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Pre implantation psychological functioning preserved in majority of implantable cardioverter defibrillator patients 12 months post implantation

Susanne S. Pedersen a,b,*, Madelein T. Hoogwegt a, Luc Jordaens b, Dominic A.M.J. Theuns b

a CoRPS — Center of Research on Psychology in Somatic diseases, Tilburg University, Tilburg, The Netherlands
b Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands

1. Introduction

The impact of implantable cardioverter defibrillator (ICD) therapy, including complications, device advisory notifications, and ICD shocks, on patient well being is the subject of some debate [1-3]. Evidence suggests that this debate may have negative spin off effects on patients, with reports in the US of patients postponing this life-saving treatment with premature death as a consequence [4]. Studies demonstrate that 25–33% of patients experience clinical levels of symptoms of depression [5], anxiety [6], and posttraumatic stress [7]. These impairments have primarily been attributed to ICD shocks [3, 8], while studies indicate that also the underlying heart disease, such as symptomatic heart failure [9, 10], optimism [11], and personality factors (e.g. the distressed (Type D) personality) [6, 12] may contribute to psychological morbidity in ICD patients.

Efforts to elucidate the psychological impact of device therapy on patients have typically focused on mean differences between groups, changes in mean scores over time, or prevalence rates of distress at given time points, thereby neglecting changes within individuals and the identification of patients who experience a decline in psychological functioning over time [13, 14]. When discussing ICD implantation with candidate patients, it is important for physicians to be able to convey a realistic picture as to what patients might expect from a life with an ICD, including the risk of symptoms of anxiety and depression. In the clinical management and care of ICD patients, identification of this vulnerable subset of patients is important, given evidence that distress in ICD patients may increase the risk of ventricular tachyarrhythmia’s and impinge on both short- and long-term survival [15–17]. Knowledge of the characteristics typifying patients at risk for distress is important in order to design appropriate...
intervention trials for these patients and break the vicious cycle of distress leading to poor health outcomes [18].

In the current study based on a sample of first-time ICD patients seen in the real world of clinical practice, we examined (i) the prevalence of ICD patients maintaining their pre-implantation level of psychological functioning at 12 months, and (ii) factors associated with deterioration in functioning using an intra-individual approach.

2. Methods

2.1. Patients and study design

A consecutive series of patients implanted with a first-time ICD or CRT-D with cardiac resynchronization therapy (CRT-D) between August 2003 and September 2009 at the Erasmus Medical Center, Rotterdam, The Netherlands and participating in the Mood and personality as precipitants of arrhythmia in patients with an implantable cardioverter defibrillator: a prospective study (MIDAS) comprised the patient sample for the current study.

Exclusion criteria were being on the waiting list for heart transplantation, a life-expectancy of <1 year, a history of psychiatric illness other than mood or anxiety disorders, or insufficient command of the Dutch language. The Medical Ethics Committee of the Erasmus Medical Center approved the study protocol. The study was conducted according to the ethical guidelines of the Helsinki Declaration, as set out by the World Medical Association. Patients were given both written and oral information about the study and provided written informed consent prior to participation.

2.2. Procedure

A study nurse approached all patients while they were admitted to the hospital for their ICD implantation. Patients completed a set of standardized and validated self-report questionnaires at baseline (i.e., 1 day prior to ICD implantation) and at 12 months post-implantation. Patients’ medical records were checked for baseline information on demographic and clinical characteristics and additional purpose-designed questions were used to complete this data. Device interrogation was used to obtain information with respect to device therapy.

2.3. Measures

2.3.1. Baseline demographic and clinical variables

Information on baseline demographic and clinical variables were either obtained from purpose-designed questions in the questionnaire or extracted from the patients’ medical records. Demographic variables included gender, age, marital status, and educational level. Clinical variables consisted of indication for ICD therapy (primary versus secondary prevention), cardiac resynchronization therapy (CRT), a QRS duration >120 ms, left ventricular ejection fraction (LVEF) ≤35%, coronary artery disease (CAD), symptomatic heart failure (defined as New York Heart Association (NYHA) functional classes III–IV), atrial fibrillation, diabetes mellitus, smoking, the use of cardiac (i.e., amiodarone, beta-blockers, diuretics, angiotensin-converting enzyme (ACE)- inhibitors, statins and digoxin) and psychotropic medication.

