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ORIGINAL RESEARCH ARTICLE

Changes in quality of life, depression, general anxiety, and heart-focused anxiety after defibrillator implantation

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Abstract

Aims The Anxiety-CHF (Anxiety in patients with Chronic Heart Failure) study investigated heart-focused anxiety (HFA, with the dimensions fear, attention, and avoidance of physical activity), general anxiety, depression, and quality of life (QoL) in patients with heart failure. Psychological measures were assessed before and up to 2 years after the implantation of an implantable cardioverter defibrillator (ICD) with or without cardiac resynchronization therapy defibrillator (CRT-D).

Methods and results One hundred thirty-two patients were enrolled in this monocentric prospective study (44/88 CRT-D/ICD, mean age 61 ± 14 years, mean left ventricular ejection fraction 31 ± 9%, and 29% women). Psychological assessment was performed before device implantation as well as after 5, 12, and 24 months. After device implantation, mean total HFA, HFA-fear, HFA-attention, general anxiety, and QoL improved significantly. Depression and HFA-related avoidance of physical activity did not change. CRT-D patients compared with ICD recipients and women compared with men reported worse QoL at baseline. Younger patients (<median of 63 years) had higher levels of general anxiety and lower levels of HFA-avoidance at baseline than older patients. After 24 months, groups no longer differed from each other on these scores. Patients with a history of shock or anti-tachycardia pacing (shock/ATP; *N* = 19) reported no improvements in psychological measures and had significantly higher total HFA and HFA-avoidance levels after 2 years than participants without shock/ATP.

Conclusions Anxiety and QoL improved after device implantation, and depression and HFA-avoidance remained unchanged. HFA may be more pronounced after shock/ATP. Psychological counselling in these patients to reduce HFA and increase physical activity should be considered.

Keywords Implantable cardioverter defibrillator; Implantation; Heart failure; Heart-focused anxiety; General anxiety; Quality of life

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Introduction

Randomized controlled trials have demonstrated the efficacy of implantable cardioverter defibrillator (ICD) alone or in combination with cardiac resynchronization therapy defibrillator (CRT-D) in patients with chronic heart failure (CHF) and reduced left ventricular ejection fraction (LVEF),[1] in primary and secondary prevention.[2] Patients receiving an ICD often suffer from psychological co-morbidities and impaired quality of life (QoL).[3–6] General anxiety and depression are present in ~20% of device recipients[4] and are associated with increased morbidity and mortality.[7] Symptoms of pre-existing depression and impaired QoL seem to persist after device implantation.[8] Additionally, device-related concerns, such as the fear of receiving a shock, seem to further increase psychological distress and predicted higher levels of depression and anxiety.[9] A specific pattern of anxiety is heart-focused anxiety (HFA).[10,11] It comprises the fear of cardiac-related

sensations,[11] the attention to cardiac symptoms, and the avoidance of eliciting activities,[12] for example, physical or sexual activity.[13,14] HFA is associated with poor QoL,[15] breathlessness, palpitations, and chest pain, leading to preventable hospitalizations.[16] In patients with ICD, HFA predicts concerns about the ICD and feelings of disability.[17] Psychological care might reduce symptoms and hospitalizations.[18] However, in the patient–physician communication, psychological risks for device recipients are often not appropriately addressed.[19]

Although several studies investigated psychological co-morbidities in ICD recipients,[3,4,7–9] to the best of our knowledge, there are no data available on whether patients with devices have less or more HFA after implantation. In the Anxiety-CHF (Anxiety in patients with Chronic Heart Failure) study, we evaluated HFA, general anxiety, depression, and QoL across four measurement occasions before and up to 24 months after ICD or CRT-D implantation.

Methods

Patients and design

Inclusion criterion of this monocentric prospective study was the indication for ICD implantation for primary or secondary prevention of sudden cardiac death according to current guidelines.[2] Indication for primary prevention was symptomatic CHF according to the New York Heart Association (NYHA) Classes II and III with reduced LVEF (≤35%) despite 3 months of optimal medical treatment. Secondary prevention was applied in patients who survived haemodynamically relevant ventricular arrhythmias. Patients with left bundle branch block and QRS duration ≥130 ms were provided with a CRT-D. Devices were programmed according to current guideline recommendations.[20] Exclusion criteria were drug abuse, progressing dementia, and psychosis.

All patients provided written informed consent. Baseline assessment was performed at the time of hospital admission with a median of 1 day prior to device implantation. At baseline, as well as 5 months (5M), 12 months (12M), and 24 months (24M) after implantation, participants completed self-report questionnaires assessing HFA, general anxiety, depression, and QoL. Furthermore, number and triggers of shocks and anti-tachycardia pacing (ATP) as well as CHF-related hospitalizations were recorded at each follow-up. Baseline characteristics included co-morbidities, medications, cardiovascular risk factors, blood pressure, laboratory parameters, and demographic characteristics and are summarized in *Table 1*.

The study was approved by the Ethics Committee of the Saarland Medical Association in accordance with the Declaration of Helsinki. Detailed description of the Anxiety-CHF study design and cross-sectional baseline data were reported previously.[21]

Psychological measures

Psychological assessment was based on validated self-report questionnaires (German versions). Cut-off scores are provided in Supporting Information, *Table S1*. The Cardiac Anxiety Questionnaire served to measure HFA, including 17 items rated on a 5-point Likert-scale from 0 (never) to 4 (always).[11] It yields a total HFA score and three subscores (HFA-fear, HFA-attention, and HFA-avoidance) with age-dependent and sex-dependent cut-off scores.[22] Higher scores indicate higher levels of HFA. The Hospital Anxiety and Depression Scale (HADS) was used to assess symptoms of general anxiety (HADS-A) and depression (HADS-D).[23] It consists of 14 items rated on a 4-point Likert-scale from 0 (no/does not apply) to 3 (yes/applies most of the time). Seven items determine symptoms of general anxiety and depression, respectively, with higher sum scores referring to higher symptom levels. Scores >7 indicate increased anxiety or depressive symptoms.[24] The Minnesota Living with Heart Failure Questionnaire was applied to record CHF-specific QoL.[25] It consists of 21 items rated on a 6-point Likert-scale from 0 (no) to 5 (very much), with higher scores representing lower QoL. Impaired QoL is indicated by sum scores >24.[26]

Medical measures

Assessment of NYHA class, LVEF, and N-terminal pro-brain natriuretic peptide (NT-proBNP) at follow-up was not scheduled. However, when the information was available, changes from baseline to 5M, 12M, and 24M were evaluated. Routine follow-up with device interrogation was performed for 117 patients at our outpatient heart failure clinic and for 15 in other outpatient units.

