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Original Article

Influence of primary and secondary prevention indications on anxiety about the implantable cardioverter-defibrillator



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ABSTRACT

Background: Implantable cardioverter-defibrillators (ICDs) have been established for primary and secondary prevention of fatal arrhythmias. However, little is known about the influence of ICD indications on quality of life (QOL) and psychological disturbances. This study aimed to examine whether there were differences in QOL and psychological distress in patients that have an ICD for primary or secondary prevention of fatal arrhythmias.

Methods: A multicenter survey of 179 consecutive outpatients (29.1% primary prevention) with ICD implantations completed the Short Form-8 (SF-8), Beck Depression Inventory (BDI), Impact of Event Scale-Revised (IES-R), State-Trait Anxiety Inventory (STAI), and Worries about ICD (WAICD).

Results: Patients with an ICD for primary prevention had a higher trait anxiety score and worries about ICD score than patients with an ICD for secondary prevention (41.7 ± 12.4 vs. 34.7 ± 12.3 , $p=0.001$ and 39.6 ± 18.0 vs. 30.0 ± 18.9 , $p=0.002$, respectively), even after adjusting for demographic and clinical characteristics. In multivariable analysis of variance, primary prevention ICD recipients reported a poorer QOL on the vitality subscale of the SF-8.

Conclusions: In our study population, which mostly consisted of New York Heart Association (NYHA) class I and II subjects, primary prevention ICD recipients were more prone to experience worries about their ICD, anxiety, and a poorer QOL compared to secondary prevention ICD recipients. In clinical practice, primary prevention ICD patients should be closely monitored. If warranted, they should be offered psychological intervention, as anxiety and low QOL were predictors of mortality.

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1. Introduction

The implantable cardioverter-defibrillator (ICD) is well-established as the superior choice compared to anti-arrhythmic drugs for the prevention of sudden cardiac death (SCD) [1,2]. The use of ICDs has been expanded to certain patient populations who

have either survived an episode of life-threatening ventricular arrhythmia (secondary prevention) or who are at risk for ventricular arrhythmia (primary prevention) [2]. Although acceptance of the device is generally high among patients and their families, quality of life (QOL) and psychosocial issues associated with use of an ICD deserve greater attention [3]. Anxiety, depression, anger, and fear are the most common psychosocial responses after ICD implantation [3,4]. Nearly half of the patients with an ICD have depression and anxiety [5].

SCD occurs in approximately 40 cases per every 100,000 persons annually in each country of Asia [6]. A previous study showed

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that during a 5-year period, the Japan Cardiac Device Therapy Registry demonstrated a significant increase in the utilization of prophylactic ICDs [7]. Paradoxically, limited data exist regarding the effect of ICD indications on QOL and psychological distress in Japanese patients. A previous study suggested that there was no evidence to suggest that patients receiving an ICD for primary prophylaxis had a subsequently poorer QOL and greater distress than patients receiving an ICD for secondary prophylaxis [8]. However, patients identified to receive an ICD for primary prophylaxis differ from patients who receive the device for secondary prevention. In particular, primary prophylaxis patients may fail to understand why they need the device. In relation to health-related QOL, one study found that the QOL did not significantly differ between primary and secondary prevention ICD recipients [9]. Another study showed no differences in mean depression and mean anxiety scores between primary and secondary prevention ICD patients [5].

The aims of this study were to examine (1) whether primary prevention ICD recipients were at a greater risk for increased anxiety, depression, post-traumatic stress disorder (PTSD), and worries about their ICD, and (2) whether primary prevention ICD recipients had poorer health-related QOL compared to secondary prevention ICD recipients, adjusting for demographic and clinical characteristics.

2. Materials and methods

2.1. Patients and study design

In this cross-sectional research study, we examined 179 outpatients with ICDs based on our previous study [10]. Patients were recruited consecutively and the survey was given once during an outpatient clinic visit. The eligibility criteria were as follows: patients who had an ICD implanted, were aged > 18 years, were judged capable of completing the survey physically and cognitively, and were capable of understanding spoken and written Japanese. All patients were given information about this study and provided written informed consent. The institutional review board and ethics committee of Kyushu University Graduate School of Medical Sciences and Tokyo Metropolitan Hiroo Hospital approved this study (IRB approval number #258, approval date July 6, 2005).

