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Psychological correlates, allostatic overload and clinical course in patients with implantable cardioverter defibrillator (ICD)

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ABSTRACT

Background: Implantable cardioverter defibrillator (ICD) is a key treatment option for both primary and secondary prevention of sudden cardiac death. Despite this, there is a growing number of studies showing that ICD is often associated with post-implantation deleterious psychosocial effects, even in the absence of medical complications. Knowledge about the predictive role of pre-ICD psychological profile is scant. The present research aims to describe patients' pre-ICD psychological profile, focusing on acute and chronic distress, such as anxiety, depression, type D personality, psychosomatic syndromes and allostatic overload (AO), and to evaluate if these psychological variables could affect ICD outcomes and survival.

Methods: 117 consecutive patients (74.4% males; mean age = 63.1 ± 13.7 years) underwent psychological assessment prior to ICD implantation. Data on ICD-related complications and death were collected up to 26 months after the intervention.

Results: At baseline, 36.8% of the sample had anxiety and 17.9% depression. Among psychosomatic syndromes, psychological factors affecting medical conditions were the most frequent (37.6%). 12.8% presented with type D personality, whereas 16.2% showed moderate AO and 4.3% severe AO. 25.6% of the patients had post-ICD complications and 6% died. Severe AO was the only predictor of survival.

Conclusion: Our findings show that a reliable evaluation of stress and the inability to cope with it (allostatic overload) may help to identify patients at higher risk of post-ICD complications and death. Such sensitive index, more than traditional psychiatric diagnostic criteria, may help the physician to identify easily manifestations of distress and clinically relevant information, which could affect medical illness outcomes.

1. Introduction

Implantable cardioverter defibrillator (ICD) has emerged as an important treatment option for patients who are at risk of sudden cardiac death (SCD) [1]. Randomized trials have consistently shown that ICD implantation decreases mortality in patients with heart failure and reduced left ventricular function, as well as patients who have suffered a cardiac arrest [2,3]. Recent guidelines recommend ICD for both primary and secondary prevention of SCD [4,5]. Primary prevention consists in reducing total mortality of patients with non-ischemic dilated cardiomyopathy or ischemic heart disease at least 40 days post-myocardial infarction, with left ventricular ejection fraction (LVEF) of 35% or less, NYHA Class II or III symptoms, on chronic guideline-directed medical therapy, who have reasonable expectation of meaningful survival for more than 1 year [5]. Secondary prevention by means of ICD is indicated before discharge of patients who survive sustained ventricular tachycardia or fibrillation, provided that arrhythmia is not due to transient or reversible ischemia, re-infarction, or metabolic abnormalities [4].

Although the implantation is quite simple, medical complications such as bleeding, infection, pneumothorax, cardiac perforation, lead dislodgement, and death, have to be taken into account [6]. Among long term unwanted events, inappropriate shocks occur nowadays in 2 up to 6% ICD patients [7,8]. ICD implantation is often associated with deleterious psychosocial effects, with about 50% of recipients reporting elevated levels of anxiety and depression resulting from the fear of ICD discharge and device failure, decrease in physical activity, and negative lifestyle changes (such as the inability to drive or return to work) [9]. In addition, some patients develop severe psychiatric problems, such as post-traumatic stress disorder (PTSD), after receiving inappropriate

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shocks [10]. However, even in absence of medical complications and inappropriate shocks experience, 25–33% of ICD patients report psychological problems following ICD implantation [11]. For these reasons, most of research have focused on psychological problems risen after ICD implantation. The difficulties in adaptation for both these patients and their families [12] resulted in an increasing need to address psychological distress [13,14].

