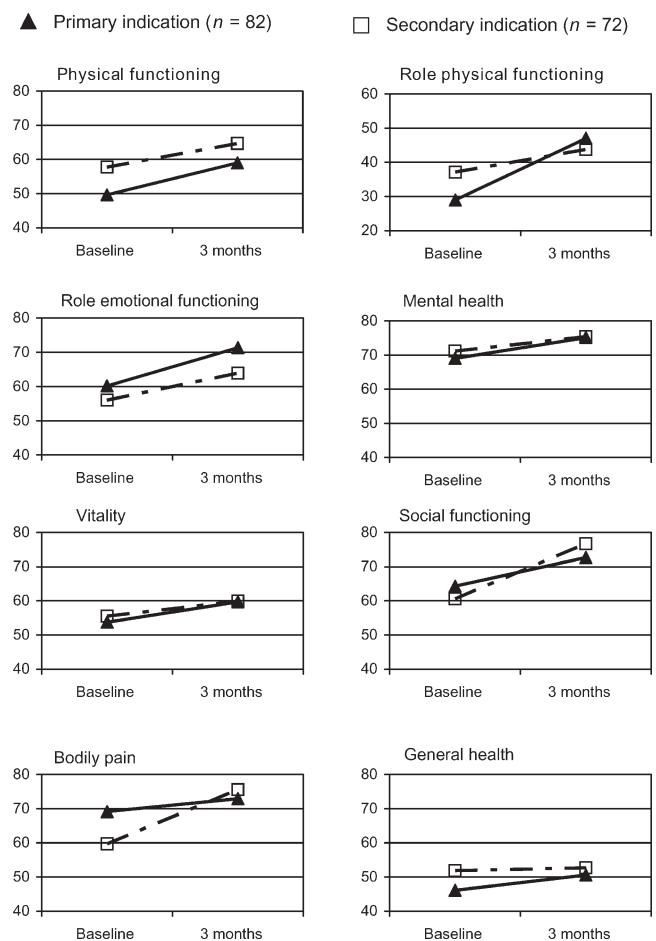


Figure 2 Health-related quality of life scores stratified by ICD indication (ANOVA for repeated measures (univariable analysis); a high score indicates better health-related quality of life with a high score on bodily pain representing absence of pain).

Primary prevention indication patients improved in all HRQL subdomains of the SF-36 ($P_s < 0.05$) except for pain ($P = 0.24$), as shown by paired *t*-tests. By comparison, secondary prevention patients only improved in the physical functioning, social functioning, and pain subdomains ($P_s < 0.05$), although there was also a trend for an improvement in mental health ($P = 0.072$) and vitality ($P = 0.084$).

ICD indication, personality, and HRQL

Further stratification by personality showed that there was a main between subjects effect for type-D personality [$F(1,150) = 14.795$; $P < 0.001$], with type-D patients generally experiencing poorer HRQL compared with non-type D patients (Figure 3). Again, there was no main effect for ICD indication [$F(1,150) = 0.576$; $P = 0.45$], and the interaction effect indication by type-D was also not significant ($F(1,150) = 1.515$; $P = 0.22$). As for within subjects effects, there was a general significant improvement in HRQL over time [$F(1,150) = 12.145$; $P = 0.001$] (Figure 3), whereas neither the interaction effects for indication by time ($P = 0.79$) or type-D by time ($P = 0.64$) nor the two-way interaction time by indication by type-D were

significant ($P = 0.74$). In other words, type-D personality exerted a stable influence on HRQL over time.

In order to rule out that the main effect of type-D personality on HRQL over time could be attributed to confounders, we performed an ANCOVA entering the main effects of ICD indication and type-D and their interaction effect, adjusting for cardiac resynchronization therapy, CHF, and digoxin (i.e. significant differences between primary- and secondary-ICD indication, as shown in Table 1) and shocks during the follow-up period. Given that echocardiography was only performed in a subsample of patients ($n = 96$), we did not include LVEF as a covariate in the initial ANCOVA, as this would have led to reduced power. In addition, reduced LVEF is already comprised within the definition of CHF (which was more prevalent in patients with primary indication), which we did adjust for. Type-D remained an independent predictor of impaired HRQL in adjusted analyses [$F(1,142) = 14.666$; $P < 0.001$] and there was a trend for CHF [$F(1,142) = 2.967$; $P = 0.087$]. However, the within subjects effect for time [$F(1,142) = 2.762$; $P = 0.099$] was no longer significant, although there was a trend. This shows that with adjustment for covariates generally there was no longer a significant change in HRQL between ICD implantation and 3 months, but type-D patients still experienced significantly poorer HRQL compared with the non-type D patients. Inclusion of LVEF as a covariate in a subsequent ANCOVA on the subsample of patients for whom information on LVEF was available did not change the overall results, as type-D was still associated with a higher risk of impaired HRQL ($P = 0.002$).