2.2. Measures

2.2.1. Demographic and clinical variables

Demographic variables included sex and age. Information on clinical variables, including left ventricular ejection fraction (LVEF), presence of appropriate shocks (with and without syncope), presence of inappropriate shocks, comorbidities (including hypertension, stroke, systemic embolization, diabetes mellitus, dyslipidemia, and renal failure), medications, device-related complications (including presence of inappropriate shocks, pulmonary embolization, and device infection), and the predominant cardiac diagnosis were obtained from the medical records. Duration of ICD therapy and shock frequency were also collected via the medical records. The predominant cardiac diagnoses consisted of myocardial infarction, dilated cardiomyopathy, hypertrophic cardiomyopathy, Brugada syndrome, cardiac sarcoidosis, valvular heart disease, arrhythmogenic right ventricular dysplasia (ARVD), myocarditis, angina pectoris, long QT syndrome, and hypertensive heart disease.

The indication for ICD use was defined retrospectively using certain criteria. Primary prevention of SCD refers to the use of ICDs in individuals who are at risk for, but have not yet had an episode of sustained ventricular tachycardia (VT), ventricular fibrillation, or

resuscitated cardiac arrest. Secondary prevention refers to prevention of SCD in patients who survived a prior sudden cardiac arrest or sustained VT [11,12]. Primary prevention indications for ICD therapy were defined as (1) coronary artery disease (CAD), non-sustained VT, LVEF < 40%, and inducible sustained VT/VF; (2) CAD, prior myocardial infarction, and LVEF < 30%; or (3) other (CAD, non-sustained VT, EF ≥ 40%, and inducible VT/VF). Secondary prevention indications were defined as (1) VF or cardiac arrest without a transient or reversible cause, (2) spontaneous sustained VT with structural heart disease, or (3) spontaneous syncope or syncope of unknown etiology and inducible sustained VT/VF [13,14].

2.2.2. Health-related quality of life assessment

Health-related quality of life was assessed with the Japanese version of the Medical Outcomes Study (MOS) Short Form 8-Item Health Survey (SF-8) that evaluates both physical and mental component summaries (PCS and MCS, respectively) [15]. Items are answered on a 5- or 6-point Likert scale. The 8-domain scaled scores range from 0 to 100, with 100 representing optimal health and functioning. The SF-8 is divided into an 8-dimension health profile, including physical functioning (PF), role functioning-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role functioning-emotional (RE), and mental health (MH) [16].

2.2.3. Self-reported symptoms of anxiety

The state version of the State-Trait Anxiety Inventory (form Japanese Y-1, STAI) is a 20-item self-reported measure. The STAI was used to assess the presence of general symptoms of state and trait anxiety [17]. This form of anxiety refers to a transient emotional status, characterized by feelings of apprehension (i.e. worries and concerns) and tension as well as increased autonomic nervous system activity. Items are scored on a four-point Likert scale from 1 (not at all) to 4 (very much so). Scores range from 20 (low level of state anxiety) to 80 (high level of state anxiety). To indicate clinically elevated levels of state anxiety, a cut-off of > 44 has been used in previous studies [10]. Additionally, the cut-off values of 40 in men and 42 in women for trait anxiety have been used to dichotomize subjects into low and high levels of trait anxiety [10,18].

2.2.4. Assessment of depression

Depressive symptoms over the prior week were assessed using the Beck Depression Inventory (BDI) [19]. The BDI is a 21-item interview, measuring the characteristic attitudes and symptoms of depression. BDI has a maximum score of 63, and a score of 0–15 indicates being healthy, 16–30 indicates a minimal level of depression, 31–46 indicates mild depression, and 47–63 indicates severe depression. We dichotomized the presence of depression by combining mild and severe depression into one group.

2.2.5. Evaluation of post-traumatic stress disorder (PTSD)

PTSD was assessed using the Impact of Event Scale-Revised (IES-R) [20]. The IES-R is a 22-item scale that is rated on a scale of 0 (not at all) to 4 (extremely), with respect to how distressing each item has been during the past week. Scale scores are formed from the three subscales, which reflect intrusion (8 items), avoidance (8 items), and hyperarousal (6 items), and show a high degree of intercorrelation [21]. Good internal consistency and test-retest values have been reported with the Japanese translation of the IES-R [22]. A cut-off value of ≥ 20 was used to indicate clinically significant levels of PTSD [23].