Studies on the role of a previous history of psychiatric disorders are rare. Pedersen et al. [11] found that pre-ICD psychological impairments, such as specific personality traits, rather than ICD-related complications, could be strongly associated with post-ICD emotional distress, such as anxiety. It has been found that a positive history of depression predicts poor health status, such as impaired health-related quality of life [15,16]. The manifestation of psychological distress such as anxiety and depression prior to ICD implantation may be independent or attributed to a combination of factors, including fear for ICD implantation or the underlying heart disease [17–19]. Several studies also found high rates of type D personality in pre-ICD patients [20,21] associated with the risk for developing adverse health outcomes [22,23]. Thus, as highlighted by Pedersen and colleagues [24], the identification and treatment of subgroups of patients with stable high emotional distress levels is necessary, since chronic emotional distress and impaired health status may precipitate ventricular arrhythmias and mortality in patients with ICD. Recent studies performed in medical settings have focused on the importance to detect allostatic overload (AO), which occurs when cumulative interactions of life events and chronic stressors exceed individual resources [25,26]. In cardiology, it discriminated patients at high risk for psychological distress [27,28]. No studies, however, have been conducted among ICD patients.

Other research revealed that psychosomatic syndromes, evaluated by Diagnostic Criteria for Psychosomatic Research-DCPR [29,30], are strictly associated to cardiac diseases [27,30]. To our knowledge, only a small study [31] assessed DCPR syndromes among patients with ICD.

Only few studies have examined the role of baseline psychological characteristics such as anxiety [31], type D personality and self-reported health-related quality of life [10,24,32,33] as risk factors for ventricular arrhythmias and death in ICD patients.

The present study aims to describe the baseline psychological and psychosomatic profile of patients undergoing the implantation of ICD, focusing on acute and chronic distress, and evaluate if these psychological variables could affect the clinical course of ICD patients. Specifically, the goal and novelty of this study is to verify if pre-existing psychological correlates could predict ICD outcomes and survival.

2. Methods

2.1. Sample

The study includes a sample of 117 consecutive patients (74.4% males; mean age = 63.1 ± 13.7 years, range from 26 to 86 years) undergoing ICD implantation from July 2012 to November 2015 at the Department of Cardiology of the Policlinico S. Orsola-Malpighi, Bologna. Patients underwent the psychological assessment before the intervention and at multiple follow-up, up to 24 months after the implantation. Written informed consent was obtained from all the participants. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in *a priori* approval by the Local Ethic Committee.

2.2. Assessment

2.2.1. Anxiety and depression

Structured Clinical Interview for DSM-IV-TR Disorders (SCID) [34,35], Axis I, was administered in order to identify anxiety and depressive diagnoses. SCID is an excellent tool that meets the needs of both clinician and investigator. The SCID can be applied to any person thanks to his easy understanding, except to people with severe cognitive impairment. Time of administration varies from 45 to 90 min, depending on the complexity of patient medical history and psychological status.

2.2.2. Psychosomatic syndromes

The Diagnostic Criteria for Psychosomatic Research (DCPR) [29,30] integrate somatic disorders with the DSM-IV and International Classification of Disease (ICD-10) in a multiaxial approach. The basic idea of this new classification system is to think in terms of psychosomatic syndromes, highlighting the variety of somatic and mental responses that individuals may have produced in various circumstances during life [36]. The DCPR allows translating into operational tools psychosocial variables resulting from psychosomatic research. According to the psychosomatic approach, patient condition must be considered holistically, as the psychological factors and the biological components interact during an organic disorder, affecting its course and the psychological response of the subject [37]. Twelve psychosomatic syndromes were operationalized with a specific diagnostic criterion, and divided into three clusters: "abnormal illness behavior" (nosophobia, thanatophobia, health anxiety, illness denial), "psychological factors affecting medical conditions" (alexithymia, type A behavior, irritable mood, demoralization), and "somatization" (functional somatic symptoms secondary to a psychiatric disorder, persistent somatization, conversion, reaction to anniversaries). The DCPR is an observer rated, semi-structured interview with closed questions, and dichotomous yes or no answers, referring to the last twelve months. The instrument showed good psychometric properties [38].

