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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, cross-sectional study in 610 patients

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Aims To identify correlates of impaired quality of life (QOL), anxiety, and depression in patients with an implantable cardioverter-defibrillator (ICD).

Methods and results Surviving patients ($n = 610$) who received an ICD in our institution since 1989 completed the Short Form Health Survey (SF-36) and the Hospital Anxiety and Depression Scale. Mean age was 62.4 years with 18% females. In a multivariate logistic regression analysis, symptomatic heart failure was the most important correlate of impaired QOL (SF-36) across all eight subscales [odds ratios (ORs) ranging from 5.21 to 22.53], whereas psychotropic medication, age, comorbidity, amiodarone, and ICD shocks all correlated to a lesser extent. Symptomatic heart failure was also the most dominant correlate of anxiety [OR 5.15 (3.08–8.63), $P < 0.001$] and depression [OR 6.82 (3.77–12.39), $P < 0.001$]. Implantable cardioverter-defibrillator shocks correlated less yet significantly with anxiety [OR 2.21 (1.32–3.72) $P < 0.01$] and depression [OR 2.00 (1.06–3.80), $P < 0.05$].

Conclusion Symptomatic heart failure was the single most important clinical correlate of impaired QOL, anxiety, and depression, with ICD shocks playing only a secondary role. This suggests that comorbidity rather than ICD therapy *per se* influences patients' device acceptance, supporting the increasing use of prophylactic ICD implantation.

Introduction

Treatment with an implantable cardioverter-defibrillator (ICD) has been shown to reduce mortality significantly in patients at risk of sudden arrhythmic death¹ and in combination with cardiac resynchronization therapy (CRT) also to relieve chronic heart failure (CHF) symptoms, leading to improved quality of life (QOL), exercise capacity, and cardiac function.² However, the well-being of an ICD patient can be negatively influenced by a number of factors apart from the risk of dying suddenly or having

painful shocks, including the underlying heart disease (e.g. ischaemic vs. non-ischaemic), comorbidity (e.g. CHF), presence of the ICD (e.g. cosmetic), social or professional restrictions (e.g. driver's license), a negative effect on partner and family life or non-optimal information and support from the healthcare system.

Although there has been a strong focus on optimizing the clinical aspects of ICD therapy, only more recently attention has been paid to the psychological issues. Importantly, a subset of patients is prone to experience high levels of ICD concerns, with a negative impact on acceptance of the ICD.³ Thus, when advocating the widespread use of ICDs, particularly in asymptomatic patients, the psychological

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impact of living with an ICD should also be considered, because the full benefits of ICD therapy can only be achieved if the patient's QOL and emotional well-being are preserved.

To date, no studies have evaluated QOL, anxiety, and depression and their correlates in a large cross-sectional population of patients with an ICD. Hence, we approached all surviving patients having received an ICD in our institution, with a view to examine the potential influence of a multitude of factors on the QOL and psychological health of the ICD patient.

Methods

Patients

The study population consists of all patients implanted with an ICD at the Aarhus University Hospital (Skejby) since 1989 and still alive on 1 November 2006. Patients with a first ICD implant within the last 3 months were not included. In 95% of the patients, the main indication for ICD was secondary prevention, as primary prevention was not generally implemented in Denmark before 2007. A flow chart of the patient selection is presented in *Figure 1*.

All surviving patients received a questionnaire by mail, which they were asked to complete and return in a self-addressed, stamped envelope. If the questionnaire was not returned within 2 weeks, a

reminder was sent including a duplicate of the questionnaire. The patient was asked to complete a number of questions on clinical and demographic data and a set of standardized and validated psychological questionnaires. The study was conducted according to the Helsinki Declaration.

Demographic and clinical variables

Data were retrieved from the patients' medical records and the Danish ICD Registry⁴ and from purpose-designed questions in the questionnaire. All re-operations caused by device or lead malfunctioning or infection, as registered by the Danish ICD Registry,⁴ were considered as complication to ICD therapy. Comorbidity (e.g. gait, diabetes, muscular dystrophy, stroke, cancer, pulmonary disease, and renal insufficiency) and number of ICD shocks were based on self-report. Symptomatic CHF was determined using the Minnesota living with heart failure (MLHF) questionnaire.⁵ The 21-item MLHF is a valid and reliable, disease-specific measure of QOL, with items scored on a 6-point Likert scale from 0 (no) to 5 (very much). The total MLHF score ranges from 0 to 105, with a lower score indicating good QOL. Dichotomization was undertaken in order to enhance the interpretation of the results in clinical practice.⁶ An MLHF score above 40 represents New York Heart Association (NYHA) classes III-IV (i.e. symptomatic CHF).⁷ As the 75% upper percentile in our data was 41, we used a cut-off value of >40 as a marker of symptomatic CHF.

