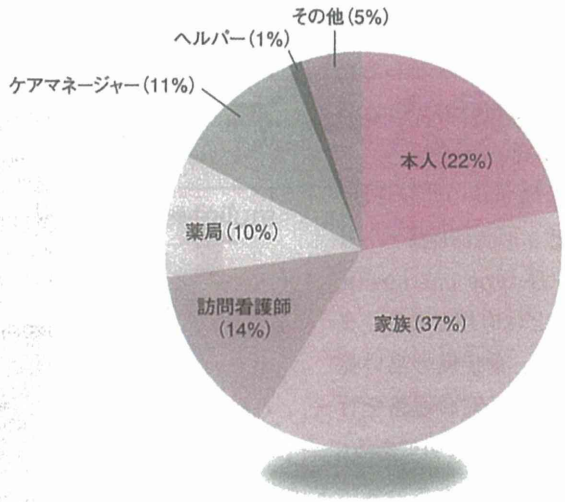

図2 24時間電話通報者の内訳

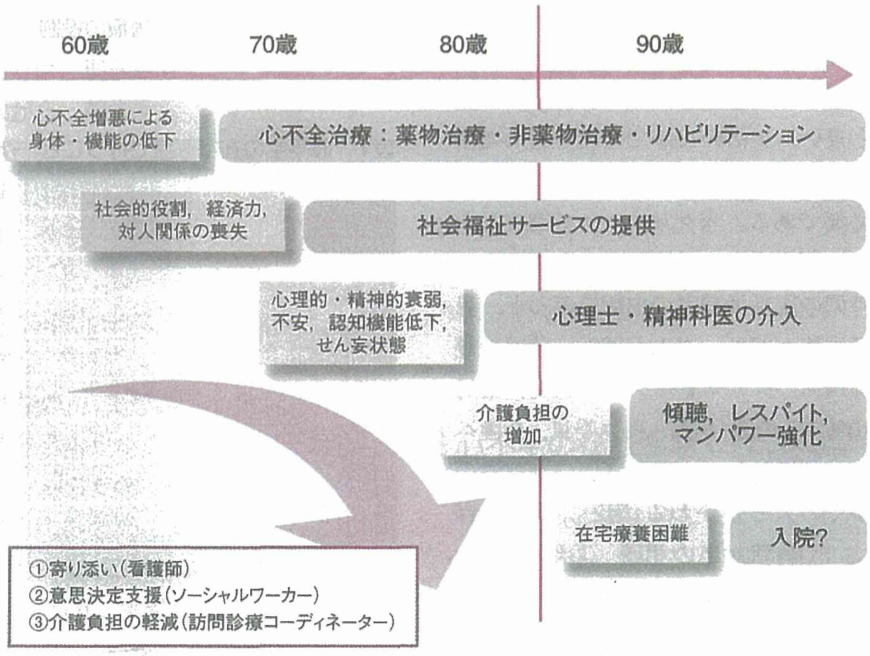

図3 高齢者心不全の在宅療養の典型的な経過(当院在宅ケア患者の平均年齢85歳)

ションの導入が必要となる。また社会的，経済的，対人関係の喪失からも，さまざまな社会福祉サービスの提供を考慮に入れる必要がある。

そして，心不全の悪化とともに，心理的・精神的な衰弱，認知機能が低下，

終末期の患者においては在宅でもせん妄が起きてくる。これらを早い段階で察知し，臨床心理士や精神科医の介入も検討する。また実際そうなると，近親者の介護負担が増加する。在宅療養の継続のためには，介護負担の軽減は大切である。傾聴，レスパイト，マンパワー強化などを考慮に入れる。

このように，心不全の在宅医療の継続には，医師や看護師だけでなく，専門知識を要した多職種でのチームアプローチが重要となる(図3)。

(2)課題

チームアプローチの課題として，多職種間での疾患に対する知識の差が，患者の捉え方に相違を生じさせることがあげられる。在宅ケアにおいては，医療が生活をサポートする介護側に立ち，患者家族にとって何が最善かを協働することが重要である。また多施設，多職種にわたるため，定期的なカンファレンスの開催計画に多くの時間を要する。慢性疾患で病状が変化しやすいのが循環器疾患の特徴である。病期，治療やケア方針など，多職種での意思決定支援を行いながらの，コミュニケーション・情報共有が大切となる。