Biometry and statistics

Data analyses were performed using IBM (Armonk, NY) SPSS Statistics 25 for Windows.[27] Baseline data were evaluated by means and standard deviation for metric variables, by median and inter-quartile range (IQR) for NT-proBNP, and by frequencies and percentage for categorical variables. To compare subgroups according to device (ICD vs. CRT-D), shock/ATP (yes vs. no), sex (women vs. men), or age (<63 vs. ≥63 years), *t*-tests were used for continuous variables. For the highly skewed NT-proBNP, we applied a Mann–Whitney *U* test. If Levene's test revealed a violation of homoscedasticity, we used the Welch *t*-test. Categorical variables were analysed by χ^2 tests. For the analysis of mean changes over time in the whole sample, one-way repeated

Table 1 Demographic and clinical baseline characteristics of the Anxiety-CHF cohort ($N = 132$) before ICD/CRT-D implantation

		Sex			Age			Device		
	Total	Female	Male	*P*	<63 years	≥63 years	*P*	ICD	CRT-D	*P*
N (%)	132	38 (29)	94 (71)	**<0.001**	63 (48)	69 (52)	0.602	88 (67)	44 (33)	**<0.001**
Age (years), mean ± SD	61 ± 14	55 ± 16	63 ± 12	**0.002**	50 ± 12	71 ± 5	**<0.001**	58 ± 14	68 ± 10	**<0.001**
Device, *N* (%)				**0.03**			**0.001**			
ICD		20 (53)	68 (72)		51 (81)	37 (54)				
CRT-D		18 (47)	26 (28)		12 (19)	32 (46)				
Indication, *N* (%)				0.562			0.636			0.266
Primary prevention	121 (92)	34 (90)	87 (93)		57 (91)	64 (93)		79 (90)	42 (96)	
Secondary prevention	11 (8)	4 (10)	7 (7)		6 (9)	5 (7)		9 (10)	2 (4)	
LVEF (%), mean ± SD	30.6 ± 8.7	32.2 ± 10.1	30 ± 8.1	0.206	31.1 ± 10.5	30.1 ± 6.8	0.534	31.5 ± 9.6	28.8 ± 6.4	0.098
Underlying disease, *N* (%)				**0.043**			**0.027**			0.249
ICM	57 (43)	12 (32)	45 (48)		22 (35)	35 (51)		40 (46)	17 (39)	
DCM	67 (51)	21 (55)	46 (49)		34 (54)	33 (48)		41 (47)	26 (59)	
Others[a]	8 (6)	5 (13)	3 (3)		7 (11)	1 (1)		7 (8)	1 (2)	
NYHA class, *N* (%)[b]				0.255			0.106			**<0.001**
I	9 (7)	3 (8)	6 (6)		7 (11)	2 (3)		9 (10)	0	
II	79 (60)	18 (49)	61 (65)		39 (62)	40 (59)		63 (72)	16 (37)	
III	43 (33)	16 (43)	27 (29)		17 (27)	26 (38)		16 (18)	27 (63)	
Blood pressure (mmHg), mean ± SD										
Systolic	128 ± 21	125 ± 22	129 ± 21	0.372	125 ± 20	131 ± 22	0.100	126 ± 21	132 ± 21	0.111
Diastolic	75 ± 11	71 ± 11	77 ± 11	**0.016**	74 ± 10	76 ± 12	0.319	75 ± 12	76 ± 9	0.563
CVRF, *N* (%)										
History of hypertension	94 (71)	22 (60)	72 (77)	**0.032**	40 (63)	54 (78)	0.061	61 (69)	33 (75)	0.497
Diabetes mellitus	55 (42)	18 (47)	37 (39)	0.398	15 (24)	40 (58)	**<0.001**	29 (23)	26 (59)	**0.004**
Dyslipidaemia	76 (58)	24 (63)	52 (55)	0.409	37 (59)	39 (56)	0.798	49 (56)	27 (61)	0.534
Smoking status, *N* (%)[b]				0.564			**0.002**			0.567
Currently	25 (19)	9 (24)	16 (17)		20 (32)	5 (7)		19 (21)	6 (14)	
Previously	53 (40)	13 (34)	40 (43)		21 (33)	32 (47)		35 (40)	18 (42)	
Never	53 (40)	16 (42)	37 (40)		22 (35)	31 (46)		34 (39)	19 (44)	
Laboratory values										
NT-proBNP (pg/mL), median (IQR)	1280 (653–2714)	1718 (434–1719)	1235 (667–2396)	0.982	845 (339–2213)	1884 (1054–4855)	**0.001**	1075 (481–2423)	1884 (842–5317)	**0.045**
Creatinine GFR (mL/min/1.73 m^2, CKD-EPI), mean ± SD	63 ± 25	66 ± 22	61 ± 26	0.319	76 ± 22	45 ± 17	**<0.001**	68 ± 25	48 ± 21	**<0.001**
CRP (mg/L), mean ± SD	5.7 ± 9.4	3.8 ± 3.6	6.5 ± 10.9	0.146	4.7 ± 7.5	6.6 ± 10.9	0.242	5.5 ± 8.7	6.2 ± 10.6	0.672
Hb (g/dL), mean ± SD	13.8 ± 1.6	13.3 ± 1.4	14 ± 1.7	**0.027**	14.2 ± 1.8	13.4 ± 1.4	**0.006**	14.1 ± 1.6	13.2 ± 1.6	**0.001**
Medication, *N* (%)										
Beta-blocker	130 (99)	38 (100)	92 (98)	1	61 (97)	69 (100)	0.226	86 (98)	44 (100)	0.552
ACE inhibitor/AT_1 antagonist	122 (92)	35 (92)	87 (93)	1	58 (92)	64 (93)	1	81 (92)	41 (93)	1
Diuretic	117 (89)	32 (84)	85 (90)	0.366	53 (84)	64 (93)	0.170	74 (84)	43 (98)	**0.020**
Aldosterone antagonist	104 (79)	31 (82)	73 (79)	0.692	49 (79)	55 (80)	1	65 (75)	39 (89)	0.063
Digitalis	10 (8)	5 (13)	5 (5)	0.15	1 (2)	9 (13)	**0.018**	6 (7)	4 (9)	0.731

