Original Article

Post-traumatic stress disorder and its risk factors in Japanese patients living with implantable cardioverter defibrillators: A preliminary examination

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ABSTRACT

Background: Trauma reactions, including post-traumatic stress disorder (PTSD), in patients with implantable cardioverter defibrillators (ICDs) have recently garnered increased attention. The aim of this preliminary study was to examine the incidence of and risk factors for PTSD and to assess its impact on psychosocial distress and health-related quality of life (QOL) in Japanese patients with ICD.

Methods: Seventy-four outpatients with ICD (63 men, 11 women; age 59.3 ± 13.6 years) completed a questionnaire comprising a modified PTSD Checklist Specified for a stressor that included arrhythmias and ICD shocks, the Zung Self-Rating Depression Scale (SDS), the State-Trait Anxiety Inventory (STAI)-State scale, and Medical Outcomes Study 36-item Short-Form (SF-36) for health-related QOL. We compared relevant sociodemographic and medical variables of patients with and without PTSD. The mean number of days since ICD implantation was 2471 ± 703.

Results: Of 74 patients, 28 (37.8%) had received ICDs for secondary prevention, 42 (56.8%) had experienced ICD shocks, 36 (48.6%) had experienced ≥1 appropriate ICD shock, and 12 (16.2%) had experienced electrical storms. We diagnosed 19 patients (25.8%) with PTSD. Compared with the non-PTSD group, the PTSD group had significantly higher SDS and STAI-S scores and significantly lower scores in all eight subscales of the SF-36. Multiple logistic regression analysis identified experiencing ≥1 appropriate ICD shock (odds ratio [OR]: 6.0, 95% confidence interval [CI]: 1.45–24.63, and p < 0.013) and anxiolytic use (OR: 15.0, 95% CI: 3.38–66.26, and p < 0.001) as independent risk factors for PTSD.

Conclusions: Our study shows that PTSD in patients with ICD has significant psychosocial impact with associated impairment of both physical and mental QOL and suggests that, in particular, patients who experience appropriate ICD shocks or take anxiolytics require psychiatric/psychological intervention.

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1. Introduction

Implantable cardioverter defibrillators (ICD) are an established form of therapy for both primary and secondary prevention of lethal cardiac arrhythmias [1]. Previous studies have shown that ICD implantation improves the quality of life (QOL) of most patients with ICD [2,3]. However, underlying diseases or comorbidity, poor social support, or ICD-specific problems such as frequent shocks and poor understanding of ICD therapy can increase anxiety and depressive symptoms and reduce QOL in patients with ICD [2,4,5]. Ten percent to 41% of the patients with ICD experience significant depressive symptoms, whereas general or ICD-specific anxiety occurs in 13–38% [6]. Some preliminary studies have suggested that psychological distress can precipitate arrhythmic events [7,8]. Moreover, a vicious cycle may ensue, characterized by ICD implantation leading to anxiety and depression, which in turn precipitates arrhythmic events, leading to further distress [9].

Recently, trauma reactions, including post-traumatic stress disorder (PTSD), have garnered increased attention as a form of psychosocial distress that partly overlaps depressive symptoms or anxiety in patients with ICD [6,10–18]. According to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) [19], PTSD occurs in people who have been exposed to a traumatic event that involves actual or threatened death (criterion A). PTSD symptomatology is categorized into: (1) “intrusive recollection” (persistent re-experiencing of the traumatic event, criterion B); (2) “avoidant/numbing” (persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness that was
not present before the trauma, criterion C); and (3) “hyper-arousal” (persistent symptoms of increasing arousal that were not present before the trauma, criterion D).

ICD shocks are potential traumatic stressors in patients with ICD because they may act as continuous reminders of having a potentially fatal disease [10,11]. Traumatic events experienced by patients with ICD vary widely and are complex. Furthermore, even being told that they are at risk for life-threatening arrhythmias patients with ICD vary widely and are complex. Furthermore, even being told that they are at risk for life-threatening arrhythmias may be traumatic for patients [6]. Therefore, threats to patients’ lives and well-being are not isolated events, but are persistent and enduring. Patients with PTSD symptoms may be particularly stressed by agonizing ruminations and involuntary preoccupation with the underlying disease process [13].

