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Time-Dependent Changes in Psychosocial Distress in Japanese Patients with Implantable Cardioverter Defibrillators

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This prospective study clarified changes in the mood states of Japanese patients with implantable cardioverter defibrillators as well as factors related to the mood states. Using a longitudinal repeated-measure design, 29 patients with implantable cardioverter defibrillators completed the Profile of Mood States-Short Form Japanese Version questionnaire before discharge and 1, 4, 7, and 13 months after implantation. One month after discharge, the mood states of the patients with implantable cardioverter defibrillators improved. From 7 to 13 months after discharge, moods deteriorated; 13 months after discharge, moods were equivalent to those at the time of discharge. No relationship with defibrillation experience was detected in this study, but employment, age, sex, and lack of experience of syncopal attack were factors related to poor mood states for patients with implantable cardioverter defibrillators. Therefore, Japanese patients with implantable cardioverter defibrillators with any factor deteriorating their mood state should be monitored so that their mood state does not deteriorate again between six months and one year after implantation.

INTRODUCTION

Implantation of an implantable cardioverter defibrillator (ICD) is a non-drug therapy to help prevent sudden cardiac death caused by lethal arrhythmia. Patients with ICD in Japan are dramatically increasing recently due to extension of the indication criteria and aging. Additionally, while the patients have a sense of security because they have escaped death through the implantation, there are significant psychosocial issues, including excessive self-control of living activities, depression, anxiety, and post-traumatic stress disorder (PTSD) due to living restrictions, such as avoidance of electromagnetic interference, driving a vehicle, and/or fear of defibrillation (1, 2). For that reason, the Japanese Circulation Society (3) has proposed that construction of a comprehensive support system involving multiple professionals is an urgent task. However, in Japan, the composition of the underlying diseases and indication criteria for ICD implantation are different from Europe and America. Investigating the kinds of effects obtained by changing the timing and methods of patient support given as well as by patient characteristics is needed.

We have clarified the illness experience of Japanese patients with ICD after implantation to understand the situations leading to anxiety and/or depression; the aim is to construct a support system based on this experience (4). We clarified the following process leading to adaptation: *The patients continue "confirming and managing lifestyle activities" of their own by "bewilderment" arising from a constant fear of death, uncertainty about their own bodies, and dissatisfaction with the device. In this process, the patients compromise in terms of "living with arrhythmia and an ICD" by giving meaning to the value of the ICD through the facing of the arrhythmia, ICD, and themselves*.

The preceding studies on the psychosocial aspects of patients with ICDs revealed that women, young, elderly, with defibrillation experience, employed, and so forth are likely to have psychological problems (5-11). However, these studies were mainly retrospective investigations that used various scales to measure the psychological aspects. Their results also varied depending on the composition of the participant characteristics and measurement timing. Thus, no consensus is currently available. For that reason, it is necessary to clarify the timing and types of psychosocial conditions patients with ICD experience (2).

Therefore, our aim is to clarify the timing and type of psychological conditions patients experience and social factors related with these psychological aspects. This is to provide Japanese patients with ICDs support based on their experiences in the adaptation process to life after implantation. Through this clarification, we may be able to obtain indications regarding the timing of patient support after ICD implantation, as well as the type of social

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factors and mood states Japanese patients possess. This study prospectively clarifies the mood states of Japanese patients with ICDs after implantation as well as the factors related with the mood states.

METHODS

Design

A longitudinal repeated-measures design was used to assess psychosocial distress in patients with ICDs over 12 months.

Participants

The survey was conducted at a certified implant facility located in the Kinki region of Japan. The participants were patients receiving first-time implantation during the study year and who provided their consent to participate in this survey. Patients expected to have difficulty answering our questionnaire, including those with cognitive decline, mental disease, or developmental disorder, were excluded.