2.3.2. ICD therapy during follow-up

Information regarding delivered ICD therapy was stored in our institutional database from the time of ICD implantation. Patients were advised to contact the outpatient clinic as soon as possible in case of a symptomatic event. In addition, all patients were monitored at 3-month intervals. Stored electrocardiograms that resulted in therapeutic therapies were analyzed and categorized by two experienced electrophysiologists. In case of disagreement between the two reviewers, a third reviewer was approached and a consensus was reached. Arrhythmias were classified as (a) ventricular arrhythmia or (b) atrial tachyarrhythmia without a coexistent ventricular arrhythmia. Appropriate therapy was defined as therapy triggered by ventricular tachyarrhythmia’s, whereas therapy as a result of atrial tachyarrhythmia’s (including atrial fibrillation, atrial flutter, atrial tachycardia and sinus tachycardia) or T-wave oversensing were considered inappropriate.

2.3.3. ICD concerns

The Dutch version of the Patient ICD Concerns questionnaire (ICDC), consisting of 8 items scored on a 5-point Likert scale from 0 (not at all) to 4 (very much so), was used to assess patient concerns related to ICD therapy [19]. The total score ranges from 0 to 32, with higher scores indicating more ICD-related concerns. Instead of measuring general symptoms of anxiety and depression, the ICDC is a disease-specific measure which focuses specifically on symptoms frequently reported by ICD patients (e.g., “I am worried about my ICD firing” and “I am worried about symptoms/pain associated with my ICD firing”). The ICDC is a psychometrically sound instrument, with high Cronbach’s alphas of 0.94 and 0.91 for the original and Dutch translated version, respectively [19, 20]. In order to differentiate patients with low versus high levels of ICD concerns, we used a cut-off of ≥13 (highest ICDC tertile) to indicate patients with high levels of concerns. Using this cut-off in a previous study, we have shown that ICD patients with high levels of ICD concerns are at increased risk of short-term mortality [17].

2.3.4. Symptoms of anxiety and depression

The Hospital Anxiety and Depression Scale (HADS), a 14-item self-report questionnaire, was used to measure symptoms of anxiety and depression [21]. The HADS has shown to distinguish well between symptoms of anxiety and depression in patients in non-psychiatric hospital settings [22]. Both anxiety and depression are measured by 7 items (HADS-A and HADS-D respectively), which are scored on a 4-point Likert scale. Scores range from 0 to 3, with a total score range of 0–21 for each subscale. Higher scores are indicative of more symptoms [21]. Mean Cronbach’s alphas are 0.83 and 0.82 for the HADS-A and HADS-D respectively, making the HADS a consistent and reliable scale. In a Dutch population, the test–retest reliability over 3 weeks was high with a Pearson coefficient of 0.89 and 0.86 for the anxiety and depression scale, respectively [23]. In order to detect clinically significant levels of anxiety and depression, a cut-off score of ≥8 was used. This cut-off represents an optimal balance between sensitivity and specificity, as indicated by sensitivities and specificities for both subscales of around 0.80 [22].

2.3.5. Type D personality

Type D personality, defined by the combined tendency to experience increased negative affectivity and social inhibition, was assessed at baseline with the 14-item Type D Scale (DS14) [24]. Negative affectivity is measured by 7 items (i.e., “I often feel unhappy”) as is social inhibition (i.e., “I am a closed kind of person”). Items are answered on a 5-point Likert scale ranging from 0 (false) to 4 (true), with a total score range from 0 to 28 for both subscales [24], and a cut-off ≥10 indicating a high score for each subscale [24, 25]. The internal consistency of the DS14 is good, with Cronbach’s alpha’s of 0.88, 0.86 and 3-month test–retest reliability of r = 0.72, 0.82 for the negative affectivity and social inhibition subscales, respectively [24]. Type D personality has shown to be a stable construct during an 18 month period in post myocardial infarction patients [26] and to be an independent predictor of morbidity and mortality in cardiac patients [27].