2.2.3. Type D personality

Type D personality is measured by 14-item Type D Scale (DS-14) [39]. The scale consists in 14 items, divided into two scales (7 items each): negative affectivity and social inhibition. The answers are on a 5-point *Likert* scale, ranging from 0 (false) to 4 (true). Both scales have a cut-off value ≥10, beyond which the presence of type D personality can be assumed.

2.2.4. Sub-clinical symptoms of psychological distress

Symptom Questionnaire (SQ) [40] is a self-report measure, based on the Symptom Rating Test by Kellner and Sheffield [41]. It consists of 92 dichotomous (yes/no, true/false) items that make the instrument easy to understand and fulfill (those are important features when the questionnaire is administered to people with poor verbal skills). The questionnaire consists in four scales (depression, anxiety, anger-hostility and somatic symptom) and the scoring is calculated by assigning one point for each positive response. The maximum score is 23 and higher scores indicate higher psychological distress; if the score exceeds one or two standard deviations (SD) from the average of general population, the distress is being considered as moderate, but if it exceeds two SD the presence of severe psychological distress can be assumed [40]. Due to its sensitivity, SQ proved to be a highly effective instrument in predicting the change in psychological and psychosomatic issues.

2.2.5. Psychological well-being

The Psychological Well-Being scale (PWB), short version (42 items), measures the presence of psychological well-being [42]. PWB is a self-rating and multidimensional questionnaire, which includes the six domains of Ryff's psychological well-being model: autonomy, environmental mastery, personal growth, positive relations with others, purpose in life and self-acceptance [43]. The higher the score, the higher psychological well-being is. Patients must indicate their level of agreement or disagreement with the items using a 7-point *Likert* scale, ranging from 0 ("not my case") to 6 ("that is exactly my case").

2.2.6. Health-related quality of life

The 36-item Short Form Health Survey (SF-36) [44] is a self-rated test, accurate and fast to be administered. Usually, it is used for medical population and it is very sensible in valuating health status changes [45]. The 36 questions refer to eight subscales: physical activity (10 items), role limitations due to physical health (4 items), role limitations due to emotional problems (3 items), physical pain (2 items), perception of general health status (5 items), vitality (4 items), social activities (2 items), mental health (5 items), and a single question about the change in health status. The different dimensions are included in three main domains: physical quality of life, mental quality of life, overall quality of life. All SF-36 questions are referred to the four weeks prior the assessment, except for the question about the change of the health status, which considers the last year. The test includes both dichotomous (yes/no) and on a *Likert* scale answers.

2.2.7. Allostatic overload

The operationalization of the concept of allostatic overload is based on specific clinimetric criteria developed by Fava and colleagues [26]. Since the assessment of life events by a detailed interview method, such as the Interview for Recent Life Events [46] is unlikely to be endorsed in practice, even if certainly the gold standard, the Psychosocial Index (PSI) [47] has been chosen as a reliable compromise. PSI is a short clinimetric index, tailored to a busy clinical setting, for the assessment of stress and related psychological distress (allostatic load). It offers a synthesis of previously validated instruments: the Screening List for Psychosocial Problems [48], the Stress Profile [49], the Psychological Well-Being scales [50,51] and the Illness Attitude Scales [52]. All this information may help formulate a global clinical judgment of an individual's assets and coping skills in dealing with his/her current life situation. AO Criterion A requires the presence and identifiable stressor, either as a recent life event or as prolonged exposure; the stressor must be judged as exceeding or taxing the individual's coping skills when evaluated. The presence of an acute or chronic stressor was established on patient's reporting of at least one chronic stressor or life event comprised in the Psychosocial Index [47] stress subscale, as assessed by items 32–40 and 47–54. The perceived feeling of inability to cope proficiently with the situation was identified through at least one positive answer to items 43 and/or 44. Both conditions were deemed necessary to satisfy criterion A requirements. Criterion B requires the stressor to be associated with at least 1 manifestation among psychiatric symptoms (B1), psychosomatic symptoms (B2), impaired functioning (B3) or compromised well-being (B4). Furthermore, the manifestations must occur within 6 months after the onset