ACE, angiotensin-converting enzyme; AT, angiotensin; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; CRP, C-reactive protein; CRT-D, cardiac resynchronization therapy defibrillator; CVRF, cardiovascular risk factors; DCM, dilated cardiomyopathy; GFR, glomerular filtration rate; Hb, haemoglobin; ICD, implantable cardioverter defibrillator; ICM, ischaemic cardiomyopathy; IQR, inter-quartile range; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide; NYHA, New York Heart Association; SD, standard deviation.

P-values were determined by independent samples *t*-tests for continuous, normally distributed variables or by Mann–Whitney *U* test for non-normally distributed variables. Categorical values were analysed by χ^2 tests. *P*-values representing significant effects are printed in bold.

[a]Others were non-compaction cardiomyopathy ($N = 2$), Takotsubo cardiomyopathy ($N = 1$), cardiac sarcoidosis ($N = 1$), restrictive cardiomyopathy in systemic amyloidosis ($N = 1$), malignant ventricular arrhythmia ($N = 1$), idiopathic ventricular fibrillation ($N = 1$), and hypertrophic cardiomyopathy ($N = 1$).

[b]One missing value for NYHA class in women and patients with CRT-D and one missing value for smoking status.

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measures analyses of variance (ANOVAs) with the within-subject factor time (baseline, 5M, 12M, and 24M) were conducted. If the Mauchly sphericity test was significant, a Huynh–Feldt correction was applied for mild violation ($\varepsilon > 0.75$). To control for α-error accumulation, the SPSS tool Bonferroni correction was applied in *post hoc* analyses. For changes in the NYHA class and NT-proBNP, we applied the Friedman test. The two-tailed significance level was set at $\alpha < 0.05$. To avoid list-wise case exclusion, we imputed missing psychological data in the follow-up surveys based on a linear regression approach.

Results

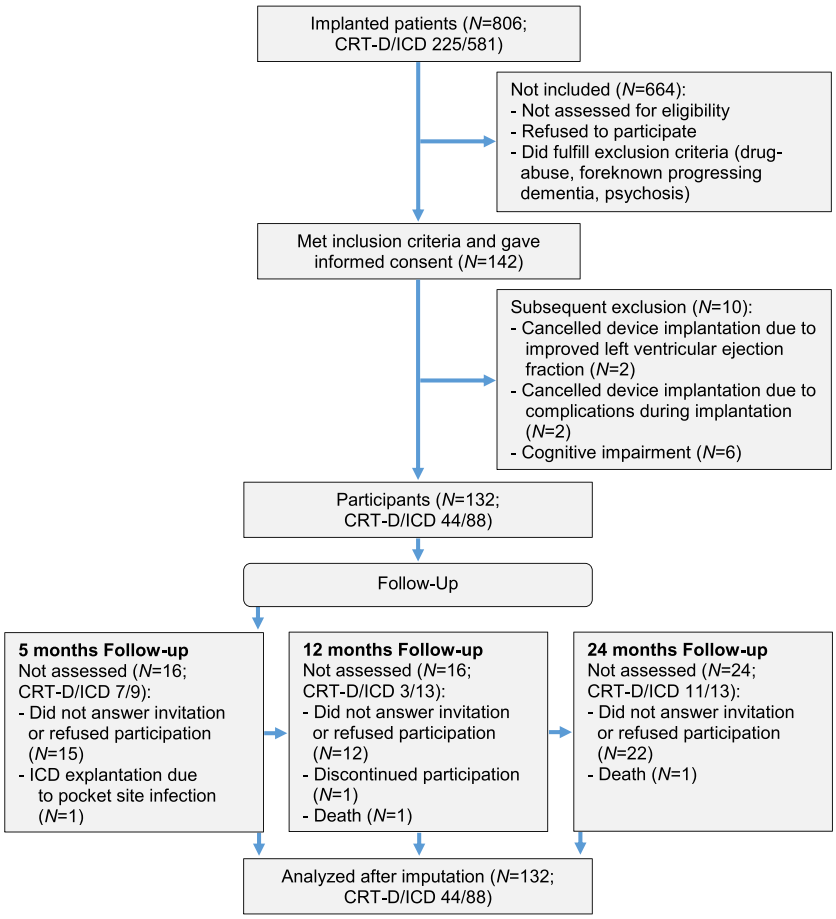
Between July 2010 and October 2015, 142 patients were enrolled. Ten participants were subsequently excluded because of cancelled device implantation (N = 4) or cognitive impairment (N = 6), leading to a final sample of N = 132 (*Figure 1*). The follow-up surveys were attended by 116 (5M), 100 (12M), and 76 (24M) patients, and 119 patients completed at least one follow-up.

Baseline demographic and medical characteristics

The mean age of the patients was 61 ± 14 years (71% male). Mean LVEF was 31 ± 9%, and the majority of participants received the device for primary prevention (92%). Preoperative NYHA class, blood pressure, laboratory results, and medication, as well as underlying disease, are summarized in *Table 1*.

Patients with indication for CRT-D implantation differed significantly from ICD recipients in demographic and medical characteristics. CRT-D patients were older (68 ± 10 vs. 58 ± 14 years, $P < 0.001$) and had higher median (IQR) NT-proBNP [1884 (842–5317) vs. 1075 (481–2423) pg/mL, $P = 0.045$]. They were significantly more often in NYHA Class III (63% vs. 18%, $P < 0.001$), and less likely in NYHA Class II (37% vs. 72%, $P < 0.001$). Patients with indication for CRT-D implantation more often presented with diabetes mellitus (59% vs. 23%, $P = 0.004$), received more often

Figure 1 The CONSORT flow diagram demonstrating the distribution of participants and dropouts. CRT-D, cardiac resynchronization therapy defibrillator, ICD, implantable cardioverter defibrillator.