2.2.6. Assessment of worries about the ICD

The Worries About ICDs Scale (WAICD) is a modification of the 26-item Index of Subjective Concerns for People with ICDs (ISCP-ICD) that examines QOL issues associated with having an ICD, such as driving restrictions, traveling problems, exercise limitations, or job conditions after ICD implantation [10,24]. The items are measured on a 5-point Likert scale anchored at one end by 0 (not at all true) and at the other end by 4 (extremely true) reflecting the degree to which the respondent experiences each problem [24].

2.3. Statistical analyses

Data were presented as means \pm standard deviation for continuous variables and percentages for categorical variables. Differences between groups stratified by ICD indication (primary vs. secondary) were examined with the chi-square test (Fisher's exact test when appropriate) for nominal variables and are presented as *n* (%). The Student's *t*-test was used for independent samples (Mann–Whitney *U* as alternative) with continuous variables, with between group differences presented as mean (SD). Multivariable analysis of variance (MANOVA) was performed to examine the influence of ICD implantation indication on health-related QOL, as measured by SF-8 subscales. Results from the SF-8 were adjusted for older age, female gender, NYHA class III/IV, appropriate shocks, inappropriate shocks, device-related complications, comorbidities, and LVEF. MANOVA was also used to determine whether ICD implantation indication was independently associated with trait anxiety, state anxiety, depression, PTSD, and worries about the ICD, adjusting older age, female gender, NYHA class III/IV, appropriate shock, inappropriate shock, device-related complications, comorbidities, and LVEF. All the covariates entered in the adjusted analysis were selected either on the basis of the literature or results of univariable analysis. A *p*-value < 0.05 was used to indicate statistical significance and all the tests were two-tailed. All analyses were performed using Statistical Package for Social Sciences (SPSS) software (Version 22.0, SPSS Inc., Chicago, IL, USA).

Table 1
Demographic and clinical characteristics stratified by implantable cardioverter-defibrillator (ICD) implantation indication.

	Primary (<i>n</i> =52)	Secondary (<i>n</i> =127)	<i>p</i> -Value
Demographics			
Age, years (mean \pm SD)	62.0 \pm 14.4	59.9 \pm 16.4	0.393
Female patients, <i>n</i> (%)	10 (19.2)	24 (18.9)	0.959
Clinical factors			
NYHA class III/IV, <i>n</i> (%)	3 (5.8)	17 (13.4)	0.142
LVEF, mean (SD)	54.2 (18.5)	53.7 (18.8)	0.879
Appropriate shock, <i>n</i> (%)	10 (19.2)	51 (40.5)	0.007
With syncope, <i>n</i> (%)	3 (5.8)	16 (12.7)	0.173
Without syncope, <i>n</i> (%)	8 (15.4)	43 (34.4)	0.011
Inappropriate shock, <i>n</i> (%)	13 (25.5)	33 (26.0)	0.946
Comorbidity, <i>n</i> (%)	32 (61.5)	77 (60.6)	0.910
Complication, <i>n</i> (%)	17 (32.7)	48 (37.8)	0.519
Duration of ICD therapy in months, mean \pm SD	65.2 \pm 46.1	73.3 \pm 58.7	0.418
Shock frequency, mean \pm SD	0.7 \pm 1.5	1.2 \pm 1.3	0.037
Predominant cardiac diagnosis, <i>n</i> (%)			0.908
Myocardial infarction	14 (26.9)	34 (26.8)	
Dilated cardiomyopathy	6 (11.5)	16 (12.6)	
Hypertrophic cardiomyopathy	11 (21.2)	14 (11.0)	
Long QT syndrome	0	6 (4.7)	
Brugada syndrome	19 (36.5)	18 (14.2)	
Hypertensive heart diseases	0	3 (2.4)	
Others	2 (3.8)	36 (28.4)	

NYHA, New York Heart Association; LVEF, left ventricular ejection fraction.