2.4. Statistical analysis

The chi-square test (Fisher’s exact test when appropriate) was used to compare groups on nominal variables, while Student’s t-test for independent samples was used for continuous variables. Multivariable linear regression analysis was used to examine predictors of mean change scores in ICD concerns, symptoms of anxiety and depression. A priori based on the literature, we had decided to include the variables gender, age, ICD indication, symptomatic heart failure (i.e., NYHA classes III–IV), LVEF ≤35%, atrial fibrillation, diabetes mellitus, Type D personality, use of beta-blocker, use of psychotropic medication, and ICD shock during the 12-month follow-up period in multivariable analyses. In addition to this list of covariates, we decided to include the baseline level of psychological functioning in order to taken into account regression to the mean. All tests were two-tailed, and a p-value < 0.05 was used to indicate statistical significance. Data were analyzed using SPSS 17.0 for Windows (SPSS Inc., Chicago, Illinois).

3. Results

3.1. Participants versus non-participants on baseline characteristics

Of 423 consecutive patients implanted with a first-time ICD or CRT-D, 405 patients (response rate 95.7%) agreed to participate and completed the baseline set of questionnaires. Of the 405 patients, 14 died during the course of the 12-month follow-up period and 59 patients did not return the 12-month questionnaire. Hence, all statistical analyses are based on 332 patients. Patients included in analyses did not differ systematically on baseline demographic and clinical characteristics from patients excluded from analyses (all ps > 0.05).

3.2. Baseline characteristics and ICD shock

Baseline characteristics for the total sample and stratified by ICD shock (cumulative of appropriate or inappropriate) are displayed in Table 1. During the 12-month follow-up period, 12.7% (42/332) of patients experienced a shock. Patients receiving a shock did not differ systematically on demographic and clinical characteristics, except for shocked patients being less likely to be prescribed beta-blocker therapy compared to non-shocked patients (59.5% versus 82.4%; p = .001).

3.3. ICD shock and baseline psychological functioning

Given that we were primarily but not exclusively interested in the influence of ICD shock on deterioration in psychological functioning
at 12 months post implantation compared to psychological functioning at implantation, we examined whether ICD patients receiving a shock during the follow-up period differed on psychological functioning at the time of implantation. Shocked versus non shocked patients neither differed significantly on baseline levels of ICD concerns, nor on baseline levels of anxiety and depressive symptoms (all ps > .37; results not shown).

### 3.4. Changes in distress between pre implantation and 12 months post implantation

At baseline, the mean score for the total sample on ICD concerns was $9.47 \pm 7.57$, $5.21 \pm 3.78$ on symptoms of anxiety, and $4.75 \pm 3.94$ on depressive symptoms. At 12 months, the mean score on ICD concerns was $5.75 \pm 6.93$, $3.93 \pm 3.70$ on symptoms of anxiety, and $3.97 \pm 3.85$ on depressive symptoms. At baseline, the proportion of patients within the clinical range of psychological morbidity was 30.1% for ICD concerns, 24.1% for anxiety, and 22.9% for depression. At 12 months, 15.4% of patients were within the clinical range on ICD concerns, 15.7% on anxiety, and 20.8% on depression. Based on clinical cut-off values for ICD concerns, anxiety, and depression, the majority of patients were below the clinical level at baseline and remained below this level at 12 months follow-up (range 63.7% to 70.2% of patients). By comparison, between 9.1% and 12.7% of patients reported levels of distress above the clinical cut-off values both at baseline and at 12 months. Taken together, the majority of patients (i.e., 72.8% to 81.7%) preserved their pre implantation level of psychological functioning 12 months post implantation (Table 2). Only between 5% and 8% of patients crossed over from low to high levels of distress, while between 10% and 21% changed from high to low levels of distress during the 12-month follow-up period.

### 3.5. Mean score change in psychological functioning stratified by shock

Patient change scores in ICD concerns (ICDC) and anxiety and depressive symptoms (HADS) between baseline and 12 months post implantation were derived by subtracting the follow-up score from the baseline score. Given that a high score on both the ICD and the HADS reflects more distress, a negative change score is equivalent to a decline in psychological functioning, while a positive change score represents an improvement in functioning. When stratifying psychological functioning by patients who received a shock versus no shock during the 12-month follow-up period, shocked patients were more likely to experience a significant deterioration in well being, as indicated by an increase in ICD concerns and symptoms of anxiety and depression compared to non-shocked patients (Fig. 1). Although statistically significant, the deterioration across the three domains was negligible from a clinical perspective, as indicated by a mean change score < 1 point from the time of implantation to 12 months post implantation. ICD shock explained 5.1% of the variance in changes of ICD concerns, and 3.1% and 3.5% of the variance in changes of symptoms of anxiety and depression, respectively.