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diuretic medication (98% vs. 84%, $P = 0.020$), and had lower mean creatinine GFR (48 ± 21 vs. 68 ± 25 mL/min/1.73 m^2, $P < 0.001$) and Hb values (13.2 ± 1.6 vs. 14.1 ± 1.6 g/dL, $P = 0.001$). Further subgroup comparisons of baseline characteristics according to device (CRT-D vs. ICD), sex (women vs. men), and median age (<63 vs. ≥63 years) are reported in *Table 1*.

Changes in medical variables after device implantation

In patients with indication for CRT-D, median (IQR) NT-proBNP before compared with 24 months after implantation was 3357 (1049–6122) and 1338 (494–3669) pg/mL, $P = 0.102$ ($N = 6$). A decreased NYHA class was observed in eight patients, an increased NYHA class in three patients, and no change in one patient, $P = 0.227$ ($N = 12$). Mean LVEF was 31 ± 10% before vs. 37 ± 11% 24 months after implantation, $P = 0.471$ ($N = 6$).

Implantable cardioverter defibrillator patients had a median (IQR) NT-proBNP of 849 (562–2202) pg/mL at baseline and 639 (126–3070) pg/mL 24 months after implantation, $P = 0.439$ ($N = 15$). NYHA class decreased in 5 patients, increased in 12 patients, and was stable in 17 patients, $P = 0.090$ ($N = 34$). Mean LVEF was 29 ± 7% vs. 29 ± 13% before and 24 months after implantation, $P = 0.959$ ($N = 22$).

During follow-up, 44 participants (38%) were hospitalized at least once for cardiovascular reasons; 19 patients (16%) had ventricular arrhythmias, which were terminated in 12 patients by ATP only and in seven patients by shock ($N = 3$ CRT-D and $N = 16$ ICD).

Psychological status and quality of life before and after device implantation

Mean scores (standard deviation) of the psychological variables, as well as single comparisons of subgroups as a function of visit (baseline, 5M, 12M, and 24M), are provided in *Table 2*. Results of the repeated measures ANOVA and *post hoc* single comparisons between baseline and 5M, 12M, and 24M, respectively, for all patients and subgroups are presented in *Figure 2* for HFA and related subscores and in *Figure 3* for general anxiety, depression, and QoL.

Heart-focused anxiety and related subscores

Before implantation, 44% of participants had clinically relevant HFA (total score). HFA-related fear, attention, and avoidance were increased in 38%, 26%, and 44% of the patients. Significant improvements after implantation were observed in the mean total HFA score [$F(3, 393) = 9.31$, $P < 0.001$, $\eta_p^2 = 0.07$], as well as in the HFA-attention and HFA-fear scores [$F(2.79, 364.82) = 16.94$, $P < 0.001$, $\eta_p^2 = 0.12$ and $F(2.89, 378.29) = 5.68$, $P = 0.001$, $\eta_p^2 = 0.04$]. HFA-related avoidance of physical activity did not change ($P = 0.375$). Two years after implantation, 30% of patients reported clinically relevant HFA (total score). HFA-fear, HFA-attention, and HFA-avoidance were increased in 26%, 14%, and 37% of participants.

Subgroup analyses for heart-focused anxiety outcomes

At baseline, older participants reported higher HFA-avoidance than younger patients [mean difference (MD) = 0.5, 95% confidence interval (CI) 0.1–0.8, $P = 0.014$]. Mean total HFA, HFA-fear, and HFA-attention did not differ between age groups. All other subgroups had similar mean total HFA and related subscores before device implantation (patients with CRT-D vs. ICD indication, patients with shock/ATP vs. no shock/ATP, and women vs. men).

After implantation, HFA-avoidance did not change in any of the groups. Total HFA, HFA-fear, and HFA-attention decreased in most of the groups. But in younger patients, total HFA and HFA-fear did not improve. In patients with ICD implantation, HFA-fear did not change. Patients after shock/ATP reported no improvements in any of the HFA scores.

General anxiety, depression, and quality of life

Increased levels of general anxiety were reported by 37% of patients at baseline. Depressive symptoms were increased in 33%, and QoL was impaired in 68% of participants. Mean scores of general anxiety and QoL decreased significantly after implantation [$F(2.84, 371.87) = 6.17$, $P = 0.001$, $\eta_p^2 = 0.05$ and $F(2.68, 351.40) = 6.74$, $P < 0.001$, $\eta_p^2 = 0.05$]. Depression did not change ($P = 0.146$). After 2 years, increased levels of general anxiety and depression were reported by 33% and 35% of patients, respectively, and impaired QoL by 58%.

Subgroup analysis for general anxiety, depression, and quality of life outcomes

Younger patients experienced significantly higher general anxiety than older participants at baseline (MD = 2.0, 95% CI 0.5–3.5, $P = 0.012$). The other subgroups did not differ significantly in mean general anxiety scores. After implantation, general anxiety improved in older participants, patients with CRT-D and without shock/ATP, and men, but not in younger participants, patients with ICD and shock/ATP, or women.

Depression scores were similar between all subgroups at baseline and did not change in any of the subgroups after implantation, except for patients without shock/ATP. In this subgroup, the main effect for time in the repeated measures ANOVA was significant [$F(2.84, 275.68) = 3.06$, $P = 0.031$, $\eta_p^2 = 0.03$], but Bonferroni-corrected *post hoc* single comparisons between baseline and 5M, 12M, and 24M, respectively, were not.