Ethical considerations

This study was conducted with the approval of the Research Ethics Committee of Kobe University, Graduate School of Health Sciences. After confirmation of the inclusion criteria with the physicians in charge, the investigator explained the study outline before obtaining the patients' consent. Participants were assured that participation and consent withdrawal were voluntary and would cause no disadvantage to the patients' medical and nursing care. The data were processed so that no individual would be identified. In addition, the investigator checked whether the patient was *attention required* or *visit required* when collecting the questionnaire and provided feedback to the participant. The investigator also reported this to the physician in charge for evaluation when the physician examined the patient.

Survey details and data collection

The mood states of the patients with ICDs were assessed five times, including before discharge and 1, 4, 7, and 13 months after ICD implantation when the outpatients visited the facility. The participants completed our questionnaire independently while they were waiting for the outpatient examination.

To measure the mood states, the Profile of Mood States-Short Form Japanese Version (POMS-SFJ) was used; this questionnaire asks about "mood states during a week that can change depending on the patient's situation" (12). The Japanese version's reliability and validity were verified by Yokoyama (13). The POMS is used in a wide range of fields for process assessment and screening of psychological disorders, including depression and anxiety disorders. It has six subscales: Tension-Anxiety (T-A), Depression-Dejection (D), Anger-Hostility (A-H), Vigor (V), Fatigue (F), and Confusion (C). The items are rated on a five-point Likert scale ranging from 0 (*not at all*) to 4 (*extremely*). The total mood disturbance (TMD), reflecting psychological distress, is the sum of the scores of the five subordinate items other than V, subtracted by the V score. The TMD and subscale scores are standardized with adjustments for age and sex to T-scores (20–85). T-scores under 60 (below mean + 1 SD), 60–75 (mean + 1–2.5 SD), and above 75 (mean + 2.5 SD) indicate *healthy*, *attention required*, and *visit required*, respectively. Higher subscale scores, except V, indicate poorer mood states, whereas a lower V score indicates being less vigorous.

In this study, we chose age, sex, occupation, experience of syncopal attack before implantation, and experience of ICD shock therapy after implantation as characteristic factors associated with mood states. Although the results are varied, these factors were investigated in previous studies of factors associated with psychological condition such as quality of life, anxiety, or/and depression.

Analytical methods

Sex- and age-adjusted TMD and subscale T-scores as well as descriptive statistics were calculated. Nonparametric analysis was chosen because no normal distribution was obtained from a check of normality and variation and the number of participants was low.

The Friedman test was used to examine the presence of TMD changes and individual factors over one year. Wilcoxon signed rank test was used to verify the significance of the differences at each survey point from the preceding time point as well as from before discharge, which was used as the baseline.

Age, sex, employment, experience of a syncopal attack before implantation, and defibrillation experience after implantation were analyzed as background factors related to mood states of patients with ICDs. The mean values of TMD and the six subscales at the five time points were individually calculated. Spearman's rank correlation coefficient was used for age; for the other four factors, the Mann-Whitney U test was used to

ascertain the differences between groups. The significance level was 5%; IBM SPSS Statistics 21.0 (Japanese version) was used for analysis.

RESULTS

Participant characteristics

There were 36 new patients with ICDs; 29 of these participated in the yearlong study period. Three patients complicated by other diseases, including cognitive and mental disorders, were excluded; three patients withdrew from the study due to re-hospitalization; one patient withdrew consent. Table I shows participant characteristics. The average age and the men:women ratio was 63 ± 12.4 (42–80) years and 21:8, respectively. Eleven participants (38%) experienced defibrillation in the year after implantation; all experienced defibrillation 1–4 months after the implantation.

Table I. Characteristics of the participants **n = 29**

Demographics	Mean age (± SD)	63 ± 12.4
	Men	21 (72%)
	Employed	17 (59%)
Clinical factors	Primary prevention indication	5 (17%)
	Ischemic heart failure etiology	16 (55%)
	Brugada syndrome	10 (34%)
	NYHA class < III	16
	Mean LVEF (%)	39.1 ± 9.00%
	ICD-therapy (both appropriate and inappropriate)	11 (38%)

SD = standard deviation, NYHA = New York Heart Association, LVEF = left ventricular ejection fraction, ICD = implantable cardioverter defibrillator

Changes in the mood states of patients with ICDs during one year

Table II shows the changes and fluctuations of the TMD (total mood) median and six mood states: Tension-Anxiety (T-A), Depression (D), Anger-Hostility (A-H), Vigor (V), Fatigue (F), and Confusion (C).The mood states of the patients with ICDs showed a valley-like shape indicating low vigor throughout the year in contrast to the healthy individuals who showed a mountain-like shape indicating high vigor. The mean values from all study participants were in the range of *healthy* regardless of mood state and timing. However, there were participants who showed *attention required* for T-A, F, and/or C.