To our knowledge, five published studies have assessed the incidence of PTSD after ICD implantation and estimated it at 7.6–26% [13–16]. However, these studies used disparate definitions of criterion A of PTSD (i.e., exposure to a traumatic event that involves actual or threatened death), presenting a methodological problem. Some reports classified rapid onset of the cardiac condition (cardiac arrest or acute myocardial infarction) as criterion A [13,15], whereas another used arrhythmia or its treatment (i.e., having an ICD) [14]. In the former, researchers excluded patients receiving ICDs for primary prevention. To cover patients with ICDs for both primary and secondary prevention, we believe that rapid onset of the cardiac condition, life-threatening arrhythmia, and ICD shocks should all separately qualify as meeting criterion A.

The aim of this preliminary study was to examine PTSD incidence and risk factors and to assess its impact on psychosocial distress and health-related QOL of Japanese patients with ICD.

2. Method

2.1. Participants and procedures

This preliminary study was conducted as a component of routine care in a clinical setting where patients with ICD had been recognized as experiencing psychosocial difficulties. During the 4 months from February to May, 2006, collaborative care between cardiologists and psychologists was offered to patients attending the ICD clinic of the Department of Cardiology, Tokyo Women’s Medical University. During this period, psychologists assessed patients with ICD for psychosocial problems. Informed consent for this assessment was obtained from all participating patients; all were aged over 18 years and able to communicate in Japanese. The patients completed self-completing questionnaires (in the same order for all patients) to assess the psychological and health-related factors under investigation on the same day as their cardiacological assessment. To ensure that they did not miss any questions and to help them understand the items, an experienced psychologist (S.K.) was present while the patients completed the questionnaires, which took 20–30 min. Where psychosocial problems were suspected, the psychologist recommended that the participant receive psychosocial care. The 72 patients who completed their questionnaires during the study period were retrospectively evaluated.

2.2. Measures

2.2.1. Assessment of post-traumatic stress symptoms

PTSD symptoms were assessed with a modified PTSD Checklist Specified for a stressor (PCL-S) [20]. The specified stressor was “potentially fatal cardiac arrhythmias or ICD shocks, both appropriate and inappropriate”. The PCL-S is a widely used, self-reporting, extensively validated 17-item Likert scale that corresponds to the DSM-IV [19] criteria for PTSD. Participants were asked to rate specific PTSD symptoms resulting from their potentially fatal cardiac arrhythmias or ICD shocks. To make the PCL-S easier to complete, the checklist was modified from a 5-point (“not at all”, “a little bit”, “moderately”, “quite a bit”, and “extremely”) to a four-point response scale (“not at all or a little of the time”, “some of the time”, “good part of the time”, and “most of the time”) to match the format of the other questionnaires. A presumptive PTSD diagnosis was made when a participant met the DSM-IV symptom criteria, namely, at least one item from criterion B (intrusive recollection), three items from criterion C (avoidant/numbing), and two items from criterion D (hyper-arousal). Symptoms those were rated as “some of the time” or above (responses three through four for individual items) were classified as present.

2.2.2. Assessment of other psychological/health-related variables

The Zung Self-Rating Depression Scale (SDS) was used to screen for depression and to measure the severity of the depression in numerous settings [21]. The SDS is a self-reporting scale for assessing the psychological and somatic symptoms of depression. It contains 20 questions and is used to assess depression in clinical studies on cardiovascular disease [22,23].

The State-Trait Anxiety Inventory (STAI) was used to measure anxiety symptoms [24]. As state anxiety is characterized as a temporary change in a patient’s emotional state due to medical illness or other external cause and because state anxiety has previously been used in clinical studies on cardiovascular disease [25,26], only the state scale measurement was used in this study. STAI scores range 20–80; higher scores indicate greater degrees of anxiety.

The Medical Outcomes Study 36-item Short-Form (SF-36) [27,28] was used to assess health-related QOL. This is a widely used self-reporting measure of general physical and mental health functioning across eight domains that include physical functioning; role-physical (limitations in the kinds/amount of work/activities due to physical functioning); bodily pain; general health; vitality; social functioning; role-emotional (limitations in the kinds/amount of work/activities due to emotional functioning); and mental health. Higher scores are indicative of greater health-related QOL. A number of validation studies have been conducted in the general and various medically ill populations. The Japanese version has demonstrated good reliability and validity in the general population of Japan [27,28].

2.3. Clinical variables associated with implantable cardioverter defibrillators

Data on the relevant clinical characteristics of the participants and the conditions under which their ICDs were implanted were obtained from medical records. The collected data included indicators for ICDs, underlying heart disease, New York Heart Association functional class, shock therapy history (times of shocks, both appropriate and inappropriate; electrical storm [ES] experiences, defined as the occurrence of ≥3 separate episodes of ventricular tachycardia or ventricular fibrillation within 24 h; days since ICD implantation; days since last shock), medications, living with/without family, and employment status.