Quality of life was lower in CRT-D compared with ICD recipients at baseline (MD = 8.1, 95% CI 0.4–15.8, $P = 0.040$) and in women compared with men (MD = 9.7, 95% CI 1.7–17.7, $P = 0.018$). After implantation, QoL improved significantly in CRT-D recipients and in women. Improvements in

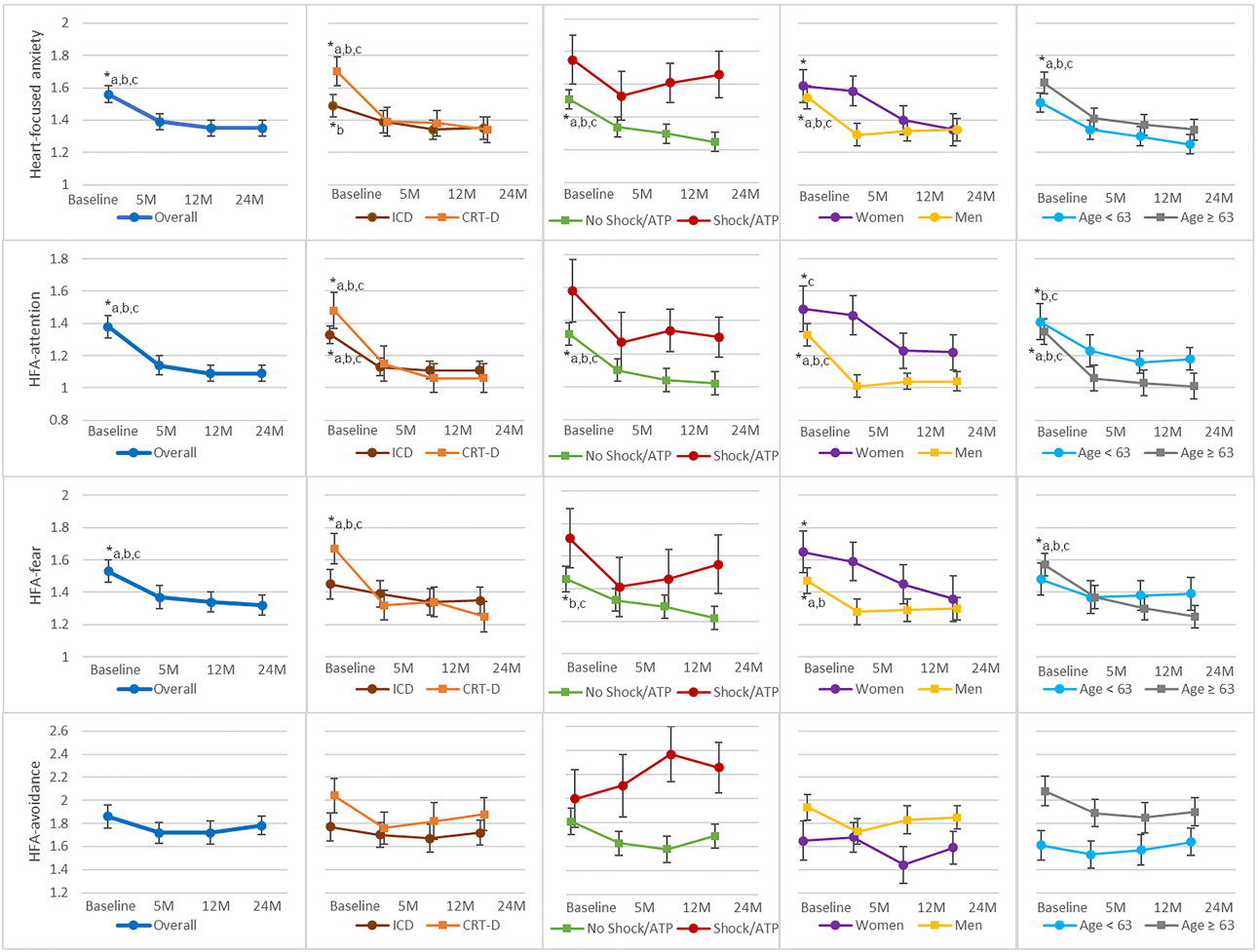
Table 2 Means (SD) and group comparison for psychological measures at baseline and follow-up