### 3.6. Predictors of deterioration in psychological functioning between ICD implantation and 12-month follow-up

In adjusted multivariable analysis, shock during follow-up remained an independent predictor of deterioration in well being across all domains, as indicated by an increase in ICD concerns, symptoms of anxiety and depression (Table 3). Type D personality (all ps < .05) was an independent predictor of deterioration in psychological functioning at 12 months across all domains, while baseline

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### Table 1

Patient baseline characteristics for the total sample and stratified by shocks (appropriate and inappropriate) during follow-up.”

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total (N=332)</th>
<th>Shock (n=42)</th>
<th>No shock (n=290)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>266 (80.1)</td>
<td>35 (83.3)</td>
<td>231 (79.7)</td>
<td>0.58</td>
</tr>
<tr>
<td>Age, mean ± SD</td>
<td>58.0 ± 12.0</td>
<td>59.4 ± 14.2</td>
<td>57.8 ± 11.7</td>
<td>0.43</td>
</tr>
<tr>
<td>Single/no partner</td>
<td>19 (5.8)</td>
<td>4 (9.5)</td>
<td>15 (5.2)</td>
<td>0.44</td>
</tr>
<tr>
<td>Lower education a</td>
<td>186 (57.2)</td>
<td>25 (61.0)</td>
<td>161 (56.7)</td>
<td>0.73</td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary prevention indication</td>
<td>212 (63.9)</td>
<td>22 (52.4)</td>
<td>190 (65.5)</td>
<td>0.14</td>
</tr>
<tr>
<td>CRT</td>
<td>91 (27.4)</td>
<td>9 (21.4)</td>
<td>82 (28.3)</td>
<td>0.46</td>
</tr>
<tr>
<td>QRS &gt; 120 ms</td>
<td>169 (50.9)</td>
<td>27 (64.3)</td>
<td>142 (49.0)</td>
<td>0.09</td>
</tr>
<tr>
<td>LVEF ≤ 35% b</td>
<td>247 (73.5)</td>
<td>32 (65.6)</td>
<td>215 (71.5)</td>
<td>1.00</td>
</tr>
<tr>
<td>CAD</td>
<td>192 (57.8)</td>
<td>24 (57.1)</td>
<td>168 (57.9)</td>
<td>1.00</td>
</tr>
<tr>
<td>Heart failure</td>
<td>132 (39.5)</td>
<td>17 (40.5)</td>
<td>115 (39.5)</td>
<td>1.00</td>
</tr>
<tr>
<td>NYHA III–IV</td>
<td>93 (27.8)</td>
<td>10 (23.8)</td>
<td>83 (28.3)</td>
<td>0.92</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>76 (22.9)</td>
<td>14 (33.3)</td>
<td>62 (21.4)</td>
<td>0.13</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>46 (13.9)</td>
<td>9 (21.4)</td>
<td>37 (12.8)</td>
<td>0.20</td>
</tr>
<tr>
<td>Smoking</td>
<td>33 (10.0)</td>
<td>6 (14.3)</td>
<td>27 (9.4)</td>
<td>0.47</td>
</tr>
</tbody>
</table>

---

### Table 2

Changes in psychological functioning between pre implantation and 12 months post implantation.

| Baseline ICD concerns (n=328) |
|-----------------------------|-------------------|
| Normal levels (Score 0-12)  | Increased levels (Score 13) |
| 63.7% [49.0-81.4]           | 21.3% [13.2-32.5]  |
| 5.8% [2.0-12.8]             | 9.1% [4.1-17.2]    |

| Baseline anxiety symptoms (n=332) |
|-------------------------------|-------------------|
| Normal levels (Score 0-7)     | Probable clinical levels (Score ≥ 8) |
| 70.2% [54.7-88.7]             | 14.2% [7.7-23.8]  |
| 5.7% [2.0-12.7]               | 9.9% [4.7-18.3]   |

| Baseline depressive symptoms (n=332) |
|------------------------------------|-------------------|
| Normal levels (Score 0-7)          | Probable clinical levels (Score ≥ 8) |
| 69.0% [53.6-87.3]                  | 10.2% [4.9-18.7]  |
| 8.1% [3.5-15.9]                    | 12.7% [6.6-21.9]  |

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*Results are presented as % [95% CI] unless otherwise indicated; the proportion of patients preserving their pre implantation psychological functioning are indicated in bold face.
psychological status was associated with an improvement (all
ps < .05). Primary prevention indication was associated with a reduc-
tion in ICD concerns (p = .03) and anxiety (p = .006), and older age
(p = .04) with a reduction in anxiety at 12 months, while left ventricu-
lar dysfunction (p = .007) and atrial fibrillation (p = .02) were relat-
ed to deterioration in anxiety at follow-up.