2.4. Statistical analyses

Student’s t-test was used to identify differences in continuous variables between groups, and categorical variables were compared by the χ2 test. To identify independent risk factors for PTSD, the variables were analyzed in two steps. In the first step, univariate analysis was performed. In the second step, multiple logistic regression analysis was performed, with forward stepwise
variable selection. In the regression analysis, data sets that were significantly \((p < 0.05)\) or almost significantly \((p < 0.25)\) associated with the PTSD group were used in the first step. Regression coefficients were used to calculate the odds ratio (OR) and 95% confidence interval (CI) of the OR. In all statistical analyses, \(p < 0.05\) was taken to indicate statistical significance. Data analyses were performed by using SPSS (version 16, SPSS, Chicago, IL, USA).

3. Results

3.1. Relevant clinical and other characteristics of participants

The relevant clinical and other characteristics of the study group are listed in Table 1. In all, 74 patients (63 men and 11 women; age, 59 ± 14 years [mean ± SD]) completed the surveys. Eight patients (11%) lived alone and 35 (47%) were not working at the time of the survey. The underlying heart disease was coronary artery disease in 19% of cases. Twenty-eight patients (38%) underwent ICD implantation for secondary prevention. The mean number of days since ICD implantation was 2471 ± 703 days. Of the 74 patients, 42 (57%) had experienced ICD shocks and 12 (16%), ES. No patients in had received non-pharmacological therapy, such as cognitive behavioral therapy (CBT), for any psychiatric condition.

3.2. Incidence of post-traumatic stress disorder and its effect on psychological distress and health-related quality of life

Nineteen of the 74 patients (25.8%) were diagnosed with PTSD. The incidence of PTSD according to the indication for ICD and ICD shock experience is shown in Fig. 1. No differences in incidence of PTSD were found between patients who received ICD for primary prevention and those who received ICD for secondary prevention (Table 1). Remarkably, of the 21 patients with ICDs for primary prevention who had never experienced ICD shocks, four (21.1%) were diagnosed with PTSD.

Analyses of SDS and STAI-S scores as well as the eight subscales of the SF-36 are shown in Table 2. Compared with the non-PTSD group, the PTSD group had significantly higher SDS and STAI-S scores and significantly lower scores in all eight subscales of the SF-36.

3.3. Risk factors for post-traumatic stress disorder

Table 1 also lists the results of the univariate analysis performed in the first step to identify risk factors for PTSD. Compared

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Characteristics of subjects with or without PTSD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (n=74)</td>
<td>PTSD (n=19)</td>
</tr>
<tr>
<td>Male</td>
<td>63(85.1)</td>
</tr>
<tr>
<td>Age in years</td>
<td>59.3 ± 13.6</td>
</tr>
<tr>
<td>Indication for ICD</td>
<td></td>
</tr>
<tr>
<td>Primary prevention</td>
<td>46(62.2)</td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>28(37.8)</td>
</tr>
<tr>
<td>Underlying heart disease</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>14(18.9)</td>
</tr>
<tr>
<td>Idiopathic dilated cardiomyopathy</td>
<td>14(18.9)</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>11(14.9)</td>
</tr>
<tr>
<td>Arrhythmogenic right ventricular cardiomyopathy</td>
<td>2(2.7)</td>
</tr>
<tr>
<td>Unclassified cardiomyopathy</td>
<td>2(2.8)</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>3(4.1)</td>
</tr>
<tr>
<td>Idiopathic VF/long QT syndrome</td>
<td>22(29.7)</td>
</tr>
<tr>
<td>Others</td>
<td>6(8.1)</td>
</tr>
<tr>
<td>NYHA functional class</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>51(68.9)</td>
</tr>
<tr>
<td>II</td>
<td>22(29.7)</td>
</tr>
<tr>
<td>III</td>
<td>1(1.4)</td>
</tr>
<tr>
<td>Clinical variance</td>
<td></td>
</tr>
<tr>
<td>≥1 ICD shock, total</td>
<td>42(56.8)</td>
</tr>
<tr>
<td>≥1 ICD shock, appropriate</td>
<td>36(48.6)</td>
</tr>
<tr>
<td>≥1 ICD shock, inappropriate, never appropriate</td>
<td>6(8.1)</td>
</tr>
<tr>
<td>Number of shocks (in those receiving shocks)</td>
<td>13.5(21.7)</td>
</tr>
<tr>
<td>≥1 Electrical storm</td>
<td>12(16.2)</td>
</tr>
<tr>
<td>Days since ICD implantation</td>
<td>2471.2 ± 702.5</td>
</tr>
<tr>
<td>Days since last shock</td>
<td>806.4 ± 749.6</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
</tr>
<tr>
<td>β-Blockers</td>
<td>35(47.3)</td>
</tr>
<tr>
<td>ACE inhibitors/ARBs</td>
<td>36(48.6)</td>
</tr>
<tr>
<td>Amiodarone/sotalol</td>
<td>34(37.8)</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>4(5.4)</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>15(20.3)</td>
</tr>
<tr>
<td>Hynontics</td>
<td>10(13.5)</td>
</tr>
<tr>
<td>Not living with family</td>
<td>8(10.8)</td>
</tr>
<tr>
<td>Unemployed/retired</td>
<td>35(47.3)</td>
</tr>
</tbody>
</table>