In this study, TMD, D, A-H, and C fluctuated very significantly ($p < 0.01$) and V and F also significantly fluctuated ($p < 0.05$). However, T-A fluctuated minimally. Moreover, Table II shows time-dependent changes in the mood states. Therefore, all mood states improved after discharge, but deteriorated again 7–13 months after discharge. Additionally, they deteriorated 13 months after discharge to a level equivalent to or poorer than the level at the time of discharge.

TMD (total mood) showed a significant change throughout the year after implantation ($\chi^2 = 13.40$, $p < 0.01$). It improved one month after discharge, but deteriorated very significantly 7–13 months after implantation ($Z = -4.24$, $p = 0.00$).

Tension-Anxiety showed no significant change throughout the year after implantation ($\chi^2 = 8.31$, $p = 0.08$); it improved one month after discharge, but gradually increased by 13 months after discharge higher than the level before discharge. Additionally, when the state before discharge was used as the baseline, T-A improved significantly both one and four months later ($Z = -2.12$, $p = 0.03$; $Z = -2.18$, $p = 0.03$).

Depression showed a very significant change throughout the year after implantation ($\chi^2 = 18.62$, $p = 0.001$); it did not change much seven months after discharge from before discharge, but deteriorated 7–13 months after discharge, showing higher D than before discharge. Additionally, when the state before discharge was used as the baseline, D improved significantly 1, 4, and 7 months later ($Z = -2.07$, $p = 0.04$; $Z = -2.07$, $p = 0.04$; $Z = -2.36$, $p = 0.02$, respectively).

Anger-Hostility showed a very significant change throughout the year after implantation ($\chi^2 = 30.05$, $p = 0.000$); it improved gradually over seven months after discharge, but strengthened 13 months after discharge to equivalent to the level before discharge. In particular, it significantly improved 4–7 months after discharge ($Z = -2.73$, $p < 0.01$) and deteriorated very significantly 7–13 months after discharge ($Z = -4.41$, $p = 0.00$). Additionally, when the state before discharge was used as the baseline, A-H improved significantly four and seven months later ($Z = -2.40$ and -3.59, $p = 0.02$ and 0.00, respectively).

Vigor showed a significant change throughout the year after implantation ($\chi^2 = 13.10$, $p = 0.01$). It significantly increased one month after discharge ($Z = -2.06$, $p = 0.04$) and gradually lowered again.

Fatigue showed a significant change throughout the year after implantation (χ^2 = 13.38, p = 0.01); it gradually strengthened over 13 months after discharge. In particular, it very significantly strengthened 7–13 months after discharge (Z = -3.32, p = 0.001). When the state before discharge was used as the baseline, F very significantly strengthened 13 months later (Z = - 2.63, p < 0.01).

Confusion showed a significant change throughout the year after implantation (χ^2 = 25.30, p = 0.00); it reduced seven months after discharge, but strengthened again 13 months after discharge. In particular, it reduced very significantly from 4–7 months after discharge (Z = -3.04, p < 0.01), but deteriorated very significantly 7–13 months after discharge (Z = -4.28, p = 0.00). Additionally, when the state before discharge was used as the baseline, C reduced very significantly seven months later (Z = -3.44, p < 0.01).

Background factors related to mood states of patients with ICDs

Table III shows the results of analyses of the relationships between the mean values of each mood state of the patients with ICDs throughout the year and the five factors: age, sex, employment, experience of a syncopal attack before implantation, and defibrillation experience by ICD. In this study, no relationship was detected between defibrillation experience by ICD and any of the mood states.