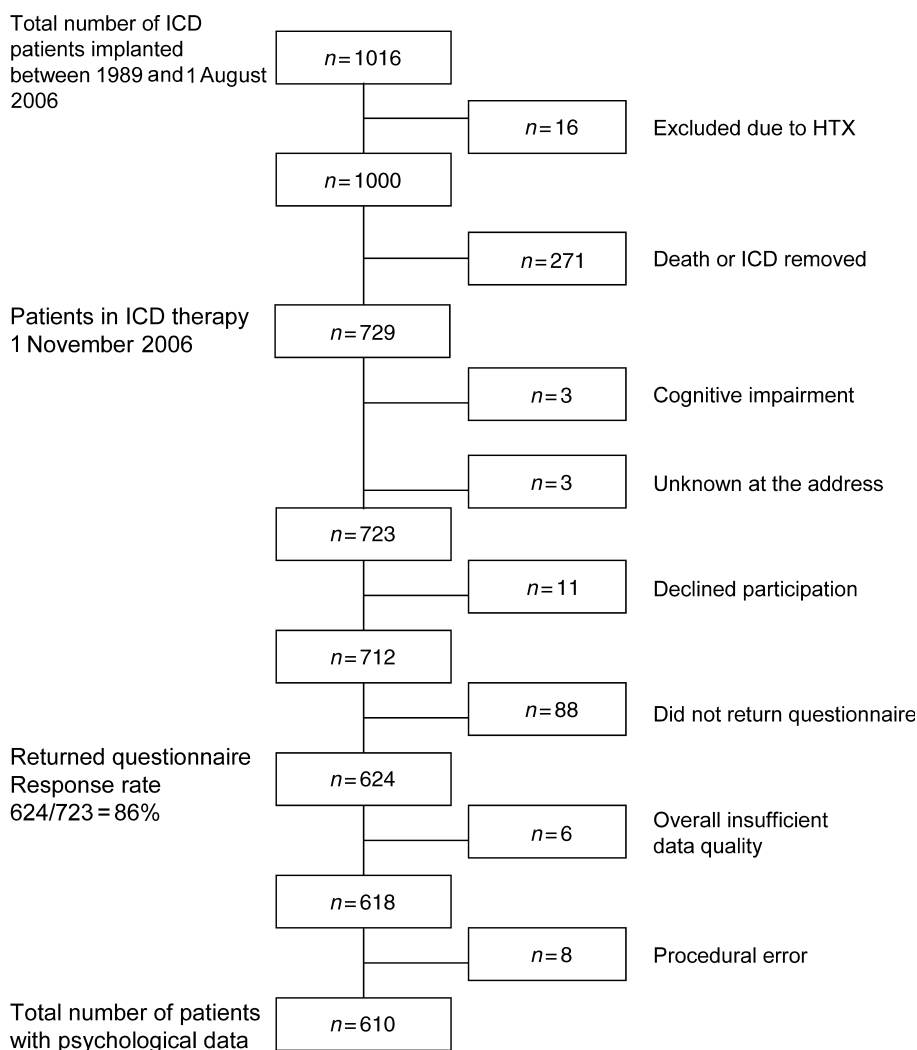


Figure 1 Flowchart for the study group.

Anxiety and depression symptoms

The 14-item Hospital Anxiety and Depression Scale (HADS)[®] (see Appendix) was used to assess the symptoms of anxiety (seven items) and depression (seven items).⁸ Items are answered on a 4-point Likert scale ranging from 0 to 3 (score range 0–21). The HADS is a valid and reliable instrument across countries in cardiac and non-cardiac populations,^{9–11} with a recent review demonstrating that a cut-off ≥ 8 on both subscales represents probable clinical levels.¹¹ An advantage of the use of HADS in the context of patients with somatic disease is that it is devoid of somatic items and hence more likely to reflect real depressive symptoms rather than underlying disease.¹⁰