Paired *t*-tests showed that type-D patients with a primary ICD indication only improved in role physical functioning ($P = 0.041$) between implantation and 3-month follow-up, whereas non-type D patients with a primary indication improved in all HRQL subdomains ($P_s < 0.05$) except for role emotional functioning and pain. Similarly, type-D patients with a secondary indication experienced no statistically significant changes in HRQL over time, although trends were found for improvements in mental health ($P = 0.086$) and social functioning ($P = 0.088$). In contrast, non-type D patients with a secondary indication improved in physical functioning ($P = 0.01$), social functioning ($P = 0.001$), and pain ($P < 0.001$).

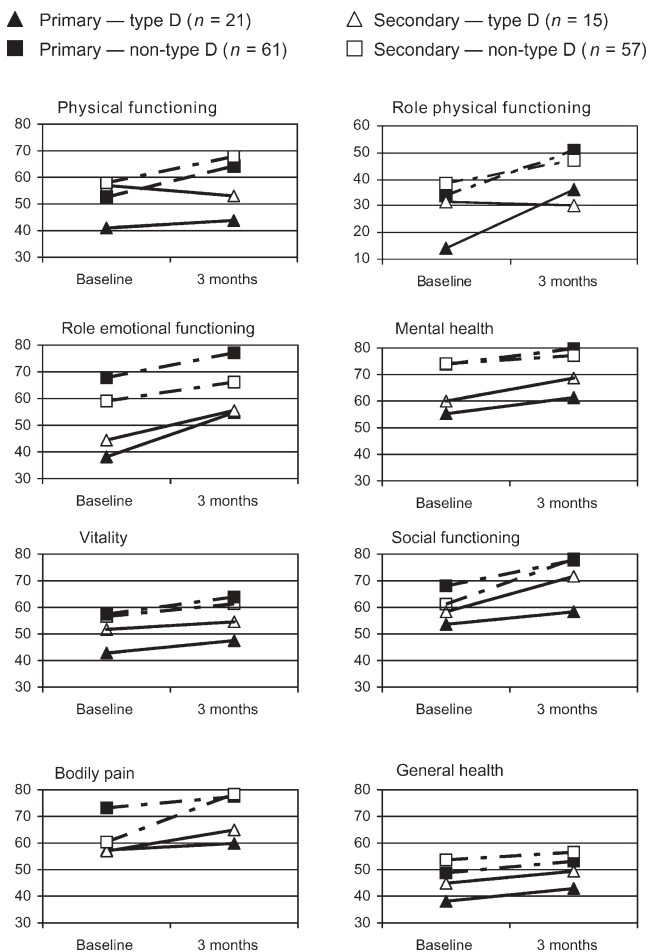


Figure 3 Health-related quality of life scores stratified by ICD indication and type-D personality (ANOVA for repeated measures (univariable analysis); a high score indicates better health-related quality of life with a high score on bodily pain representing absence of pain).

Discussion

Few studies have examined the impact of ICD indication on HRQL, and to our knowledge this is the first study to use a prospective design also investigating the potential interaction effects between indication and psychological factors. We found no main effect for ICD indication, but there was a general improvement in HRQL for both primary and secondary indication patients between ICD implantation and 3-month follow-up. When further stratifying by type-D personality, we found a main effect for type-D, with type-D patients generally experiencing poorer HRQL; there was no main effect for ICD indication nor was the interaction effect indication by type-D significant.

The impact of type-D personality on HRQL could not be attributed to differences between primary- and secondary-indication patients on clinical variables at baseline nor shocks during follow-up.

In the current study, we could not confirm that ICD indication influences HRQL. This finding is in line with the PainFREE Rx II trial, which also found no differences in HRQL between patients who received an ICD due to primary- or secondary-prevention indication, although it is important to point out that their results were based on a retrospective subgroup analysis.⁸ However, conform to our results both groups in the PainFREE Rx II trial experienced significant improvements in several dimensions of HRQL over a 12-month period. The antiarrhythmics vs. implantable defibrillators (AVID) trial¹⁷ and the Canadian implantable defibrillator study (CIDS)¹⁸ also found that ICD patients generally experience improvements in HRQL over time. In a recent retrospective cross-sectional study, ICD indication also had no impact on symptoms of anxiety and depression.¹⁹ Despite these negative results, it may be premature to write off the notion that ICD indication may interact with other factors of a clinical or psychological nature. Although we found no significant interaction effect between indication and type-D personality, the power of the current study may have been insufficient to detect such a difference, if present, due to the relatively few number of patients in the type-D/primary and type-D/secondary indication groups.