		HFA Total	*P*	HFA- attention	*P*	HFA-fear	*P*	HFA- avoidance	*P*	Anxiety	*P*	Depression	*P*	QoL Total	*P*
Baseline	Overall (*n* = 132)	1.6 ± 0.7		1.4 ± 0.8		1.5 ± 0.8		1.9 ± 1.1		6.3 ± 4.4		6.3 ± 4.5		35.2 ± 21.4	
	ICD (*n* = 88)	1.5 ± 0.7	.079	1.3 ± 0.8	.278	1.5 ± 0.8	.129	1.8 ± 1.1	.176	6.3 ± 4.7	.741	6.1 ± 4.6	.483	32.5 ± 21.4	**.040**
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	CRT-D (*n* = 44)	1.7 ± 0.6		1.5 ± 0.7		1.7 ± 0.7		2.0 ± 1.0		6.1 ± 3.9		6.7± 4.4		40.6 ± 20.5	
	Shock/ATP (*n* = 19)	1.8 ± 0.7	.128	1.6 ± 0.8	.184	1.7 ± 0.8	.192	2.0 ± 1.0	.539	6.1 ± 4.4	.889	6.1 ± 5.3	.936	33.2 ± 19.9	.867
	vs.	vs.		vs.		vs.		vs.		vs.		6.0 ± 4.6		vs.	
	No shock/ATP (*n* = 98)	1.5 ± 0.6		1.3 ± 0.7		1.5 ± 0.7		1.8 ± 1.1		5.9 ± 4.5				34.1 ± 22.2	
	Women (*n* = 38)	1.6 ± 0.7	.620	1.5 ± 0.9	.272	1.7 ± 0.8	.234	1.7 ± 1.1	.169	7.4 ± 4.7	.051	6.3 ± 3.8	.996	42.1 ± 21.9	**.018**
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Men (*n* = 94)	1.5 ± 0.7		1.3 ± 0.7		1.5 ± 08		1.9 ± 1.1		5.8 ± 4.2		6.2 ± 4.7		32.4 ± 20.6	
	Age <63 (*n* = 63)	1.5 ± 0.7	.243	1.4 ± 0.8	.662	1.5 ± 0.8	.491	1.6 ± 1.1	**.014**	7.3 ± 4.9	**.012**	6.6 ± 4.8	.485	37.0 ± 24.9	.343
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Age ≥63 (*n* = 69)	1.6 ± 0.6		1.4 ± 0.7		1.6 ± 0.8		2.1 ± 1.0		5.3 ± 3.7		6.0± 4.3		33.5 ± 17.6	
5 M	Overall (*n* = 132)	1.6 ± 0.7		1.4 ± 0.8		1.5 ± 0.8		1.9 ± 1.1		6.25 ± 4.40		6.27 ± 4.52		35.2 ± 21.4	
	ICD (*n* = 88)	1.4 ± 0.7	1	1.1 ± 0.7	.903	1.4 ± 0.8	.611	1.7 ± 1.1	.735	5.5 ± 4.4	.282	5.9 ± 4.9	.889	28.5 ± 21.9	.665
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	CRT-D (*n* = 44)	1.4 ± 0.6		1.2 ± 0.7		1.3 ± 0.7		1.8 ± 1.0		4.7 ± 3.8		5.7 ± 4.4		26.8 ± 17.8	
	Shock/ATP (*n* = 19)	1.5 ± 0.6	.224	1.3 ± 0.8	.328	1.4 ± 0.8	.630	2.1 ± 1.1	.062	6.00 ± 4.4	.266	6.3 ± 5.2	.371	29.5 ± 19.1	.519
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	No shock/ATP (*n* = 98)	1.3 ± 0.6		1.1 ± 0.7		1.3 ± 0.7		1.6 ± 1.0		4.8 ± 4.2		5.2 ± 4.6		26.2 ± 20.4	
	Women (*n* = 38)	1.6 ± 0.6	**.028**	1.5 ± 0.7	**.001**	1.6 ± 0.7	**.039**	1.7 ± 0.8	.804	7.0 ± 4.2	**.002**	6.3 ± 4.0	.475	30.3 ± 16.5	.402
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Men (*n* = 94)	1.3 ± 0.7		1.0 ± 0.7		1.3 ± 0.8		1.7 ± 1.1		4.5 ± 4.1		5.6 ± 5.0		27.0 ± 22.0	
	Age <63 (*n* = 63)	1.4 ± 07	.644	1.2 ± 0.8	.190	1.4 ± 0.8	.960	1.5 ± 1.0	**.046**	6.1 ± 4.5	**0.22**	6.1 ± 4.7	.522	28.6 ± 20.0	.709
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Age ≥63 (*n* = 69)	1.4 ± 06		1.1 ± 0.7		1.4 ± 0.8		1.9 ± 1.0		4.4 ± 3.8		5.6 ± 4.7		27.3 ± 21.2	
12 M	Overall	1.4 ± 0.6		1.1 ± 0.6		1.3 ± 0.7		1.8 ± 1.0		5.1 ± 4.5		5.6 ± 4.5		28.8 ± 19.5	
	ICD	1.3 ± 0.6	.670	1.1 ± 0.6	.651	1.3 ± 0.7	.995	1.7 ± 1.0	.366	5.4 ± 4.8	.988	5.8± 4.8	.359	27.8 ± 18.9	.433
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	CRT-D	1.4 ± 0.5		1.1 ± 0.6		1.3 ± 0.7		1.9 ± 1.0		4.4 ± 3.7		5.4 ± 4.1		30.7 ± 20.7	
	Shock/ATP (*n* = 19)	1.6 ± 0.5	**.029**	1.3 ± 0.6	**.037**	1.5 ± 0.8	.321	2.3 ± 0.9	**.022**	6.5 ± 5.4	.065	6.9 ± vs.	.134	35.3 ± 17.8	.053
	vs.	vs.		vs.		vs.		vs.		vs.		5.1 ±		vs.	
	No shock/ATP (*n* = 98)	1.3 ± 0.6		1.0 ± 0.6		1.3 ± 0.7		1.7 ± 1.0		4.5 ± 4.0				25.8 ± 19.7	
	Women	1.4 ± 0.6	.503	1.2 ± 0.7	.085	1.5 ± 0.7	.244	1.6 ± 0.9	.157	6.5 ± 4.9	**.017**	5.8 ± 4.5	.776	32.8 ± 17.9	.131
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Men	1.3 ± 0.6		1.0 ± 0.5		1.3 ± 0.7		1.9 ± 1.0		4.5 ± 4.2		5.6 ± 4.6		27.1 ± 20.0	
	Age <63	1.3 ± 0.6	.674	1.2 ± 0.6	.205	1.4 ± 0.7	.528	1.6 ± 0.9	.127	6.2 ± 4.8	**.008**	6.1 ± 4.8	.281	29.9 ± 19.8	.541
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Age ≥63	1.4 ± 0.6		1.0 ± 0.6		1.3 ± 0.7		1.9 ± 1.0		4.1 ± 3.9		5.2 ± 4.3		27.8 ± 19.3	
24 M	Overall (*n* = 132)	1.3 ± 0.6		1.1 ± 0.6		1.3 ± 0.7		1.7 ± 1.1		5.7 ± 4.3		6.1 ± 4.7		29.1 ± 18.8	
	ICD	1.4 ± 0.7	.901	1.1 ± 0.6	.656	1.4 ± 0.8	.460	1.7 ± 1.1	.455	5.8 ± 4.7	.442	6.3 ± 5.2	.433	30.5 ± 20.6	.187
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	CRT-D	1.3 ± 0.5		1.1 ± 0.6		1.3 ± 0.7		1.8 ± 1.0		5.3 ± 3.3		5.6 ± 3.50		26.4 ± 14.5	
	Shock/ATP (*n* = 19)	1.7 ± 0.6	**.009**	1.3 ± 0.5	.061	1.5 ± 0.8	.062	2.4 ± 1.0	**.004**	6.6 ± 4.8	.203	7.0 ± 5.0	.300	28.9 ± 20.3	.912
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	No shock/ATP (*n* = 98)	1.3 ± 0.6		1.0 ± 0.6		1.2 ± 0.7		1.6 ± 1.1		5.2 ± 4.2		5.8 ± 4.8		29.5 ± 19.4	
	Women	1.4 ± 0.6	.890	1.2 ± 0.7	.114	1.4 ± 0.9	.722	1.4 ± 1.0	.074	6.4 ± 4.5	.219	5.9 ± 4.7	.768	31.6 ± 20.4	.329
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Men	1.3 ± 0.6		1.0 ± 0.6		1.3 ± 0.7		1.8 ± 1.1		5.4 ± 4.2		6.2 ± 4.7		28.1 ± 18.1	
	Age <63	1.4 ± 0.7	.835	1.2 ± 0.6	.113	1.4 ± 0.8	.269	1.6 ± 1.1	.146	6.2 ± 4.5	.145	6.5 ± 5.2	.382	31.7 ± 18.7	.130
	vs.	vs.		vs.		vs.		vs.		vs.		vs.		vs.	
	Age ≥63	1.3 ± 0.6		1.0 ± 0.6		1.3 ± 0.7		1.8 ± 1.1		5.1 ± 4.0		5.8 ± 4.2		26.7 ± 18.8	

