

# ***In rhythm***

*The impact of an ICD on quality of life*

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# In Rhythm

## The Impact of an ICD on Quality of Life

In Ritme  
De Invloed van een ICD op Kwaliteit van Leven

(met een samenvatting in het Nederlands)

Proefschrift

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door

Helena Christina Margien Kamphuis  
geboren op 22 april 1964, te Groningen

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**In memory of my dad.**

Cuius mors initium erat fascinationis meae.



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## Chapter 1

# **Introduction**



## **Out-of-hospital cardiac arrest**

Sudden cardiac death is a major health problem around the world, claiming approximately 50000 deaths annually in the Netherlands, a country with 16 million inhabitants. In other words, 35% (1) of all deaths in the Netherlands are due to cardiovascular disease of which 24% are related to arrhythmias and conduction disorders (2). Sudden cardiac death claimed 39% of all deaths in the United States, approximately 20% is related to ventricular fibrillation (3). Sudden cardiac death can be defined as unexpected, non-traumatic loss of vital signs, such as consciousness, arterial pulse, blood pressure and respiration without preceding complaints or within 24 hours of the onset of complaints (4, 5). The concept arrhythmic death or sudden cardiac death is usually used when life could be continued had the arrhythmia been prevented or terminated (6). The most common cause of sudden cardiac death is ventricular tachycardia that converts to ventricular fibrillation or abrupt ventricular fibrillation (7).

When the arrhythmia originates in the bottom chambers (ventricles) of the heart, it is called ventricular tachyarrhythmia (extremely rapid but ineffective beating of the heart's lower chambers). With ventricular tachyarrhythmia, less blood is pumped throughout the body and brain. If ventricular tachyarrhythmia is not treated properly, it may be life-threatening. When a ventricular arrhythmia shows a fast disorganized electrical activity, it is called ventricular fibrillation. During ventricular fibrillation (quivering of the heart's lower chamber) no blood is pumped to the body or the brain. A person with immediate ventricular fibrillation passes out within about 10 seconds, is unresponsive to gentle shaking, stops normal breathing and after two rescue breaths, has no signs of circulation such as normal breathing, coughing or movement. Irreversible brain damage and death will occur if not treated within 5 minutes. Thus, ventricular fibrillation causes (arrhythmic) death.

In the late nineties, two studies on victims of unexpected out-of-hospital sudden cardiac death were conducted, one in the region of Maastricht and the other in the region of Amsterdam (8, 9). In both studies, approximately a half of all subjects had a history of heart disease (2). Of those who were resuscitated outside the hospital only a small percentage (13%) left the hospital

alive (10). It is a dramatic event often occurring in people in the prime of their lives (5). These patients have a high chance (70-90%) of clinical recurrence if a suitable regimen capable of suppressing the arrhythmias cannot be found (11). Today, in countries with highly developed health care systems, the implantable cardioverter defibrillator (ICD) is a widely used form of treatment of patients with documented or suspected life-threatening sudden cardiac arrest as a result of malignant ventricular dysrhythmia. The therapy has dramatically improved the survival rates, although the underlying cause of the arrhythmia still exists (12).

At the start of the present study other treatment modalities for survivors of cardiac arrest were: antiarrhythmic drugs, revascularization, and surgery. During the time of the study, the ICD became a treatment of first choice in selected patients. Although the indications for ICD therapy are increasing in the Netherlands, ICD therapy is currently used primarily for patients with life-threatening arrhythmias, including cardiac arrest. As more people are receiving this form of treatment, the need for insight in how the therapy and their illness affects social and personal activities (including general activities of daily living) becomes necessary. The impact of the therapy needs to be addressed as well as being able to pinpoint particular problems that might occur. In our study the focus is on the quality of life of cardiac arrest survivors who have either received an ICD or were treated otherwise in the Netherlands.

## **The Implantable Cardioverter Defibrillator**

Since the first implantation of an ICD in 1980 in the United States of America, technological advances have enabled ICD's to pace, convert and defibrillate survivors of sudden cardiac arrest, ventricular tachycardia, and ventricular fibrillation (13). ICD therapy is often considered for patients who have generally experienced at least one episode of ventricular tachycardia or ventricular fibrillation, previous cardiac arrest, or drug therapy that was ineffective in controlling the tachyarrhythmia.

The ICD system consists of a pulse generator and one or more insulated wires (called leads). The pulse generator consists of a electronic circuitry and a battery, both of which are enclosed in a sealed titanium capsule. The ICD serves as the "brain" of the implanted system, monitoring the heart's activity and generating therapy when appropriate. ICD's are high-tech devices that contain sophisticated detection algorithms (to ensure therapy is appropriate and that patients do not receive unnecessary shocks) and series of therapy options. When the ICD senses an abnormal rhythm, it verifies if the condition is persistent before it offers therapy. Then, the action taken depends upon the type of arrhythmia it is programmed to treat. Therapy options include pacing (a burst of critically timed low-energy output pulses), cardioversion (low-level shocks delivered during the tachyarrhythmia), and defibrillation.