Quality of life

The Short Form Health Survey (SF-36) was used to assess the QOL.¹² The SF-36 is a generic QOL measure comprising eight subdomains: role physical functioning, role emotional functioning, physical functioning, mental health, vitality, social functioning, bodily pain, and general health. Scale scores are obtained by summing the items together within a domain, dividing this outcome by the range of scores, and then transforming the raw scores to a scale from 0 to 100. A higher score on the SF-36 subdomains represents better functioning, with a high score on the bodily pain scale indicating the absence of pain. The scale has good reliability with Cronbach's alpha ranging from 0.65 to 0.96 for all subscales.¹³

Statistics

Continuous variables were compared with Student's *t*-test for independent samples and discrete variables with the χ^2 test. In multivariable logistic regression, we analysed demographic and clinical factors as correlates of impaired QOL, anxiety, and depression. Prior to analyses, we dichotomized all QOL scores using the lower tertile on the SF-36 to indicate impaired QoL. In all analyses, we entered age, gender, years in ICD therapy, complication to ICD therapy, smoking, ICD shocks, comorbidity, amiodarone, other anti-arrhythmic medication, psychotropic medication, living with a spouse, ischaemic vs. non-ischaemic aetiology for ICD, and CHF (as expressed by MLHF > 40), which were selected *a priori* on the basis of the literature. A *P*-value less than 0.05 was chosen to indicate statistical significance, and all tests were two-tailed. Odds ratios (ORs) with their corresponding 95% confidence intervals (CIs) are reported for the logistic regression analyses. All analyses were performed using SPSS 13.0 for Microsoft Windows.

Results

Of the 723 potentially eligible patients, 624 returned the questionnaire (response rate 86%) and data were adequate for 610 patients (84%). Patients included in the study were slightly older 62.4 ± 14.2 vs. 58.8 ± 16.2 ($P < 0.05$, Student's *t*-test), and those included also had a higher prevalence of ischaemic aetiology for ICD therapy (63 vs. 52%, $P < 0.05$, χ^2), compared with those not included. Years of ICD treatment, gender, proportion of cardiac resynchronization therapy device and defibrillator (CRT-D), and complications were evenly distributed (data not shown).

Baseline characteristics

Basic demographic and clinical data for the 610 patients who constituted the study group (Figure 1) are shown in Table 1. The mean age was 62.4 years, which is comparable with other studies, whereas male gender was more dominant (82%) in comparison with 76–80% seen in other major studies.^{14,15} Only 110 patients (18.0%) were implanted

with a CRT-D and 578 patients (95%) had secondary prevention as indication, reflecting the historical data. A total of 51 (8.4%) patients had device-related complications such as infection, premature end of life of the device, lead fracture, and so on, causing re-operation. Major findings were ischemic heart disease in 384 patients (63.0%), comorbidity in 134 patients (22.0%), CHF in 150 patients (24.6%), and treatment with amiodarone in 142 patients (23.3%). As expected, patients with CHF, as measured by an MLHF score > 40 , were significantly more often treated with CRT-D, CHF medication, and amiodarone (Table 2). The only exception was β -blockers, which was evenly distributed. A total of 263 patients (43.1%) reported having experienced ICD shocks, with 96 patients (15.7%) having received more than three shocks.

Correlates of impaired quality of life

The dominant independent correlate of impaired QOL, as shown in Table 3, was CHF, which was an independent correlate across all eight subscales of the SF-36. Other independent correlates of impaired QOL were psychotropic medication (six of eight subscales), age (four of eight subscales), comorbidity (four of eight subscales), and amiodarone (two of eight subscales). Interestingly, ICD shocks only had a negative effect on one of the eight QOL subscales of the SF-36 (i.e. physical functioning), and no effect was seen on ICD-related complications or years with ICD therapy.

Correlates of anxiety and depression

Chronic heart failure and, to a lesser degree, ICD shocks were correlates of symptoms of anxiety and depression (Table 4), with women being likely to report anxiety than men and patients using psychotropic medication more likely to report depression. Again, ICD-related complications and years with ICD therapy were not associated with anxiety or depression.