3. Results

3.1. Patient characteristics

Patient characteristics for each group are displayed in Table 1. The total group was comprised of 52 primary prevention ICD recipients and 127 secondary prevention ICD recipients. Patients with an ICD for secondary vs. primary prevention experienced more appropriate shocks (40.5% vs. 19.2%, respectively, *p*=0.007) and therefore, the frequency of shocks was higher in secondary prevention patients than in primary prevention patients (1.2 \pm 1.3 vs. 0.7 \pm 1.5, respectively, *p*=0.037). Additionally, patients receiving ICD implantation for secondary prevention experienced more appropriate shocks without syncope compared to patients receiving ICD implantation for primary prevention (34.4% vs. 15.4%, respectively, *p*=0.011). There were no differences in both groups in age, gender, NYHA class III/IV, LVEF, comorbidities, and device-related complications. Additionally, although the survey was conducted once during outpatient clinic visits, there were no significant differences between primary and secondary prevention groups in terms of the duration of ICD therapy (65.2 \pm 46.1 months vs. 73.3 \pm 58.7 months, respectively, *p*=0.418). The incidence of inappropriate shocks was high in both groups (25.5% vs. 26.0% for primary and secondary prevention groups, respectively). The high incidence of atrial fibrillation (AF, data not shown) in our study population is one of the causes of vulnerability to inappropriate shocks from an ICD[25].

3.2. Impact of ICD indication differences on anxiety, depression, post-traumatic stress disorders, and worries about ICD

Descriptive characteristics for each ICD indication are presented in Table 2. The mean score of trait anxiety and worries about ICD were greater in primary prevention ICD recipients than in secondary prevention ICD recipients (41.7 \pm 12.4 vs. 34.7 \pm 12.3, *p*=0.001 and 39.6 \pm 18.0 vs. 30.0 \pm 18.9, *p*=0.002, respectively). Based on Fig. 1, trait anxiety was more prevalent in primary prevention ICD recipients than in secondary prevention ICD recipients (51.9% vs. 30.7%, respectively, *p*=0.008). There were no differences between the two groups regarding depression, state anxiety, and PTSD, in either the mean score or the prevalence. Table 3 presents the independent associates of the psychological endpoints, including

Table 2
Psychological characteristics and health-related quality of life scores stratified by implantable cardioverter-defibrillator (ICD) indication.

	Primary (<i>n</i> =52)	Secondary (<i>n</i> =127)	<i>p</i> -Value
Psychological characteristics			
Trait anxiety, mean (SD)	41.7 (12.4)	34.7 (12.3)	0.001
State anxiety, mean (SD)	40.7 (12.9)	38.1 (10.5)	0.203
Depression, mean (SD)	7.6 (9.5)	6.0 (7.0)	0.347
PTSD, mean (SD)	12.7 (19.4)	11.4 (15.1)	0.670
Worries about ICD, mean (SD)	39.6 (18.0)	30.0 (18.9)	0.002
Health-related quality of life scores			
Physical functioning, mean (SD)	45.3 (8.4)	45.4 (9.9)	0.905
Role physical functioning, mean (SD)	46.5 (8.6)	46.2 (9.2)	0.854
Bodily pain, mean (SD)	52.5 (9.6)	54.0 (8.4)	0.368
General health, mean (SD)	44.4 (7.2)	45.5 (7.0)	0.367
Vitality, mean (SD)	48.2 (8.9)	52.4 (7.6)	0.004
Social functioning, mean (SD)	48.6 (8.4)	49.3 (8.5)	0.615
Role emotional functioning, mean (SD)	45.4 (7.3)	46.0 (8.5)	0.686
Mental health, mean (SD)	48.3 (9.6)	49.3 (8.7)	0.538

PTSD, post-traumatic stress disorder.

state anxiety, trait anxiety, depression, PTSD, and worries about the ICD. Of note, the primary prevention indication was associated with trait anxiety and worries about the ICD. Additionally, female gender was associated with depression, PTSD, and worries about ICD, whereas appropriate shock was associated with PTSD.