12M, 12 month follow-up; 24M, 24 month follow-up; 5M, 5 month follow-up; ATP, anti-tachycardia pacing; CRT-D, cardiac resynchronization therapy defibrillator; depression and anxiety, symptoms of general anxiety and depression assessed by the Hospital Anxiety and Depression Scale; HFA, heart-focused anxiety assessed by the Cardiac Anxiety Questionnaire; ICD, implantable cardioverter defibrillator; QoL, quality of life assessed by the Minnesota Living with Heart Failure Questionnaire; SD, standard deviation.

P-values were determined by independent samples *t*-tests with the grouping variables device (ICD/CRT-D), shock/ATP (yes/no), sex (women/men), and age (<63/≥63 years). *P*-values representing significant effects are printed in bold.

Figure 2 Heart-focused anxiety (HFA) and related subscores before and 5, 12, and 24 months after implantable cardioverter defibrillator (ICD)/cardiac resynchronization therapy defibrillator (CRT-D) implantation in all patients and subgroups. Results of the repeated measures ANOVA with the within-subject factor time [baseline, 5 month follow-up (5M), 12 month follow-up (12M), and 24 month follow-up (24M)] and Bonferroni-corrected *post hoc* comparisons of baseline vs. 5M, 12M, and 24M, respectively. *$P < 0.05$ for the main effect of time in the repeated measures ANOVA. [a]$P < 0.05$ for differences between baseline and 5M according to Bonferroni-corrected *post hoc* analyses. [b]$P < 0.05$ for differences between baseline and 12M according to Bonferroni-corrected *post hoc* analyses. [c]$P < 0.05$ for differences between baseline and 24M according to Bonferroni-corrected *post hoc* analyses. Data points represent mean scores of the Cardiac Anxiety Questionnaire and subscores (total HFA, HFA-fear, HFA-attention, and HFA-avoidance). The error bars indicate the standard error. ATP, anti-tachycardia pacing.



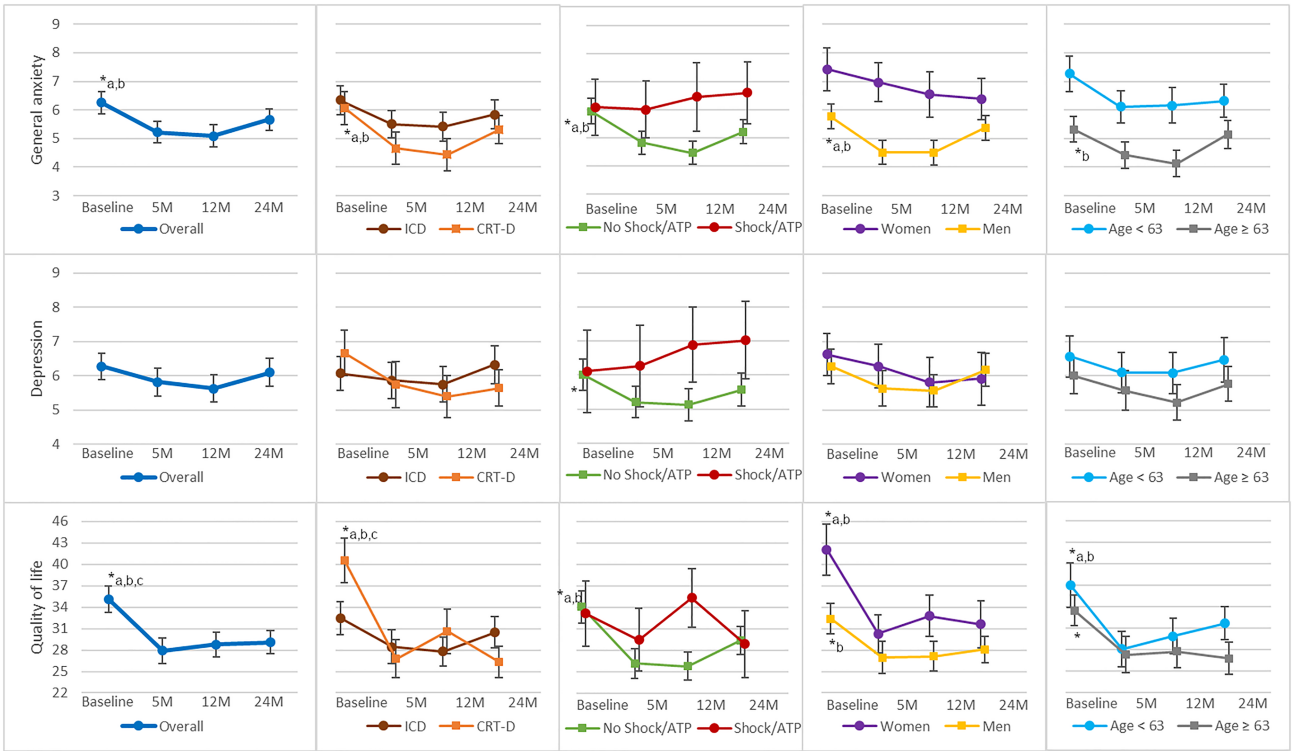
QoL after implantation were also reported by men, patients without shock/ATP, and patients of both age groups. QoL did not change in ICD recipients and patients with shock/ATP.

Discussion

Total HFA and related fear and attention, general anxiety, and QoL improved significantly after device implantation. Depression and HFA-avoidance remained unchanged. The device implantation did not impair psychological outcomes in our patients. Regardless of improvements, psychological symptom levels remained high compared with the general population,[22,28] and mean QoL still indicated a significant impairment after 24 months. This might be related to the high rate of psychological distress in patients with CHF[29,30] and the progression of heart failure with associated impairments (e.g. progressive loss of physical fitness, medication side effects, recurrent hospitalization, and co-morbidities).