Discussion

Despite several clinical studies having documented that ICD treatment significantly reduces sudden arrhythmic death, the implantation rate both for primary and secondary prevention shows a worldwide variation.¹⁶ With the addition of CRT to ICD therapy, the benefit of ICD implantation should be even more advantageous for larger patient groups. The extremes are the USA in comparison with the less-developed countries, but even between socio-economically comparable European countries, implantation rates vary considerably.¹⁷ The differences in the rate of ICD implantation can, therefore, only partly be attributed to the availability of economical and medical resources,¹⁷ whereas it has been suggested that local guidelines, psychological and ethical factors may also play a role.¹⁸

For many physicians, there seems to be an ethical barrier blocking implementation of the international guidelines for ICD implantation. This barrier has been suggested to be due to the physician's concern about the psychological strain on the ICD patient, especially in the case of multiple shocks or device-related complications.¹⁸ However, some of the principal findings of our study are, as also found by others,¹⁹ that shock therapy leads to increased anxiety,

Table 1 Baseline characteristics for eligible patients with psychological data ($n = 610$)

	No. of patients	Percentage of total (%)	Questionnaire scores, Mean (SD)
<i>Demographics</i>			
Female gender	108	17.7	
Age, mean (range)	62.4 (8–85)		
Living with a spouse	463	75.9	
<i>Clinical</i>			
Years in treatment, mean (range)	4.8 (0.4–15.9)		
Numbers of ICDs, mean (range)	1.5 (1–5)		
CRT-D	110	18	
Complication	51	8.4	
<i>Etiology for ICD</i>			
Ischaemic heart disease	384	63.0	
Idiopathic ventricular fibrillation	5	0.8	
Hypertrophic cardiomyopathy	11	1.8	
Dilated cardiomyopathy	44	7.2	
Arrhythmogenic right ventricle	13	2.1	
Cardiomyopathy, other	71	11.6	
Congenital heart disease	11	1.8	
Valvular heart disease	10	1.0	
Congenital long QT	4	0.7	
Primary electrical disease, other	9	1.5	
Unknown	48	7.9	
Secondary prevention as ICD indication	578	94.8	
CHF (MLHF > 40)	150	24.6	
ICD shock (≥ 1 shock)	263	43.1	
ICD shock (≥ 4 shocks)	96	15.7	
Comorbidity	134	22.0	
Smoking current	136	22.3	
<i>Medications</i>			
β -blocker	490	80.3	
ACE-inhibitors	407	66.7	
Loop diuretics	274	44.9	
Aldosterone antagonist	184	30.2	
Digoxin	96	15.7	
Amiodarone	142	23.3	
Other anti-arrhythmics	13	2.1	
Psychotropics	78	12.8	
<i>Psychological</i>			
Anxiety ^a	115	18.9	4.3 (4.1)
Depression ^a	77	12.6	3.4 (3.4)
<i>Quality of life^b</i>			
Impaired physical functioning	184	31.1	65.0 (27.7)
Impaired role physical functioning	17	2.1	48.3 (43.5)
Impaired role emotional functioning	117	19.1	67.6 (39.5)
Impaired mental health	196	32.1	78.3 (18.8)
Impaired vitality	187	30.7	59.3 (25.6)
Impaired social functioning	194	31.8	83.7 (23.8)
Impaired bodily pain	196	32.1	78.1 (26.3)
Impaired general health	202	33.1	58.5 (24.1)

^aCut-off ≥ 8 , as recommended by Bjelland and colleagues.⁹

^b'Impaired' indicates lower tertile of the total score of the subscale.

although the influence on depression is less clear. More importantly, in the present study, the negative effect induced by shock therapy on QOL was only documented for one of eight subscales of the SF-36. In addition, in contrast to another but considerably smaller study,²⁰ neither ICD-complications nor years with ICD therapy correlated with impaired QOL or anxiety and depression. The rather low complication rate of 8.4% found in this study^{21,22} may partly explain the latter finding, thereby also stressing the importance of high medical standards. Taken together,

these results show that in our large cohort of ICD patients, in general, ICD therapy was well tolerated also from a psychological point of view.

In the current study, we used the MLHF to evaluate the severity of CHF rather than the NYHA classification system, as the validity and reliability of the latter classification system are the subject of some debate.²³ The MLHF seems to be a good and integrated measure of both physical and mental impairment due to CHF.²⁴ Furthermore, the simultaneous CHF assessment by MLHF and sampling of SF-36

Table 2 Relationship between CHF as indicated by MLHF and other surrogates for CHF

CHF surrogate	No CHF (MLHF ≤ 40)	CHF (MLHF > 40)	P-value ^a
CRT-D	70 (15.2%)	40 (26.7%)	0.002
β-blocker	375 (83.3%)	115 (78.8%)	0.21
ACE-inhibitors	299 (67.0%)	108 (75.0%)	0.07
Loop diuretics	173 (38.4%)	101 (67.8%)	<0.000
Aldosterone antagonist	121 (27.1%)	63 (42.3%)	<0.000
Digoxin	63 (14.0%)	33 (22.3%)	0.017
Amiodarone	86 (19.0%)	56 (37.8%)	<0.000

^aChi-square test.

and HADS data is an advantage of this study, which evaluates the interactions between CHF and QOL and anxiety and depression.