The ICD is usually implanted below the collarbone on the left or right side of chest (pectoral implant), in a specially prepared pocket. The physician will further make a small incision near the patient's collarbone and manoeuvres one or two leads through a vein into the right ventricle of the heart. Each lead's electrode is positioned next at the inside of the heart wall (endocardium). The other end of the lead is attached to the generator (ICD).

Although the ICD has enhanced survival, it has also produced a new population of patients distinct from the general cardiac population (14). Most patients having survived a life-threatening event, influencing their look upon life. Survivors of cardiac arrest face severe challenges. They have to learn to live with a device which may deliver an electrical shock unexpectedly at any time or place.

### **Significant characteristics proceeding cardiac arrest and/or ICD shock**

When an ICD-recipient is suddenly confronted with a ventricular life-threatening arrhythmia, the blood circulation becomes dysfunctional, blood pressure will decline, no pulse can be felt and will lose consciousness within 5-15 seconds. In this phase the person may also show rapid breathing. Just before losing consciousness the person may become anxious and nervous, feels dizzy and may start to hyperventilate. Usually before the ICD recipient become unconscious, he may still be able to lay down, in some cases he will fall onto the floor. As the onset of the life-threatening arrhythmia can be felt, the person might indicate this by saying 'there I go' or ' I'm in trouble'. Seconds before the collapse (within the first 5 - 30 seconds) the person may have an insult (which looks like an epileptic insult) and the eyes can 'turn away'. Directly after the collapse the person makes a wheezing/snoring sound as the tongue and epiglottis fall back into the throat blocking the air passage. Due to relaxation of the pelvic muscles incontinence may occur. After 10 to 30 seconds the pupils will dilate and after 45 seconds they will not react to light. In this phase the person may have a pale complexion and have acrocyanosis to the ears, lips and fingernails (a bluish colour) (15). Other sensations that might precede ICD shock delivery are: fluttering sensations of the heart (due to low blood pressure), fatigue and weakness (due to lack of blood supply) and flushing sensation. At this stage, the ICD would already have detected the life-threatening arrhythmia and have given off its first shock. After the person has been shocked, he may let out a bellow, which may frighten bystanders. As the person becomes conscious, he will become aware again of his surrounding. Usually the ICD recipient feels shaky for some time but is able to return to his usual daily tasks quickly .

Defibrillation, high energy shocks, are not felt as most ICD recipients are unconscious shortly after a life threatening arrhythmia starts. Of those patients who are conscious, most describe the shock as a electric current or as a "kick in the chest". While many find the shock reassuring (the ICD works), other patients may be upset for a short time after ICD shock therapy.

## **Quality of life**

Quality of life, a central theme in this study, can be defined as 'an individual's overall satisfaction with life, and one's general sense of personal well-being' (16). In the past decade there has been increasing interest in incorporating health-related quality of life aspects in the evaluation of different treatments (17). Cella (18) has given the following definition: 'Health-related quality of life refers to the extent to which one's usual or expected physical, emotional and social well-being are affected by a medical condition or its treatment'. Health-related quality of life measures the patients perception of health and not the physiological state of the disease. The reasons for studying quality of life are diverse:

- to determine the effects of the illness or therapy on physical and emotional functioning, social and personal activities and vocation. Thus, addressing the impact of the illness or treatment.
- to pinpoint which particular problems are likely to emerge.
- comparing different treatment modalities.

## **Determinants of quality of life**

Important determinants of quality of life are: physical symptoms, limitations in physical, emotional and social functioning, uncertainty of the future and feelings of loss of control, anxiety, depression, coping and social support. Anxiety is an adaptive feeling that signals danger, threat, or harm prompting one towards a coping behavior (20). Depression is a mood disorder marked especially by sadness, inactivity, difficulty with thinking and concentration. Other symptoms associated with depression are: a significant increase or decrease in appetite and time spent sleeping, feelings of dejection and hopelessness, and sometimes suicidal thoughts (19). Uncertainty of the future and feelings of loss of control may be interpreted as danger prompting anxiety. Coping is a process of trying to manage demands that are appraised as taxing or exceeding one's resources. It is a response to a stressful event or new situation. Social support can be defined as information from other people that one is loved and cared for,