4. Discussion

The objective of the current study was to determine the preva-
ience of patients who maintained their pre implantation level of psy-
chological functioning 12 months post implantation, and the in-
fluence of ICD shock and other demographic and clinical predictors
of decline in functioning in a cohort of ICD patients seen in the real
world of clinical practice. Compared to the majority of previous stud-
ies in ICD patients who have compared differences between groups
[14], we used an intra-individual approach focusing on changes in
scores within individual patients, as also recommended by others
[13].

Of all patients, the majority (i.e., 72.8% to 81.7%) preserved their
pre implantation level of psychological functioning 12 months post
implantation, representing patients who had low or high levels of dis-
tress both prior to implantation and at 12 months. Only between 5% and 8% of patients crossed over from low to high levels of distress, while between 10% to 21% changed from high to low levels of distress during the 12-month follow-up period. This indicates that the majority of ICD patients do well [10], but also that a subset of patients starts out with higher pre implantation distress scores that seem to remain stable up to 12 months post implantation, as we have also indicated previously [28]. In the latter study, we focused on trajectories of anxiety but not depression, nor did we focus on change scores within individual patients or on the predictors of deterioration in psychological functioning.

In the current study, ICD shock was an independent predictor of decline in psychological functioning across all domains, as indicated by an increase in ICD concerns, and symptoms of anxiety and depress-
ion. It should be noted, however, that shock only explained 3% to 5%
of the variance in the mean score change in the three distress mea-
sures between pre implantation and 12-month follow-up. The magni-
tude of the changes in mean distress scores found here is similar to
the mean declines in health status identified in the DEFINITE trials of
Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE)
treatment ranging from 0.5 ± 0.2 to 1.0 ± 0.5 points per shock [29]. Given
the negligible decline both in psychological functioning in the current
study and in health status in the DEFINITE trial, these changes cannot
be considered clinically relevant despite being statistically significant
[29]. In the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),
ICD patients who received a shock within 1 month prior to a quality
of life assessment experienced a significant decline in quality of life
as compared with non shocked patients, although all comparisons
were unadjusted [30]. For patients receiving a shock within 2 months
prior to a quality of life assessment, a similar decline was seen but the
magnitude of the impact was smaller. When comparing shocked ver-
sus non shocked patients overall on quality of life during the first year
of the study, there were no statistically significant differences be-
tween groups in the SCD-HeFT trial. One might speculate that the re-
duced prescription of beta-blocker therapy in shocked versus non-
shocked patients might explain the larger deterioration in psycholog-
ical functioning in shocked patients. However, there is little evidence
to support a link between beta-blocker therapy and depression and
anxiety [31, 32]. Moreover, although ICD shock likely still represents a
critical event to many individual patients [3], the findings presented
here and from the DEFINITE and SCD-HeFT trials emphasize that we
should also look beyond ICD shocks to increase our understanding of
patients at risk of poor patient reported outcomes (PROs; e.g., qual-
ity of life and distress), as shock only explains a marginal proportion of
the variance in declines in these outcomes [2, 11, 29].

In the DEFINITE trial, other factors than shocks, including gender
– both male and female depending on which domain of health status

Table 3
Predictors of mean score changes in psychological functioning between pre implantation and 12 months post implantation.