(3)当施設での取り組み

当施設では，コミュニケーション，情報共有として，以下の取り組みを行っている。

①院内にて週1回の多職種による症例検討カンファレンスを行う

独自の重症度分類(YHC分類：心不全重症度ステージA～Dと介護度1～5を組み合わせたもの)で，重症度の高いところから多職種にて多面的に問題点をあげる。

②診療レポートを作成し，情報共有を行う

訪問診療のたびに，診療レポートを作成し，患者宅に保管してある在宅診療ファイルへ挟み，診療に同席できなかった家族，かかわる職種へ情報共有を行う。

③Medical Care Station

医療介護現場の情報共有・連携に対応できる完全非公開型の医療介護専用SNS。LINE形式のタイムラインにて「見る」「つぶやく」だけのシンプルな操作。

④地域での定期的な勉強会の開催を行う

心不全治療における最新の知見や総合病院から在宅ケアまでの症例検討を行い，多職種間で情報共有・意見交換を行う。

心不全の在宅管理の実際

症例(チーム医療，情報共有ツール)

70歳女性，夫と長女と3人暮らし。慢性心不全，修正大血管転位，心房中隔欠損，心室中隔欠損，恒久的ペースメーカ植え込み術後の患者。30年前よりB大学病院で入退院を繰り返している。平成25年度は病院で過ごす日のほうが長い状態であり，自宅が病院と考えられていた。

平成26年1月退院後より当施設からの在宅訪問診療が導入となった。リビングウィルでは心不全増悪時の救急対応は病院，また最期は病院を希望していた。在宅療養にて，軽度の呼吸苦や腹部膨満感の増悪を認め，それに伴い不安，夜間せん妄が出現し始める。そして大学病院への再入院希望を訴えるものの，明らかな心不全増悪傾向がないため，C.C.C(用語解説)を発令。これと同時に多職種での情報共有のため，Medical Care Station，e-Heart Home Care Monitoring System(用語解説)を導入した。

用語解説

C.C.C(Choco Choco Care)
在宅療養をサポートする医療と介護者が総動員となり，「ちょこちょこ」と患者宅へ頻回に顔を出し，患者だけでなく家族の身体的・精神的ケアを行うこと。

e-Heart Home Care Monitoring System
当施設と日本光電社の共同開発。1枚のワイヤレス心電図パッチを胸に貼り自宅内歩行は可能とし，在宅内ではそのデータを患者・家族がみられる心電図モニターで表示配備，そしてその心電図モニター生波形(および呼吸波形，血圧，酸素飽和度も測定可能)をクリニック内のセントラルモニターおよび医療・介護に携わる関係者のモバイル機器でタイムリーに観察可能となる。

また当院精神科医との協働により，表2のように薬剤変更および追加投与を行い，さらに訪問看護，介護ヘルパーの連日訪問を行い，心不全とせん妄状態の軽快傾向を認める。それとともに，患者のリビングウィル意思決定の変更を認め，在宅での最期を希望するようになる。

今後の課題

これまで，心不全は総合病院や大学病院を中心に診られてきた。高齢，難治性心不全患者が増加する心不全医療は，実際の生活をみて，個々の症例の生き方に寄り添いながら，医療を提供することが必要となる時代となっている。

今後の課題として，①末期・終末期心不全の定義，②オピオイド類の保険承認，心不全治療薬や輸液ポンプの使用拡大に伴う末期心不全の在宅ケアへの診療報酬拡大がある。

最後に，心不全の在宅医療は，看取り医療ではなく，多職種でのチームアプローチにより，患者・家族の生活の質の維持のため，心不全の再入院を抑える積極的医療であることを強調したい。

表2　当院精神科医との協働による薬剤変更および追加投与

訪問診療導入時	追加治療および変更
カンデサルタン1.5mg	在宅酸素療法(HOT)
ビソプロロール1.25mg	カンデサルタン，ビソプロロール，トルバプタム，ジゴキシン，アミオダロン継続
フロセミド80mg	フロセミド60mg
トルバプタム15mg	スピロノラクトン25mg
ジゴキシン0.625mg	トリクロメチアジド1mg
アミオダロン100mg	ピモベンダン1.25mg
	オキシコドン10mg
	頓服：オキノーム散，セニラン坐薬

● シンポジウム：高齢者心不全の治療戦略

S-4. 高齢者心不全の在宅医療

弓野　大[*1]