The factors significantly relating to the TMD were employment (U/p = 53.50/0.030) and syncopal attack (U/p = 15.0/0.007). In other words, those employed and those without experience of a syncopal attack had high TMD.

Age showed a significant correlation (ρ/p = -0.46/0.012) and sex (U/p = 24.0/0.002) and employment (U = 36.0/0.003) showed significant differences as factors related to T-A. Therefore, younger women and employed participants had strong T-A.

Experience of a syncopal attack showed a significant difference (U/p = 9.00/0.001) related to D. Therefore, those with experience of a syncopal attack had strong D.

Sex showed a significant difference (U/p=16.00/0.000) related to A-H. Therefore, women had strong A-H.

Age significantly correlated with V (ρ/p = 0.54/0.002) and sex (U/p = 24.00/0.002) and employment (U/p = 32.00/0.001) showed a significant difference. Therefore, younger women and employed participants had low V.

Employment (U/p = 52.00/0.027) and experience of a syncopal attack (U/p = 15.00/0.007) showed a significant difference related to F. Therefore, those employed and those with experience of a syncopal attack had strong F.

Experience of a syncopal attack showed a significant difference (U/p = 18.00/0.013) related to C. Therefore, those with an experience of a syncopal attack had strong C.

In combination, the following characteristics were revealed. Youth have strong T-A and low V; those employed have high TMD, strong T-A and F, and low V; women have strong T-A and A-H; and those without experience of a syncopal attack before implantation have high TMD and strong F and C.

DISCUSSION

One month after discharge, mood states of patients with ICDs became less severe; 7–13 months after discharge, they deteriorated; 13 months after discharge, they returned to equivalent mood states as before discharge. This study detected no relationship between mood states and defibrillation experience, but revealed that those who were employed, young, women, and without experience of a syncopal attack had poor mood states.

In the results of a survey on changes 0, 6, and 12 months after implantation for Norwegian patients (14), TMD did not clearly increase six months later, but did decrease again at one year. When looking at the changes by factor, T-A, F, TMD, and D showed significant changes. Our present results that TMD recovered temporarily six months after discharge but decreased again one year after discharge support these survey results. In a similar survey by Hamilton and Carroll (15,16), T-A changed significantly. However, in our study, T-A showed no clear change; D, A-H, and C showed a significant change; and F and V showed a tendency to change. Additionally, from six months to one year after discharge, the mood states deteriorated to the same level as prior to discharge. “The disease has a transition stages from health to illness, a accept stage of illness, and a convalescent stage of illness” . “This recovery of health involves a return of physical strength and are-integration of the personality of the patient who has been living , feeling, and thinking in a regressed, more or less infantile way. The return of physical strength and health is usually an automatic process but it is not necessarily paralleled by a restoration of healthy, adult behavior;” (17).

Further, before ICD implantation with a competitive review one year later, they control their own daily activities themselves but social roles do not recover, even after implantation for one year (2). By six months, life quieted as the physical symptoms after the discharge were relieved as patients adjusted to ICDs, evading electromagnetic interference, and avoided driving. Thus, the mood states were restored once. However, six

months after implantation, the patients recovered from the cardiac condition by the treatment device effect; physical symptoms have recovered from before implantation. Then, the patients with ICDs hold anger, dejection, and confusion. They are not able to judge daily activity suitable for their own cardiac condition with the device to regain a social life and the time when "value of the ICD" is felt. Therefore, restored mood states worsened six months later. We hypothesize that even if the patients are one year past implantation, they remain in the process of regaining their social lives and do not reach reintegration of recovery from physical disease and psychosocial function.