<table>
<thead>
<tr>
<th>ICD concerns</th>
<th>Anxiety</th>
<th>Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[95% CI]</td>
<td>p</td>
</tr>
<tr>
<td>Male gender</td>
<td>.01</td>
<td>[.02-1.56]</td>
</tr>
<tr>
<td>Age</td>
<td>.04</td>
<td>[.02-0.09]</td>
</tr>
<tr>
<td>Primary prevention indication</td>
<td>.12</td>
<td>[.20-3.73]</td>
</tr>
<tr>
<td>NYHA classes III-IV</td>
<td>.05</td>
<td>[.23-82]</td>
</tr>
<tr>
<td>LVEF ≤33%</td>
<td>.09</td>
<td>[.39-22]</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>.005</td>
<td>[.17-1.53]</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>.09</td>
<td>[.38-16]</td>
</tr>
<tr>
<td>Type D personality</td>
<td>.10</td>
<td>[.34-50]</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>.03</td>
<td>[.24-123]</td>
</tr>
<tr>
<td>Psychotropic medication</td>
<td>.03</td>
<td>[.23-142]</td>
</tr>
<tr>
<td>Shock during follow-up</td>
<td>.19</td>
<td>[.61-191]</td>
</tr>
<tr>
<td>Baseline psychological functioning</td>
<td>.57</td>
<td>[.45-64]</td>
</tr>
</tbody>
</table>

CI = confidence interval; ICD = implantable cardioverter de-
flbrillator; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association functional class (NYHA classes I and II combined was used as reference category).

a Standardized coefficient.

b p < .05.
c p < .01.
d p < .001.

Please cite this article as: Pedersen SS, et al, Pre implantation psychological functioning preserved in majority of implantable cardioverter de-
was looked at — older age, white race, duration of heart failure, and atrial fibrillation were associated with declines in some of the PROs assessed [29]. Similarly, our results indicate that atrial fibrillation and left ventricular dysfunction are associated with worsening of symptoms of anxiety. In contrast, primary prevention indication was related to reduction in ICD concerns and symptoms of anxiety.

In the current study, Type D personality was also associated with a decline in psychological functioning across all domains. Previously, Type D personality has been shown to influence anxiety trajectory membership [33], chronic anxiety [6], anxiety severity [12], general levels of anxiety [12], and quality of life in ICD patients [34]. The distressed (Type D) personality has also been implicated as a risk marker for ventricular tachyarrhythmia’s, particularly when clustering with anxiety [35], and as an independent risk marker for short-term mortality in ICD patients [17].

The limitations of the current study should be acknowledged. First, we had no information on changes in symptomatic heart failure and atrial fibrillation and adjustment in cardiac and psychotropic medication that may have occurred during the follow-up period. Such changes might potentially influence distress levels at 12-month follow-up. Second, we had no information on patients’ psychological functioning prior to admission to ICD implantation, which may influence later psychological health. However, we did include the Type D personality construct, which represents a propensity to experience general distress and a stable vulnerability factor for poor health outcomes, including morbidity and mortality [27], that does not seem to be influenced by an acute cardiac event and levels of distress at the time of the event [26]. Third, the baseline assessment (i.e., 1 day prior to ICD implantation) of psychological functioning may not be optimal, given that patient responses may reflect implantation-related anxiety rather than ‘true’ anxiety. However, this time point was chosen so as to fit with clinical practice and to standardize the baseline assessment, as all patients are admitted 1 day prior to ICD implantation in our center. The study also has several strengths, including the use of an intra-individual rather than a between groups approach to examining differences in distress over time, the high response rate of 95.7%, the use of both standardized and validated disease-specific and generic measures of psychological functioning, and the statistical adjustment of pertinent demographic and clinical factors that might potentially serve as confounders on the outcomes. Despite patients being excluded from statistical analyses, as they had not completed the 12-month follow-up questionnaires either due to death or attrition over time, these patients did not differ systematically on baseline demographic and clinical characteristics from patients included in analyses. Hence, results generalize to the total population.

In conclusion, we found that the majority of ICD patients maintained their pre implantation level of psychological functioning 12 months post implantation. A subset of patients was at risk of poor psychological adaptation, attributable to ICD shocks, atrial fibrillation, left ventricular dysfunction and the patient’s personality profile. By contrast, primary prevention indication and higher age were protective against deterioration in some domains of psychological functioning. Future studies are warranted to confirm these findings, using an intra-individual approach and a longer follow-up period. If the results of these studies will be consistent with those of the current study, we are able to communicate to patients prior to implantation that the majority of patients are able to cope with the side effects of device therapy, including device advisory notifications and expanding indications for ICD placement, as indicated elsewhere [36, 37].

Acknowledgments

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The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology [38].

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