3.3. Impact of ICD indication differences on health-related QOL

Patients receiving ICD implantation for primary prevention had an impaired health-related QOL on the vitality subscales of the SF-8

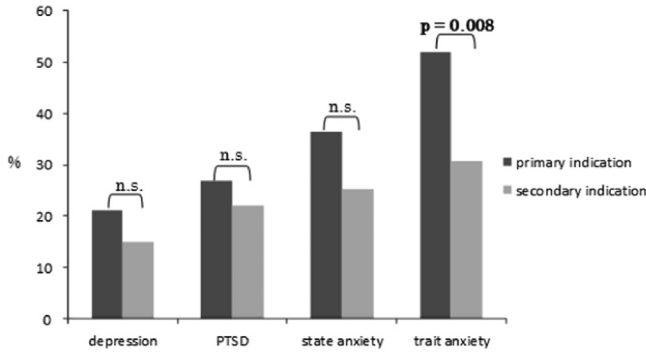


Fig. 1. Prevalence of psychological disorders stratified by ICD indication. The prevalence of depression, post-traumatic stress disorder (PTSD), state anxiety, and trait anxiety for both primary and secondary prevention indication is shown. The presence of the psychological disorders was determined using the cut-off value determined for each questionnaire. n.s. = not significant.

Table 3 Independent associates of psychological characteristics scores.

	State anxiety $F_{1,168}$	Trait anxiety $F_{1,168}$	Depression $F_{1,168}$	PTSD $F_{1,168}$	Worries about ICD $F_{1,168}$
Primary prevention indication	0.360	5.392*	1.885	1.373	4.712*
Older age	0.456	0.001	0.765	0.362	0.176
Female gender	0.257	0.009	5.313*	6.673*	5.666*
NYHA class III/IV	0.122	0.362	0.550	0.424	0.362
Appropriate shock	0.370	0.058	0.558	5.071*	0.004
Inappropriate shock	0.449	1.396	0.081	0.024	1.561
Complication	0.197	0.066	0.050	0.064	0.833
Comorbidity	0.008	0.147	0.074	0.506	0.086
LVEF	1.014	0.970	0.850	1.201	0.605

NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; PTSD, posttraumatic stress disorder; ICD, implantable cardioverter-defibrillator.

* $P < 0.05$.

Table 4 Independent associates of health-related quality of life scores^a.

SF-8 subscales	PF $F_{1,162}$	RP $F_{1,162}$	BP $F_{1,162}$	GH $F_{1,162}$	VT $F_{1,162}$	SF $F_{1,162}$	RE $F_{1,162}$	MH $F_{1,162}$
Primary prevention indication	0.818	0.015	0.891	5.304*	9.168**	1.385	1.242	3.639
Older age	1.562	0.111	2.186	1.052	0.410	0.130	0.665	0.223
Female gender	7.664**	3.880	7.520**	5.901*	3.203	0.036	1.877	2.420
NYHA class III/IV	1.859	1.193	5.775*	0.480	0.557	0.215	0.260	0.637
Appropriate shock	2.094	0.228	0.129	1.031	0.150	2.168	0.016	1.046
Inappropriate shock	0.768	0.005	0.050	0.010	0.101	0.108	0.005	0.144
Complication	1.002	0.082	0.031	0.027	0.021	0.483	0.450	0.320
Comorbidity	4.331*	1.787	0.959	0.302	1.225	0.662	2.267	0.579
LVEF	0.857	0.568	1.048	1.202	0.744	1.104	0.804	0.747

* $P < 0.05$.

** $P < 0.01$.

^a SF-8; PF, physical functioning; RP, role physical functioning; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role emotional functioning; MH, mental health, NYHA, New York Heart Association; LVEF, left ventricular ejection fraction.

(Table 2). When adjusting for older age, female gender, NYHA class III/IV, appropriate shocks, inappropriate shocks, device-related complications, comorbidities, and LVEF, the primary prevention indication was associated with an impaired health-related QOL on the general health and vitality subscales (Table 4). Table 4 presents all independent associates of health-related QOL. Of note, female gender was associated with impaired QOL on physical functioning, bodily pain, and general health subscales. Additionally, comorbidities were associated with physical functioning subscales.

