



Optimism as predictor of patient-reported outcomes in patients with an implantable cardioverter defibrillator (data from the WEBCARE study)

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ABSTRACT

Objective: The implantable cardioverter defibrillator (ICD) is the treatment of choice for prevention of sudden cardiac death. However, a subgroup of ICD patients experiences psychological adjustment problems post implant. To date, positive psychological constructs (e.g. optimism) have been understudied in this population. Hence, we examined the association between optimism and anxiety, depression, and health status at 12-months post implant.

Methods: Patients (N = 171) enrolled in the WEB-based distress management study for ICD patients were included in the analyses. Optimism and pessimism (LOT), and Type D personality (DS14) were administered at baseline, while anxiety (GAD-7), depression (PHQ-9), and health status (SF-12) were assessed at 12-months.

Results: The mean age was 59.6 ± 10.06 with 81% being male. After controlling for demographic, personality, and clinical variables, baseline optimism was associated with lower anxiety ($\beta = -0.210$; $p = 0.011$) and depression ($\beta = -0.222$; $p = 0.005$), and better physical ($\beta = 0.227$; $p = 0.004$) and mental health status ($\beta = 0.350$; $p = 0.000$) at follow-up. Optimism was also associated with change in mental health status ($\beta = 0.195$; $p = 0.007$) but not with change in anxiety, depression, and physical health status at follow-up.

Conclusions: Our findings indicate that optimism is associated with less distress and possibly helps safeguard mental health in ICD patients. Increase optimism might be the way forward to reduce long-term distress and impaired health status.

Trial registration: <http://www.ClinicalTrials.gov>. Identifier: NCT00895700

1. Introduction

The implantable cardioverter defibrillator (ICD) is the treatment of choice for patients who have experienced a sudden cardiac arrest (secondary prevention) or who are at increased risk of experiencing one in the future (primary prevention) [1]. In case of potentially life-threatening cardiac arrhythmias, the ICD is able to deliver an electric shock to the heart muscle and prevent sudden cardiac arrest [1]. Although the majority of ICD patients adapt well to living with an ICD, a subgroup experiences adjustment problems, which are largely unrecognized and untreated [2]. Approximately 25%–33% of patients experience distress (e.g. anxiety and depression) and decreased quality of life (QoL) [3,4] which, in turn, are associated with (long-term) adverse outcomes, including arrhythmias and mortality [5,6]. Hence, it is of great importance to identify patients who are at risk of developing adjustment problems in order to optimize their care.

An increasing number of studies have focused on identifying risk factors for distress and impaired QoL in ICD patients. These findings have shown that younger age [7], frequent shocks [4], Type D personality [8], heart failure [9], negative treatment expectations [10], poor understanding of their medical condition [4], and diabetes [11] are associated with increased risk of distress and/or impaired QoL post ICD implant. While the majority of the studies focused on negative correlates (e.g. patients' weaknesses), a paucity of studies have focused on patients' strengths (e.g. optimism) and their possible protective association with patient reported outcomes.

Optimistic people are characterized by their (overall) positive expectancy about future outcomes, pessimists, on the other hand, generally hold a more negative expectancy about the future [12]. Whether a person is an optimist or pessimist highly affects the way he/she copes with difficulties in life, with optimists adapting generally more effective coping strategies [13]. Optimism has shown to be associated with both

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psychological and physical well-being in the general population [14] and in patients with chronic diseases [15,16]. Within the cardiac population, optimism has been associated with rate of recovery after cardiac surgery [17], adherence to cardiac health-related behaviors [18,19], less re-hospitalizations [20,21], and even decreased risk of mortality [22].

Despite the observed association between optimism and better (mental) health in other populations, optimism and its potentially protective effect in ICD patients has received little attention. One small-scale study of 88 ICD patients found a positive association between optimism and QoL [15,23]. Others reported that optimism is the most frequently used and most effective coping strategy among ICD patients [24]. To our knowledge, no studies have focused on the association between optimism and long-term outcomes in ICD patients. Hence, in the current study, we examined whether baseline optimism is associated with patient-reported anxiety, depression, and health status 12-months post implant.

2. Methods

2.1. Study design

For the current study, we used data from the WEB-based distress management programme for implantable CARDioverter dEFibrillator patients (WEBCARE) trial [NCT00895700]. A detailed description of the trial and the primary results have been published elsewhere [25,26]. Briefly, WEBCARE was a randomized controlled trial evaluating the effectiveness of an online behavioral intervention aiming to reduce distress and increase quality of life in patients with an ICD. Patients were assessed at baseline, 3-, 6-, and 12-months post ICD implant. The intervention was not superior to usual case, neither with respect to primary nor secondary outcomes [26]. For the current study, baseline and 12 months follow-up data were used.