This study detected no relationship with defibrillation experience but revealed that those who were employed, young, women, and without experience of a syncopal attack had poor mood states. In retrospective surveys, women, youth, and those who were employed were identified as having anxiety and/or depression and low quality of life. Our present results also support these findings. A number of surveys by Kobayashi and colleagues (18) and others have reported relationships between defibrillation by ICD and anxiety/PTSD. However, prospective follow-up surveys include a report (16) in which no relationship between defibrillation and anxiety/depression was detected; the present study results concur with this. We speculate that the timing of the defibrillation experience and the timing of the survey of their psychological states might have influenced the results. All patients with defibrillation experiences in the present study experienced this within six months after implantation. No significant difference was detected in the mood states 7 and 13 months after discharge between those with and without defibrillation experience.

Dunbar et al. (16) reported that the experience of an arrhythmia event before the implantation was related to T-A, F, and C three and six months after implantation. Our present study revealed that patients without experience of a syncopal attack before ICD implantation had poor mood states. Although it was predicted from the preceding studies that those with experience of an arrhythmia event—in other words, patients with an experience of a syncopal attack—would have stronger anxiety due to a fear of loss of consciousness and/or death, our study results were the opposite. Our qualitative study on the illness experience of ICD patients (4) revealed that many patients with ICDs, who had not experienced syncopal attacks before the implantation or had not had an arrhythmic event after the implantation, doubted and became angry at the adequacy of the implantation rather than the optimism most patients experienced as time passed. Therefore, patients who experienced a loss of consciousness or life crisis due to arrhythmia are likely to have a sense of security from avoiding sudden death owing to the ICD. However, patients without such experiences have tension and anxiety due to the unknown fear associated with a loss of consciousness, sudden death, and/or defibrillation by ICD, and lose sight of the significance and/or value for oneself of the ICD implantation, resulting in a stronger generation of depression and/or confusion.

Limitations

This study has several limitations. First, the ability to generalize the results is limited as only one facility was used and the number of participants was low. Second, this study had biases including a self-administered questionnaire, management status of life events other than ICD implantation and other diseases, and a simple interview with the investigator each time. Therefore, increasing the number of participants and using multiple facilities could help increase the generalizability of the results.

Implications for practice

In the nursing support of Japanese ICD patients, it is necessary to help them adjust to their life as a patient based on their cardiac function by understanding the changes in their mental functions and living conditions, in particular, about six months following implantation. Approximately 7–13 months after discharge, their mood states deteriorate to an equivalent or poorer level than that before discharge, although they improve immediately after discharge. Particular attention is needed to an experience of syncope before implantation, age, employment, and sex as related to the mood states.

Conclusion

This prospective study clarified changes in mood states of Japanese patients with implantable cardioverter defibrillators as well as factors related to mood states. Tension-Anxiety showed no significant change during the year after implantation, but the total mood and all other mood states showed significant changes. All mood states improved after discharge, but deteriorated again 7–13 months after discharge. Additionally, 13 months after discharge, they deteriorated to the equivalent or poorer level than before discharge. Although the mood states did not significantly vary depending on defibrillation experience, those who were young, employed, women, and without experience of a syncopal attack before implantation had poor mood states.

Table II. Changes in profile of mood states (T-scores)