Ⅰ. 心不全在宅管理の役割

近年の循環器医療の発展に伴い，心不全患者の生命予後が延びている。しかしながらその反面，末期心不全患者が増加し，すでに確立された心不全治療だけでは生活の質を維持することが困難である。また本邦では急性期病院の役割の明確化，また在院日数の短縮からも，高齢者心不全の再入院をいかに予防し，また長期入院から在宅への移行が課題となっている。これらを実現するため，いま「心不全の在宅医療」が必要である。心不全の在宅医療・ケアの役割は，①長期入院から早い段階での在宅管理　②再入院の予防・ケア，③急性増悪時の治療，そして④在宅での看取りと考える。これにより，急性期病院の役割の明確化，心不全患者の可能な限りの在宅での生活が可能となる（図 1）。

Ⅱ. 当クリニックについて

東京・高田馬場にある当クリニックは，2012 年 9 月の開院から，外来から在宅まで多職種心不全クリニックをめざし，医師（循環器専門医，精神神経科専門医，リハビリテーション専門医など），看護師，ソーシャルワーカー，検査技師，栄養士，訪問診療コーディネーターらがひとつのチームとなり，心不全の付加的治療から往診・訪問診療を行っている。とくに往診・訪問診療に関しては，約 70％が心不全症例となっており，「救急車出動を減らす」をひとつのビジョンとして，緊急往診を行い，多職種協働で在宅療養をサポートしている。

Ⅲ. 心不全の在宅医療で行うこと

生活の質を保つために心不全の在宅医療において，当クリニックで行っている 10 項目をあげる（表 1）。

高齢者心不全は長期入院から在宅へ戻ることにより，気持ちと身体機能のギャップを認め，塩分過多や過労などにより，早い段階で容易に心不全の再増悪をきたす症例が少なくない。このため，退院後 2 週間は厳格な管理を必要である。また在宅には多施設・多職種の医療・介護関係者がかかわるため，心不全の病状を情報共有できる簡易な指標が必要である。たとえば，a）心不全増悪時の初発症状　b）至適体重の設定　c）血清 BNP 値などは有用となる。また週末や連休前には，重症度の高い症例，不安定な症例には，電話連絡を行い，予後予測を行うことも大切である。

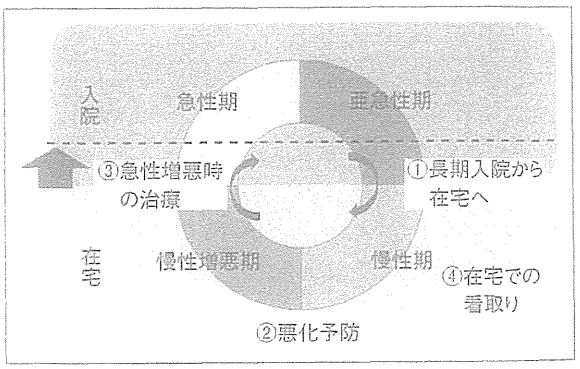

図 1　心不全患者の在宅医療の役割

Key words：高齢者，心不全，在宅医療
[*1] ゆみのハートクリニック
ICU と CCU 38：S34 ～ 35，2014

表1　心不全の在宅ケアで行うこと
—ゆみのハートクリニックの10項目—

1. 退院後の早めのフォロー	(退院前調整，退院日，1週間後，2週間後)
2. チーム医療の確立	(必要な職種の提案，情報共有)
3. 患者教育	(内服管理，生活活動制限，塩分食事制限)
4. 増悪要因を抑える	(全身要因，生活要因，薬物要因を抑える)
5. 心不全増悪を察知	(至適体重やBNP，増悪時の症状の共有)
6. 適切な薬物治療の導入，調整	(利尿薬，RAS系，β遮断薬)
7. リハビリテーション	(嚥下障害，サルコペニア)
8. 電話サポート	(週末や連休の準備)
9. 介護者のメンタルケア	(傾聴，予後通知，マンパワー強化，レスパイト)
10. 終末期の緩和ケア	(アドバンスディレクティブ，オピオイド類適応)

Ⅳ. 今後の課題

これまで心不全は総合病院や大学病院を中心に診られてきた。しかし，高齢，難治性心不全患者が増加する心不全医療は，実際の生活をみて，個々の症例の生き方に寄り添いながら，医療を提供することが必要となる時代となる。今後の課題として，1）末期・終末期心不全の定義　2）オピオイド類，心不全点滴治療薬の保険承認や輸液ポンプの使用拡大に伴う末期心不全の在宅ケアへの診療報酬加算などが必要となる。最後に，重症心不全の在宅医療は看取り医療ではなく，患者・家族の生活の質の維持のため，心不全の増悪，繰り返すことを予防する積極的医療であることを強調する。