2.2. Participants

Patients (N = 171), who were admitted for a first-time ICD implant, were included between April 2010 and February 2013 at 6 Dutch referral hospitals (Amphia Hospital, Breda; Canisius-Wilhelmina Hospital, Nijmegen; Catharina Hospital, Eindhoven; Erasmus Medical Center, Rotterdam; Onze Lieve Vrouwe Gasthuis Hospital, Amsterdam; Vlietland Hospital, Schiedam) as part of the WEBCARE trial. All patients who had a first-time ICD implant, were 18–75 years, had adequate Internet/computer skills, and had sufficient knowledge of the Dutch language were eligible to participate. Patients who had significant cognitive impairments (e.g. dementia), history of psychiatric illness other than affective/anxiety disorders, life-threatening co-morbidities (e.g. cancer), a life expectancy < 1 year, or were on the waiting list for heart transplantation were excluded.

2.3. Study procedure

Prior to or briefly after ICD implantation patients were approached for participation. The ICD nurse or technician provided the patient with study information both orally and in writing. Patients who fulfilled all of the inclusion criteria and none of the exclusion criteria, and who were willing to participate, signed the informed consent form and were asked to complete the baseline questionnaires. Patients were instructed to complete the questionnaires within 10 days after ICD implantation and return them in a pre-stamped envelope to Tilburg University. If the questionnaires were not returned within 2 weeks, patients received up to 3 reminder phone calls. Baseline information on clinical characteristics was obtained from patients' medical records at the participating hospitals.

For follow-up assessment, patients received a set of questionnaires per mail and were again instructed to fill them in within 1 week and

send them back to Tilburg University. If the questionnaires were not received within 2 weeks, patients received up to 3 reminder phone calls.

All patients provided written informed consent. The study was conducted in accordance with the Helsinki declaration and approved by the Medical Ethics Committee of the participating hospitals.

2.4. Measures

Data on demographic and clinical variables, Type D personality, optimism and pessimism were collected at baseline. Data on anxiety, depression, and health status were obtained at baseline and 12-months follow-up.

2.4.1. Demographic and clinical variables

Information on demographic (age, gender, working status, marital status, education level) and clinical data (New York Heart Association (NYHA) functional class, ICD indication, Charlson Comorbidity Index, medication) were obtained from patients' medical records and baseline questionnaires.

2.4.2. Optimism and pessimism

Optimism was assessed using the Dutch version of the Life Orientation Test (LOT) [27]. The LOT questionnaire contains 12 items of which 4 items tap into the construct of optimism (e.g. *In uncertain times, I usually expect the best*) and 4 items into the construct of pessimism (e.g. *I hardly ever expect things to go my way*). The 4 remaining items are referred to as 'filler items' and are not part of the sum scores. Items are answered on a 5-point Likert scale ranging from 0 (*very much disagree*) to 4 (*very much agree*). The 'pessimism' questions are reverse scored and the total scale sum score ranges between 0 and 32 with higher scores indicating higher optimism. The LOT has previously been used also assess optimism and pessimism separately. The total scores of the sub scales range between 0 and 16, with a higher score indicating higher levels of the respective trait.

2.4.3. Anxiety

Symptoms of anxiety were assessed with the Generalized Anxiety Disorder scale (GAD-7) [28]. The GAD-7 is a 7-item questionnaire assessing anxiety symptoms (e.g. *Feeling nervous, anxious or on the edge*) on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*almost every day*) [28]. The total score ranges between 0 and 21 with a higher score indicating higher anxiety levels.

2.4.4. Depression

Symptoms of depression were assessed with the Patient Health Questionnaire (PHQ-9) [29]. The PHQ-9 is a 9-item self-report questionnaire that taps into the 9 diagnostic criteria for DSM-IV depressive disorder (e.g. *Having little interest or pleasure in doing things*) [29]. Items are evaluated on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*almost every day*). The total score can range between 0 and 27, with higher scores indicating higher levels of depression symptomatology. The PHQ-9 was recently validated in the DEFIB-Women cohort, which was a large nationwide study of patients with a first-time ICD, focusing on gender differences in patient-reported and clinical outcomes [30].

2.4.5. Health status

Patients' physical and mental health status was assessed with the Short-Form Health Survey 12 (SF-12) [31]. Via an algorithm items on the SF-12 can be converted into a Physical Component Summary score (PCS) and Mental Component Summary score (MCS) with a score range from 0 to 100, with higher scores indicating better health status.

2.4.6. Type D (distressed) personality

We used the Type D Scale (DS14) to measure Type D personality [32]. The DS14 consists of two 7-item subscales measuring Negative

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