Values indicate number of patients (%) or the mean ± SD.
ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; PTSD, post-traumatic stress disorder; and VF, ventricular fibrillation.

* Significant and not significant.
with the non-PTSD group, the PTSD group had significantly higher New York Heart Association functional class ($p < 0.028$), more frequent ES ($p < 0.001$), experienced ≥1 appropriate ICD shocks ($p < 0.01$), and more frequent use of antidepressants ($p < 0.05$) and anxiolytics ($p < 0.001$) and according to multiple logistic regression analysis, experiencing ≥1 appropriate ICD shock and anxiolytic use were significant independent risk factors (Table 3). The OR for experiencing ≥1 appropriate ICD shock was 6.0 (95% CI: 1.45–24.63, and $p < 0.013$); that for anxiolytic use was 15.0 (95% CI: 3.38–66.26, and $p < 0.001$).

### 4. Discussion

This cross-sectional study obtained three major findings. First, the incidence of PTSD, estimated by using the modified PCL-S for cardiac arrhythmia or ICD shock, was 25.8% in Japanese patients with ICD. Second, the PTSD was associated with significantly impaired QOL in patients with ICD for both physical and mental subscales. Third, independent risk factors for PTSD were experiencing ≥1 appropriate ICD shock and anxiolytic use. To our knowledge, this is the first study to evaluate PTSD in Japanese patients with ICD.

### 4.1. Incidence of post-traumatic stress disorder in patients with implantable cardioverter defibrillators

Five studies estimated the incidence of PTSD in patients with ICD to be 7.6–26% [13–17]. This variation may be caused by several factors, including PTSD diagnostic procedure and study population characteristics such as underlying disease. In the United States, the underlying diseases in 81% of patients with ICD are ischemic heart diseases such as myocardial infarction or angina pectoris, whereas in Japan, the underlying diseases in patients with ICD are ischemic heart diseases, cardiomyopathies, and idiopathic ventricular fibrillation (arrhythmia) in 34%, 35%, and 19%, respectively [29]. In the present study, 38% of the participants received ICDs for secondary prevention. Of the 28 patients who received ICDs for secondary prevention, five developed PTSD. This finding appears consistent with those of previous studies of patients with ICDs for secondary prevention: 26% in the Living with an Implantable Cardioverter Defibrillator study [13] or 19% at baseline (average of 2 years after implantation) and 12% at final follow-up (5.5 years) in a longitudinal study [15]. As was true of study, Kapa et al. studied patients with ICD with both primary and secondary prevention indications (51% for secondary) [14]. They found that the incidence of PTSD at 2, 6, and 12 months after implantation was 21%, 12%, and 13%, respectively.

The diagnostic procedure for PTSD also affects the apparent incidence of PTSD. It remains controversial whether patients who have received ICDs for primary prevention and have not experienced ICD shocks meet criterion A for a PTSD diagnosis (exposure to a traumatic and life-threatening event) [19]. However, in the present study, 4/21 (19%) of such patients did develop PTSD. Despite the small number of subjects, this finding suggests that even being told that they are at risk of life-threatening arrhythmias and having an ICD implanted may result in the development of PTSD symptoms in some patients. PTSD occurring after receiving diagnoses of other life-threatening diseases such as HIV [30] has been reported.