Journal of Arrhythmia 30 (2014) 105–110

Contents lists available at ScienceDirect

Journal of Arrhythmia

journal homepage: www.elsevier.com/locate/joa

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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ARTICLE INFO

Article history:
Received 24 April 2013
Received in revised form
2 July 2013
Accepted 11 July 2013
Available online 14 September 2013

Keywords:
Implantable cardioverter defibrillator
Post-traumatic stress disorder
Psychological distress
Trauma

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.

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

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http://dx.doi.org/10.1016/j.joa.2013.07.004

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 that could lead to sudden cardiac death (i.e., ICD implantation for primary prevention) 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 rumination 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 cardiological 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 indications 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 χ^2 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 1
Characteristics of subjects with or without PTSD.

	Overall ($n=74$)	PTSD ($n=19$)	No PTSD ($n=55$)	p
Male	63(85.1)	18(94.7)	45(81.8)	0.16
Age in years	59.3 ± 13.6	61.3 ± 11.8	58.6 ± 14.2	0.47
Indication for ICD				
Primary prevention	46(62.2)	14(73.7)	32(58.2)	
Secondary prevention	28(37.8)	5(26.3)	23(41.8)	0.18
Underlying heart disease				
Coronary artery disease	14(18.9)	4(21.1)	10(18.2)	
Idiopathic dilated cardiomyopathy	14(18.9)	5(26.3)	9(16.4)	
Hypertrophic cardiomyopathy	11(14.9)	4(21.1)	7(12.7)	
Arrhythmogenic right ventricular cardiomyopathy	2(2.7)	0(0.0)	2(3.6)	
Unclassified cardiomyopathy	2(2.8)	1(5.3)	1(1.8)	
Valvular heart disease	3(4.1)	2(10.5)	1(1.8)	
Idiopathic VF/long QT syndrome	22(29.7)	3(15.8)	19(34.5)	
Others	6(8.1)	0(0.0)	6(10.9)	0.28
NYHA functional class				
I	51(68.9)	10(52.6)	41(74.5)	
II	22(29.7)	8(42.1)	14(25.5)	
III	1(1.4)	1(5.3)	0(0.0)	0.03
Clinical variance				
≥1 ICD shock, total*	42(56.8)	14(73.7)	28(50.9)	0.07
≥1 ICD shock, appropriate	36(48.6)	14(73.7)	22(40.0)	0.01
≥1 ICD shock, inappropriate, never appropriate	6(8.1)	0(0.0)	6(10.9)	0.33
Number of shocks (in those receiving shocks)	13.5(21.7)	12.3(22.2)	6.1(15.6)	0.13
≥1 Electrical storm	12(16.2)	8(42.1)	4(7.2)	0.00
Days since ICD implantation	2471.2 ± 702.5	2519 ± 727.5	2454 ± 699.6	0.73
Days since last shock		806.4 ± 749.6	1226 ± 1018.3	0.18
Medications				
β-Blockers	35(47.3)	10(52.6)	25(45.5)	0.39
ACE inhibitors/ARBs	36(48.6)	9(47.4)	27(49.1)	0.56
Amiodarone/sotalol	34(37.8)	11(57.9)	23(41.8)	0.17
Antidepressants	4(5.4)	3(15.8)	1(1.8)	0.05
Anxiolytics	15(20.3)	10(52.6)	5(9.1)	0.00
Hypnotics	10(13.5)	5(26.3)	5(9.1)	0.07
Not living with family	8(10.8)	3(15.8)	5(9.1)	0.33
Unemployed/retired	35(47.3)	13(68.4)	22(40.0)	0.09

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

* Appropriate and inappropriate shocks.