Heart-focused anxiety-related avoidance of physical activity was reported by 37% of patients 2 years after implantation. In a study with patients with coronary heart disease, HFA-avoidance was associated with a lack of physical activity and with non-participation in a coronary exercise group.[31] In healthy individuals, it predicted lower physical activity, too.[32] This points to the potential detrimental effects of undetected HFA in the context of cardiac rehabilitation or secondary

Figure 3 General anxiety, depression, and quality of life before and 5, 12, and 24 months after implantable cardioverter defibrillator (ICD)/cardiac resynchronization therapy defibrillator (CRT-D) implantation in all patients and subgroups. Results of the repeated measures ANOVA with the within-subject factor time [baseline, 5 month follow-up (5M), 12 month follow-up (12M), and 24 month follow-up (24M)] and Bonferroni-corrected *post hoc* comparisons of baseline vs. 5M, 12M, and 24M, respectively. *$P < 0.05$ for the main effect of time in the repeated measures ANOVA. [a]$P < 0.05$ for differences between baseline and 5M according to Bonferroni-corrected *post hoc* analyses. [b]$P < 0.05$ for differences between baseline and 12M according to Bonferroni-corrected *post hoc* analyses. [c]$P < 0.05$ for differences between baseline and 24M according to Bonferroni-corrected *post hoc* analyses. Data points represent the mean sum scores of the Hospital Anxiety and Depression Scale (depression and general anxiety) and of the Minnesota Living with Heart Failure Questionnaire (quality of life). The error bars indicate the standard error. ATP, anti-tachycardia pacing.



prevention. Moderate exercise is safe and recommended for most individuals with device implantation. It may reduce the risk of shock delivery and is effective in the secondary prevention of cardiovascular disease.[33] Exercise further improves QoL in patients with ICD or CRT-D and reduces anxiety and depression.[34,35] Recent recommendations suggest to wait for at least 6 weeks after implantation before engaging in exercise training,[36] to avoid activities that increase the risk of lead dislocation (e.g. strong upper extremity movements)[37] and, in case of ventricular arrhythmias terminated by shock/ATP, to pause exercise for at least 3 months.[36] The high rate of HFA-related avoidance of physical activity after implantation in this study may partly reflect patients' concerns for ICD shocks during exercise[38] and a lack of specific recommendations for exercise training.[39] The observation of significantly higher HFA-avoidance 24 months after implantation in patients with shock/ATP compared with those without therapy delivery supports this assumption. Patients with shock/ATP furthermore reported significantly higher total HFA at 2 years after implant. This result is consistent with studies reporting higher anxiety levels in patients after shock/ATP compared with those without[40,41] and might indicate an increased susceptibility for psychological impairment in these patients. Accordingly, patients with stable heart failure should be encouraged to exercise regularly after device implantation. In case of physical inactivity, the underlying reasons should be explored and discussed during consultation.

Current guidelines recommend the assessment and treatment of psychological co-morbidities in patients with indication for device implantation or patients with ICD/CRT-D.[42] Patients with high levels of pre-implantation ICD-related concerns are more prone to develop post-implant psychological impairments.[42] In our study, women compared with men and patients with indication for CRT-D compared with ICD implantation had a lower QoL at baseline. Younger recipients exhibited higher levels of general anxiety than older ones, while older patients reported higher HFA-avoidance. Physician awareness of subgroup-specific psychological concerns could facilitate the identification of individuals in need of psychological counselling and tailored interventions.

After implantation, the mean scores of the psychological variables did not improve in all subgroups. General anxiety

did improve neither in women nor in younger patients. Both had significantly higher mean scores 5 and 12 months after implantation, compared with men and older patients, respectively. Women, as well as younger device recipients, have been previously reported to exhibit more anxiety after implantation.[43,44] In addition, younger patients have a poorer device acceptance,[44] report body image concerns after implantation, and perceive the device as a limiting threat. In contrast, older patients tend to emphasize the life-extending aspects of the treatment.[45] Younger age and female sex may be risk markers for anxiety and poorer adjustment after implantation.

General anxiety, HFA-fear, and QoL did not change in patients with ICD, while patients with CRT-D significantly improved. Improvements of QoL in patients after CRT-D implantation but not after ICD implantation are in line with previous studies.[46] This might be the result of an improvement of the clinical status with correction of ventricular dyssynchrony by CRT leading to better exercise capacity.[47] Symptomatic heart failure is the most important clinical predictor of impaired QoL and anxiety in patients with ICD/CRT-D.[48] General anxiety is a predictor of HFA-fear in patients with heart failure and reduced LVEF[15] and is associated with reduced QoL.[49] Improvements in QoL and general anxiety in patients with CRT-D could account for the observed improvements in HFA-fear. In our study, NYHA class, NT-proBNP, and LVEF improved numerically in CRT-D recipients, but improvements did not reach statistical significance, probably related to the small sample size.

Limitations

Because of the observational nature of this prospective monocentric study, findings could be confounded by the specific composition and relatively small size of the overall study group, thus reducing generalizability. Patients with different indications for device implantation and different underlying diseases, such as ischaemic and non-ischaemic cardiomyopathy, may show different psychological patterns. The absence of a control group and small sample size in some of our subgroups further limit the interpretation of results.

Nevertheless, self-reports reflect the current gold standard of assessment of our key variables, and reported levels of psychological distress prior to implantation were comparable with values assessed in ambulatory CHF patients[15] as well as in patients undergoing ICD implantation.[49]

Regarding psychological variables, we imputed missing data by linear regression. However, as stated earlier, our results are comparable with previous studies, pointing towards the validity of the data. Results regarding HFA, indeed, are novel, and a replication is desirable.

Conclusions

The Anxiety-CHF study demonstrated improvements in anxiety and QoL after device implantation, but levels of psychological distress remained high. Physicians should be sensitive to psychological complaints of patients after ICD/CRT-D implantation. In addition to general anxiety and depression, the assessment of HFA and HFA-related avoidance of exercise especially after shock/ATP may be suitable in such populations. Psychological counselling to reduce HFA and thus increase physical activity should be considered.

Conflict of interest

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Cut-off scores for questionnaires.

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