In contrast, we found that patients with a type-D personality experienced significant impairments in HRQL at the time of ICD implantation and at 3-month follow-up. In addition, type-D patients were much less likely to experience improvements in HRQL over the 3-month period than non-type D patients. The impact of personality on HRQL could neither be attributed to differences in disease severity nor to shocks during follow-up. Although no study to date has examined the impact of type-D personality on HRQL in ICD patients, previous studies in other CVD patient groups found that type-D was associated with a two- to seven-fold increased risk of impaired HRQL in CHF,²⁰ peripheral arterial disease,²¹ and primary isolated CABG patients.²² In addition, in a recent cross-sectional study of ICD patients we showed that type-D was associated with a seven-fold increased risk of anxiety and depressive symptoms, independent of clinical risk factors including shocks.¹⁰

It is noteworthy that shocks during follow-up had no impact on HRQL in the current study. This is contrary to the findings of the AVID trial,¹⁷ although the CIDS trial showed that it may not be shocks *per se* but rather the number of shocks that determines whether shocks have a deleterious effect on HRQL.¹⁸ Alternatively, there may be other factors than shocks, such as personality and concerns about the ICD firing that may be equally pertinent as shocks as determinants of HRQL. In a recent cross-sectional study of ICD patients, we showed that type-D personality¹⁰ and ICD concerns²³ were associated with anxiety and depressive symptoms independent of shocks. Positive affect or optimism is another important factor to consider, with optimism being associated with better HRQL in ICD patients, again irrespective of shocks.²⁴ In addition, in the latter study shocks only accounted for a small proportion of the variance in HRQL compared with optimism, history of depression, trait anxiety, and social support. In addition, optimism has been shown to be protective for the onset of CVD in older men.²⁵

These results have some implications for clinical practice and the management of ICD patients. Type-D personality is not only a risk factor for poor HRQL, as shown in the

current and other studies, but also a risk factor for adverse prognosis across CVD patient groups, independent of established biomedical risk factors.⁹ In addition, poor HRQL in CVD patients has been shown to predict mortality and re-hospitalizations.^{6,7} Taken together, this indicates that type-D patients comprise high-risk patients who need to be identified in clinical practice and who likely warrant some form of psychosocial intervention. Although as yet there has been no intervention trial targeting type-D personality, small-scale trials in ICD patients show that a telephone nursing intervention,²⁶ cognitive behavioural therapy,²⁷ and cardiac rehabilitation²⁸ lead to reductions in distress, although in the former two studies the intervention had no effect on HRQL. A reduction in distress would benefit type-D patients, as this may mean the difference between being categorized as type-D or not.

This study has some limitations. First, some patients either did not complete the questionnaires at baseline or at follow-up. Nevertheless, the response rate at baseline was high with 97%, and taking into account non-response at baseline and the attrition rate during follow-up (either due to death, non-response, or incomplete data on questionnaires), the response rate is still acceptable with 82%. In addition, no differences were found on baseline characteristics between patients with complete vs. incomplete questionnaire data. Second, the study may have had insufficient power to detect a significant difference in subgroup analyses, as there were relatively few patients in the type-D/primary and type-D/secondary indication groups. Nevertheless, the findings in relation to type-D and HRQL are consistent with the results found in other CVD patient groups.²⁰⁻²² Third, the follow-up period only extended to 3 months, and it is possible that ICD indication may impact on HRQL beyond this period. However, this was not supported in the retrospective analyses of the PainFREE Rx II trial.⁸ Fourth, we used a generic rather than a disease-specific measure to assess HRQL. Although generic measures are generally considered less sensitive in patient populations, this and other studies of ICD patients using the SF-36 have been able to demonstrate changes in HRQL over time.^{8,29}

Strengths of the current study were its focus on the potential impact of ICD indication on HRQL using a prospective design with serial assessments of HRQL, the high response rate, and the inclusion of personality, which is a novel approach in arrhythmia research.¹⁰

In conclusion, we found no relationship between ICD indication and HRQL at the time of implantation and at 3-month follow-up nor did indication interact with type-D personality to influence HRQL. However, patients with a type-D personality experienced significantly impaired HRQL compared with non-type D patients, and these differences could not be attributed to differences in disease characteristics nor shocks during follow-up. In the quest for enhancing risk stratification in clinical practice, personality factors in general and type-D personality in particular should not be ignored, also given that both type-D and poor HRQL have been associated with increased risk of mortality.

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