Symptomatic CHF, seen in 25% of the patients, was the strongest correlate of impaired QOL, associated with all SF-36 subscales. This corresponds well with the findings from studies of CHF patients without ICDs.^{25,26} It also stresses the importance of optimizing CHF medication and adding CRT to ICD therapy in patients with indications for CRT to achieve the additive effect of CRT on top of conventional heart failure drug therapy.²⁷

Amiodarone, a class 3 anti-arrhythmic drug primarily used for treatment-resistant tachyarrhythmias, was in the present study independently correlated with impaired QOL on four of eight QOL subscales, likely due to its many and troublesome side effects.²⁸ Although amiodarone is a proven effective adjunct drug therapy in ICD patients,²⁹ several long-term studies have also shown that it is poorly tolerated with subsequent low compliance.^{29,30} This has also been found in other studies in non-ICD patients²⁸ and thus suggests a restricted use of amiodarone whenever possible.

Clinical levels of anxiety and depression are seen in ~25–30% of ICD patients,³¹ which is slightly more than in the current study. Similar to some^{32,33} but not all studies,³⁴ we found that CHF and ICD shocks were significant correlates of anxiety and depression. Like others³⁴ we also found that females were more likely to report anxiety compared with males, and that the use of psychotropic medication was related to depression.

Any physician dealing with ICD therapy is concerned about the constraint forced upon health economics and the complication rate related to device implantation and therapy³⁵ and the logistics connected to the rapidly increasing number of implants and follow-ups. Everybody can recall single patient cases with multiple shock therapies, being appropriate or inappropriate, leaving the patient and the family in a psychological traumatized state. However, overall findings of the current study indicate that aside from the above-mentioned troublesome but single cases, ICD treatment seems to be well accepted and tolerated by the vast majority of patients. Therefore, whenever sufficient health economics is available, ICD treatment should be offered to all eligible patients also as a primary prevention measure. This recommendation is supported by cost-benefit analyses, demonstrating that ICD treatment is

Table 3 Correlates of impaired quality of life

SF-36 subscales	Impaired PF OR (95% CI)	Impaired RPF OR (95% CI)	Impaired REF OR (95% CI)	Impaired MH OR (95% CI)	Impaired VI OR (95% CI)	Impaired SF OR (95% CI)	Enhanced BP OR (95% CI)	Impaired GH OR (95% CI)
Female gender	ns	ns	ns	2.31 (1.32–4.06) [†]	ns	ns	ns	ns
Age	1.08 (1.05–1.11) [‡]	1.13 (1.01–1.26) [*]	1.02 (1.00–1.04) [*]	ns	ns	ns	1.04 (1.02–1.06) [†]	ns
Living with a spouse	0.47 (0.26–0.83) [†]	ns	ns	1.91 (1.09–3.35) [*]	ns	ns	ns	ns
Non-ischaeamic aetiology	ns	ns	ns	ns	ns	ns	1.77 (1.07–2.93) [*]	ns
Symptomatic CHF	11.74 (6.97–19.76) [‡]	22.53 (4.68–108.46) [‡]	5.21 (3.23–8.40) [‡]	6.83 (4.23–11.02) [‡]	8.52 (5.26–13.78) [‡]	11.66 (7.00–19.41) [‡]	7.41 (4.59–11.95) [‡]	14.13 (8.37–23.83) [‡]
Comorbidity	2.27 (1.32–3.92) [†]	ns	ns	ns	ns	1.78 (1.06–2.99) [*]	2.71 (1.66–4.46) [‡]	2.61 (1.55–4.39) [‡]
ICD-related complications	ns	ns	ns	ns	ns	ns	ns	ns
ICD shocks	ns	10.58 (1.73–64.74) [*]	ns	ns	ns	ns	ns	ns
Years with ICD therapy	ns	ns	ns	ns	ns	ns	ns	ns
Current smoking	ns	ns	ns	ns	ns	ns	ns	ns
Amiodarone	ns	ns	ns	1.93 (1.18–3.16) [†]	1.67 (1.02–2.75) [*]	ns	ns	ns
Other anti-arrhythmic medication	ns	ns	ns	ns	ns	ns	ns	ns
Psychotropic medication	ns	ns	2.35 (1.29–4.27) [†]	3.05 (1.69–5.51) [‡]	2.64 (1.47–4.75) [†]	2.33 (1.26–4.30) [†]	1.83 (1.01–3.29) [*]	2.69 (1.44–5.02) [†]