4. Discussion

The results of this study showed that primary prevention ICD recipients were more likely to be worried about their ICD, and they reported high levels of trait anxiety. Additionally, although there were no differences between the two groups in total health-related QOL scores, ICD patients who received implantation for primary prevention had an impaired QOL on the vitality subscales. No statistically significant differences were found between primary and secondary prevention ICD recipients on depression, PTSD, and state anxiety. In the adjusted analysis, female gender was generally associated with worse patient-centered outcomes, including depression, PTSD, worries about ICD, and impaired health-related QOL irrespective of ICD indication. Furthermore, appropriate shock was also significantly associated with increased PTSD.

Our study demonstrated higher trait anxiety and increased worries about an ICD in ICD patients with a primary prevention indication. In contrast, Bilge et al. did not find any differences in anxiety in primary and secondary prevention indication subgroups [5]. Possible reasons for this discrepancy are the type of questionnaire and smaller sample size of the previous study. However, both this study and the study by Bilge et al. found no differences in depression between the two ICD indication groups. According to the previous study, exposure to shocks may lead to an increased risk of anxiety [26]. In this study we did not find an independent association between shocks and anxiety. However, the patients with a primary prevention ICD experienced more shocks compared to patients with a secondary prevention indication. A study by Groeneveld et al. also showed that patients receiving a ICD for secondary prevention had more shocks compared with a primary indication, and shocks were associated with a lower QOL in primary prevention patients [9]. One possible explanation is that secondary prevention patients, by definition, experienced a prior cardiac arrest or ventricular arrhythmia. Therefore, secondary prevention patients may have assessed their risk of SCD as being higher, and thus found their ICDs to be potentially lifesaving (particularly if the devices had actually delivered a shock). Besides

the primary prevention indication, being female also showed an association with worries about an ICD; this is consistent with our previous study [10]. Above all, behavioral interventions have shown promise with respect to reducing distress such as anxiety and worries in ICD patients [27].

Our findings show that primary prevention ICD recipients experienced an impaired QOL on vitality subscales, which were included in the physical health domain, compared to secondary prevention ICD recipients. Similarly, Berg et al. also found that ICD patients with a primary prevention indication had lower scores in all subscales of QOL, and larger differences were found in physical scores using other types of QOL questionnaires [11]. These results are consistent with the fact that patients with an ICD for primary prevention differ from those who receive the device for secondary prevention, particularly because primary prevention patients may fail to understand why they need the ICD [28]. Furthermore, they may have fears concerning device malfunction and recall, and device-associated complications including perforation, infection, and perhaps of greatest importance, receipt of inappropriate shocks [28,29]. On the other hand, Pedersen et al. reviewed the literature in 2009 and found five studies reporting patient-centered outcomes, and none of them found an association between indication and patient-centered outcomes such as QOL [8].

Taken together, this study suggests that although close monitoring related to education and psychological interventions targeting anxiety, depression, PTSD, worries about the ICD, and health-related QOL are important to all ICD patients, recipients of a primary prevention indication may have different needs following ICD implantation compared to a secondary prevention indication. A recent study of remote monitoring in ICD patients showed that a clear understanding of ICD implantation was associated with a higher acceptance of remote monitoring, which has been shown to be related to patient safety and survival [30,31]. Remote monitoring benefits include more rapid clinical event detection and a reduction in inappropriate shocks.

The results of this study should be interpreted with some caution. First, this was a retrospective (not prospectively defined) subgroup analysis; the study was not originally designed to evaluate differences between ICD indication groups. Second, psychological evaluation was performed on patients only after ICD implantation, and therefore a comparison with the preimplantation psychological status of the patients was not possible. In addition, there were no follow-ups to evaluate score changes in QOL and psychological functioning after any time intervals. Third, information on psychological distress was obtained by a self-report rather than a diagnostic interview, although all questionnaires were standardized and validated.

In conclusion, in this study, which mostly consisted of NYHA class I and II subjects, patients with a primary prevention ICD were more likely to experience anxiety, high levels of worry about their ICD, and an impaired health-related QOL compared to patients with a secondary prevention ICD. However, no differences were found in depression or PTSD. In clinical practice, primary prevention ICD recipients should be closely monitored. If warranted, they should be offered a psychological intervention, because anxiety and low QOL were predictors of mortality [11]. In the future, further longitudinal and larger studies are needed to examine these differences in psychological distress and QOL.

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Conflict of interest

The authors declare no conflicts of interest related to this study.

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