The gold standard for diagnosing PTSD is a structured clinical interview such as the Clinician-Administered PTSD Scale [31]. However, in all previous studies evaluating PTSD in patients with ICD, self-reporting questionnaires such as the Impact of Events Scale–Revised [13–15,32] or the Post-traumatic Stress Diagnostic Scale [16,17,33] have been used to make a presumptive diagnosis. Although the PCL-S used in this study reflects the DSM-IV symptoms of PTSD, it also provides only a presumptive diagnosis. Further studies using a structured interview procedure for a more accurate PTSD diagnosis are needed.

### 4.2. Factors associated with post-traumatic stress disorder

The following key risk factors for depression or anxiety in patients with ICD have been identified: < 50 years of age, being female, premorbid psychiatric diagnosis, poor social support, and > 5 defibrillations (appropriate or inappropriate) [6]. However, information on the risk factors for PTSD in such patients has been limited.
The effect of ICD shocks on the development of PTSD has been evaluated in five studies [13–17]; their findings are controversial. In three of the five studies, ICD shocks were associated with PTSD diagnoses [14–16]. Kapa et al. found that patients who had experienced ES had significantly higher PTSD scores within 2 months after implantation; however, they reported no difference in PTSD scores between patients who had experienced appropriate ICD shocks and those who had not [14]. Von Kanel et al. found that experiencing at least five ICD shocks (appropriate or inappropriate) was a predictor of PTSD [15]. Versteeg et al. found that ICD shock (appropriate or inappropriate) was the strongest determinant of PTSD at 3 months post-implantation, but was not associated with PTSD at 6 months post-implantation.

The role of inappropriate ICD shocks on the development of PTSD was not evaluated in the five studies mentioned above [13–17]. In the present study, inappropriate ICD shocks were not associated with PTSD. Due to the possibility of various backgrounds being associated with the development of PTSD, a more accurate role of ICD therapy as the cause of PTSD should be evaluated in different study designs, including a control population.

Psychological distress, especially PTSD symptoms, evokes sympathetic nervous system activity, which might be a trigger for a lethal arrhythmia. Although depression has been reported as a predictor for appropriate shocks (subsequent occurrence of lethal arrhythmias) among patients with ICD [34]; such a predictive effect of PTSD remains unknown. In the present study, experiencing ≥1 appropriate ICD shock was associated with PTSD, but a causal relationship cannot be inferred from this cross-sectional study.

In addition, we identified anxiolytic use as an independent risk factor. Versteeg et al. and Habibovic et al. found that baseline anxiety predicts PTSD independently [16,17]. Subjective cardiac symptoms [13] or ICD concerns [16] are reportedly associated with PTSD. It is reasonable to presume that anxiety or perceived sensitivity to cardiac conditions may lead to the subsequent prescription of anxiolytics. First-line standard pharmacologic treatment for PTSD is a selective serotonin reuptake inhibitor (SSRI), not an anxiolytic [35]. Furthermore, non-pharmacologic treatment such as CBT is generally effective for PTSD [36], and may be useful for patients with ICD [37,38]. Although the effect of SSRIs on decreasing ICD intervention is unknown, preliminary studies have reported that a SSRI [39] or SSRI in combination with CBT [40] is associated with reduced ventricular arrhythmia in patients with ICD.

Clinicians need to consider the possibility of PTSD; it is desirable to consult psychiatrists when it is suspected. We have provided examples of how PTSD symptoms may be expressed in patients with ICD according to the description of Sears et al. [6] (Table 4). Formal diagnosis requires that the disturbance (symptoms in criteria B, C, and D) last longer than 1 month and cause clinically significant distress or impairment in social, occupational, or other important areas of functioning [19].

### 4.3. Limitations of this study

This preliminary study has several limitations. First, there were possible design flaws in that it did not enroll consecutive patients, which may have created bias. Moreover, it was retrospective, of cross-sectional design, and involved a single center. Second, we used a modified version of the PCL-S, a self-reporting questionnaire, as a diagnostic tool. As explained in Section 4.1, this tool only provides a presumptive diagnosis. Furthermore, modification of the PCL-S may have influenced its discriminant properties. Third, because the number of subjects in this study was relatively small, subgroup analysis was not feasible. To clarify these issues, we suggest that further prospective clinical investigations, including a control population, must be carried out.

### 5. Conclusions

The present preliminary study shows that PTSD has a significant psychosocial impact with associated impairment of both physical and mental QOL in patients with ICD. In particular, our findings suggest that patients who have experienced appropriate ICD shocks or are taking anxiolytics require psychiatric/psychological intervention.
Conflict of interest

None of the authors has any conflicts of interest to declare.

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