PF, physical functioning; RPF, role physical functioning; REF, role emotional functioning; MH, mental health; VI, vitality; SF, social functioning; BP, bodily pain; GH, general health.
* $P < 0.05$; [†] $P < 0.01$; [‡] $P < 0.001$.

Table 4 Correlates of anxiety and depression

	Anxiety ^a OR (95% CI)	Depression ^a OR (95% CI)
Female gender	2.38 (1.32–4.29) [†]	ns
Age	ns	ns
Living with a spouse	ns	ns
Non-ischaemic aetiology	ns	ns
Symptomatic CHF	5.15 (3.08–8.63) [‡]	6.82 (3.77–12.39) [‡]
Co-morbidity	ns	ns
ICD-related complications	ns	ns
ICD shocks	2.21 (1.32–3.72) [†]	2.00 (1.06–3.80) [*]
Years with ICD therapy	ns	ns
Current smoking	ns	ns
Amiodarone	ns	ns
Other anti-arrhythmic medication	ns	ns
Psychotropic medication	ns	2.75 (1.40–5.40) [†]

^a Cut-off ≥ 8 , as recommended by Bjelland and colleagues.⁹

^{*} $P < 0.05$; [†] $P < 0.01$; [‡] $P < 0.001$.

found competitive in comparison with other already fully implemented invasive cardiac strategies.^{36–39}

Our study is addressing that which is beneficial to the majority of patients and tends to ignore the special needs of individual patients. Pedersen and colleagues have in a number of studies identified a subgroup of ICD patients who are at risk for increased anxiety and depression and poor QOL, with the distressed (Type D) personality and a high score on ICD concerns characterizing these patients.^{19,34} Besides standard ICD indications based on rigid clinical criteria, this calls for a more patient-specific selection procedure before ICD implantation, with more focus on the individual need of the patient both at the time of evaluation and implantation and in the post-hospitalization follow-up phase. More studies are warranted in this direction in order to be able to identify high-risk patients who may need further support and adjunctive intervention, e.g. of a psychosocial nature. Preliminary evidence from a recent review indicates that such intervention may successfully reduce levels of anxiety.⁴⁰

The results of this study should be interpreted with some caution, as the cross-sectional design of the study does not allow for the inference of cause and effect. In addition, symptomatic CHF was assessed by means of a proxy measure, namely the MLHF questionnaire and we had no information on left ventricular ejection fraction (LVEF), as a measure of disease severity, which could potentially serve as a confounder, although LVEF had no effect on patient-centred outcomes in other studies.^{3,19} Furthermore, some clinical variables were obtained by means of self-report, which may be subject to bias. In addition, the majority of patients had a secondary indication for ICD implantation, reflecting the historical data. This might imply that the results of the current study may not necessarily be generalizable to ICD patients seen in clinical cardiology practice today, since the number of patients with a

primary indication is increasing. Nevertheless, studies examining the influence of indication on patient-centred outcomes, such as QOL, anxiety and depression, have found no support for an effect of indication on these outcomes, including on acceptance of the device.^{3,32,41,42}

Despite these limitations, this study also has several strengths, including the relatively high response rate and that this, to our knowledge, is the largest study of ICD patients to report on a broad range of patient-centred outcomes, including QOL, anxiety, and depression.

In conclusion, the present study documents that ICD therapy, in general, is very well accepted by ICD patients, with CHF being the dominant correlate of impaired QOL. Despite ICD implantation reducing cardiac arrhythmic death, this treatment modality is very unevenly distributed among countries, a fact that cannot be fully explained by socio-economical differences. Ethical and psychological factors may play an important role in determining to what extent ICD treatment is implemented in the national health strategies. As a consequence, there seems to be a need for further education and information of the health community, so that ICD treatment is not withheld on subjective reasons, but is offered to all eligible patients including as primary prevention.

In addition, focus should be directed towards improving the QOL and reducing anxiety and depression in a subgroup of patients, particularly those with symptomatic CHF.

Conflict of interest: none declared.

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Appendix

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