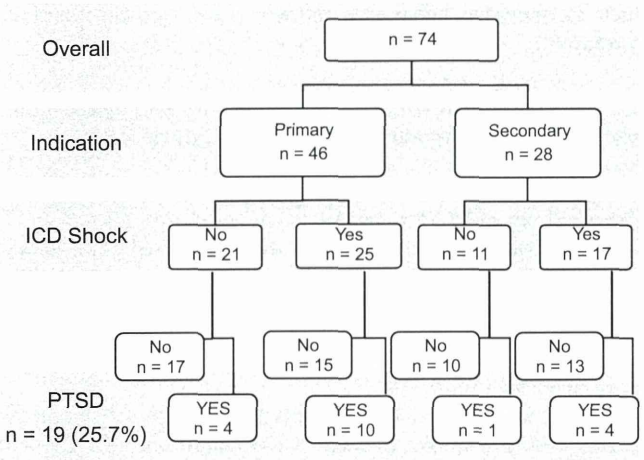

Fig. 1. The prevalence of PTSD according to indications for ICD and ICD shock experience. ICD, implantable cardioverter defibrillator and PTSD, post-traumatic stress disorder.

Table 2
Scores for psychological distress and health-related QOL with and without PTSD.

	Overall (n=74)	PTSD (n=19)	No PTSD (n=55)	t	p
SDS	39.7 ± 10.4	48.5 ± 8.4	36.3 ± 9.1	5.05	0.00
STAI-state	41.6 ± 12.7	49.1 ± 14.0	39.0 ± 11.2	3.17	0.00
SF-36					
Physical functioning	71.5 ± 22.3	61.9 ± 17.5	74.6 ± 22.9	−2.15	0.04
Role physical	73.5 ± 27.2	57.0 ± 28.8	79.1 ± 24.5	−3.17	0.00
Bodily pain	74.9 ± 25.0	65.8 ± 22.7	77.9 ± 25.2	−1.81	0.08
General health	46.5 ± 19.0	32.4 ± 15.2	51.1 ± 17.9	−3.98	0.00
Vitality	58.9 ± 19.8	47.4 ± 16.3	62.4 ± 19.5	−2.86	0.01
Social functioning	71.1 ± 27.0	52.1 ± 28.8	77.3 ± 23.5	−3.73	0.00
Role emotional	74.6 ± 26.6	56.9 ± 26.4	80.8 ± 24.1	−3.53	0.00
Mental health	70.7 ± 21.3	52.2 ± 18.0	76.7 ± 18.6	−4.85	0.00

PTSD, post-traumatic stress disorder; SDS, Zung Self-Rating Depression Scale; SF-36, Medical Outcomes Study 36-item Short-Form; and STAI, State-Trait Anxiety Inventory.

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 ($p < 0.0001$). 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.

Table 3
Logistic regression analysis of risk factors for PTSD.

Variable	B	p	Odds ratio	95% Confidence interval
Anxiolytic use	2.706	0.013	14.98	3.38–66.26
≥1 appropriate ICD shock	1.787	0.000	5.97	1.45–24.63

−2 log likelihood = 62.092; $\chi^2 = 22.214$ ($p < 0.0001$); and Nagelkerke $R^2 = 0.381$.
PTSD, Post-traumatic stress disorder and ICD, implantable cardioverter defibrillator.

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 Implanted 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 our 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.

Table 4
PTSD symptom clusters and presentation in patients with ICD[c].

Criterion A (exposure): All
- Cardiac event, SCA[a], ICD[b] implantation, shock, or electrical storm is perceived as deadly or threatening
- There is a perception of fear, helplessness, or horror

Criterion B (persistent re-experiencing): ≥1
- Recalling the cardiac event repeatedly
- Dreaming about getting shocked
- Truly believing or feeling shock is recurring (e.g., phantom shock)
- Exposure to cues that remind them of the event (e.g., couch they were on when shocked) creates psychological distress
- Exposure to cues that remind them of the event (e.g. heart racing) causes the body to react

Criterion C (persistent avoidance): ≥3
- Avoiding discussion of the event (this may include avoidance of an office visit or repeated no-shows)
- Cannot remember the event (e.g., SCA or shock)
- Avoidance of engagement in activities because of fear of shock
- Feeling estranged from family or friends following cardiac trauma
- Restricted range of affect (inability to express a range of emotions) following SCA or shock
- Belief that shock is an indicator of cardiac health and foreshortened future

Criterion D (increased arousal): ≥2
- Following cardiac trauma (e.g., surgery, SCA, shock, electrical storm)
  - Trouble falling or staying asleep
  - More irritable and angry
  - Difficulty concentrating
  - Exaggerated startle response
- Hyper-vigilant: preoccupied with heart rate, gastrointestinal and chest pain, and other bodily sensations

[a] SCA, sudden cardiac arrest.
[b] ICD, implantable cardioverter-defibrillator.
[c] Modified from Sears et al. [6].

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.