n = 29

Profile of Mood States (POMS)	T-score		differences at each point from the 0 month point			differences at each point from the previous point		
	Median	Quartile deviation	Z	p		Z	p	
Tension-Anxiety (T-A)								
0 month	52	13.0						
						-2.12	0.03	*
1 month	43	7.0	-2.12	0.03	*			
						-1.14	0.25	ns
4 months	46	7.5	-2.18	0.03	*			
						-0.70	0.48	ns
7 months	46	8.5	-1.02	0.31	ns			
						-0.02	0.98	ns
13 months	57	10.1	-1.06	0.29	ns			
change	$\chi^2 = 8.31$ p = 0.081							
Depression (D)								
0 month	45	10.5						
						-2.07	0.04	*
1 month	46	5.0	-2.07	0.04	*			
						-0.91	0.37	ns
4 months	42	4.5	-2.07	0.04	*			
						-1.41	0.16	ns
7 months	43	6.0	-2.36	0.02	*			
						-1.74	0.08	ns
13 months	48	7.5	-0.93	0.35	ns			
change	$\chi^2 = 18.62$ p = 0.001 **							
Anger-Hostility (A-H)								
0 month	46	4.5						
						-1.12	0.26	ns
1 month	43	4.0	-1.12	0.26	ns			
						-1.64	0.10	ns
4 months	41	4.5	-2.40	0.02	*			
						-2.73	0.01	**
7 months	39	3.0	-3.59	0.00	***			
						-4.41	0.00	***
13 months	46	1.5	-1.48	0.14	ns			
change	$\chi^2 = 30.05$ p = 0.000***							
Vigor (V)								
0 month	33	9.5						
						-2.06	0.04	*
1 month	41	3.0	-2.06	0.04	*			
						-1.93	0.05	ns
4 months	39	5.5	-0.87	0.38	ns			
						-1.31	0.19	ns
7 months	35	2.0	-0.01	0.99	ns			
						-1.81	0.07	ns
13 months	35	3.0	-0.83	0.40	ns			
change	$\chi^2 = 13.10$ p = 0.011*							
Fatigue (F)								
0 month	41	12.5						
						-0.90	0.37	ns
1 month	48	3.5	-0.90	0.37	ns			
						-1.40	0.16	ns
4 months	50	3.0	-0.15	0.88	ns			
						-0.62	0.54	ns
7 months	50	3.5	-1.65	0.10	ns			
						-3.32	0.00	**
13 months	54	7.5	-2.63	0.01	**			
change	$\chi^2 = 13.38$ p = 0.010*							
Confusion (C)								
0 month	54	12.0						
						-1.04	0.30	ns
1 month	51	9.0	-1.04	0.30	ns			
						-0.28	0.78	ns
4 months	41	3.5	-1.30	0.20	ns			
						-3.04	0.00	**
7 months	51	4.5	-3.44	0.00	**			
						-4.28	0.00	***
13 months	67	10.0	-0.37	0.71	ns			
change	$\chi^2 = 25.30$ p = 0.000 ***							
Total Mood (TMD)								
0 month	227	51.5						
						-1.46	0.14	ns
1 month	185	31.5	-1.46	0.14	ns			
						-0.38	0.71	ns
4 months	187	29.5	-1.61	0.11	ns			
						-0.18	0.85	ns
7 months	187	16.5	-1.66	0.10	ns			
						-4.24	0.00	***
13 months	223	31.5	-0.27	0.79	ns			
change	$\chi^2 = 13.40$ p = 0.009**							

T-score = standardized with adjustments for age and sex, Z ; Wilcoxon Signed-Rank Test , $\chi 2$ = Friedman Test

ns : not significant, *** : p<0.00, ** : p<0.01, * : p<0.05

Table III. Association between mood states and patients characteristics

n = 29

	Tension-Anxiety		Depression		Anger-Hostility		Vigor		Fatigue		Confusion		Total Mood	
	ρ	p	ρ	p	ρ	p	ρ	p	ρ	p	ρ	p	ρ	p
Age	-0.461	0.012 *	-0.185	0.336	0.051	0.791	0.544	0.002 **	-0.164	0.396	0.005	0.981	-0.226	0.239
	U	p	U	p	U	p	U	p	U	p	U	p	U	p
Sex	24.00	0.002 **	45.00	0.059	16.00	0.000 ***	24.00	0.002 **	70.00	0.518	63.00	0.324	47.50	0.075
Employed	36.00	0.003 **	59.00	0.059	100.00	0.948	32.00	0.001 **	52.00	0.027 *	99.00	0.913	53.50	0.030 *
Syncopal attack	29.00	0.078	9.00	0.001 **	57.00	0.889	40.00	0.270	15.00	0.007 **	18.00	0.013 *	15.00	0.007 **
Defibrillation	90.00	0.707	96.00	0.912	88.00	0.642	85.00	0.550	96.00	0.912	79.00	0.387	96.00	0.912

U = Mann-Whitney U ρ = Spearman's rank correlation coefficien

*: p < 0.5 **: p < 0.01 ***: p = 0.000

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Conflicts of interest

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