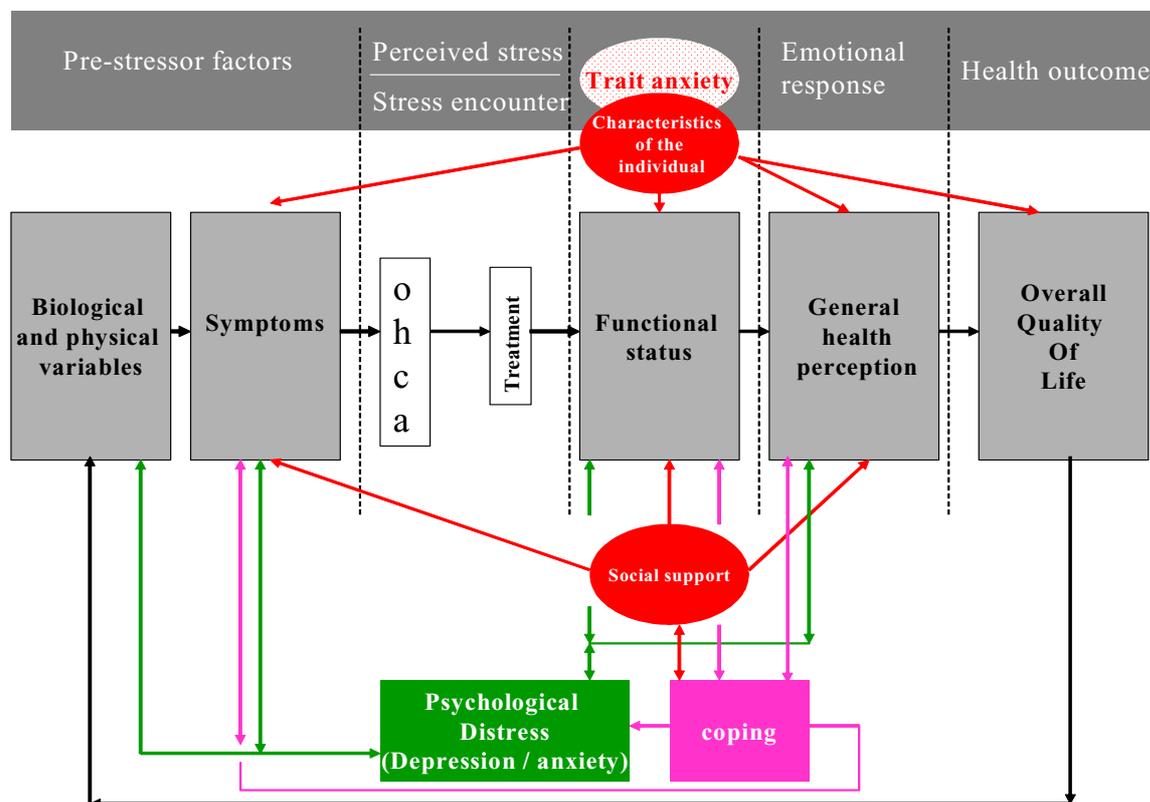
esteemed and valued, validating that one is part of a network (19).

Survivors of cardiac arrest are faced with a new situation after having survived a life-threatening event. After the out-of-hospital cardiac arrest patients are admitted to the hospital, usually undergoing a long hospital stay and multiple tests including invasive electrophysiologic study. During the invasive electrophysiologic testing patients may be confronted, while awake, with cardioversion (21). Moreover, they will be confronted with the unpredictability of reoccurrence of malignant arrhythmias during hospitalization. During this time the patient will most likely be confronted with his/her mortality, sometimes for the first time, and the uncertainty of the future becomes more apparent (11). After the diagnostic phase some patients will undergo ICD-implantation. Discharge will usually follow within one or two days after implantation. Once at home patients are faced with psychological and social adjustment to a new situation and find themselves dependent on an implanted device for their rescue, should they experience recurrence of life-threatening ventricular arrhythmias. Many ICD-recipients will eventually be confronted with the unpredictability of spontaneous ICD discharges (shocks).

The level of social support, coping, the presence of depressive symptoms and/or anxiety and biological factors (such as life-threatening arrhythmias) interact and determine quality of life. How these biological, social and psychological variables interact will be the focus of this thesis.

## Conceptual model

For this study we incorporated Wilsons and Cleary's conceptual model on health-related quality of life (22). They stated that the concept of quality of life is distinct from health, though related to it. Further they stipulated that quality of life is affected by economic, cultural, political and spiritual factors although healthcare givers generally believe that these factors do not fall under their area of expertise, and therefore these concepts have not been added to the model. Most conceptualizations of quality of life include the dimensions of physical and social functioning, role functioning, mental health and general health perceptions. The relationships between these concepts are displayed schematically in Figure 1.



The conceptual model makes explicit what we think are the causal associations between pre-stressor factors, the stressor itself, and the emotional response to the stressor contribute to the outcomes. According to Dunbar (23) the model is not linear, and the outcomes ultimately

influence the context of the situation in which the stressor is encountered. This is particularly important in an ongoing adjustment process where the ICD recipient has to learn to live with the unexpected recurrent life-threatening arrhythmia and the shock delivery that will follow directly after the detection by the ICD.

Five levels can be identified in our model: biological and physical factors, symptoms, functioning, general health perception, and overall quality of life. Biological and physical factors can be seen as fundamental determinants of health status and do not need further explanation in this paragraph. Symptoms are the utterance of patient's abnormal physical, emotional, or cognitive state. Symptom status is an important determinant of functioning. The four domains of functioning that are commonly measured in quality of life studies are: physical, psychological, social and role functioning. Wilsons and Cleary (22) agree that functional status, social, and emotional distress are associated with general health perception. General health perception is affected by the way the patient perceives his physical, emotional and cognitive state or functioning. General health perception is a subjective rating that the ICD recipient gives to his/her health.

The following concepts have been included to Wilsons and Cleary's model: out-of-hospital-cardiac-arrest (OHCA), its treatment (ICD insertion), social support and coping. OHCA and ICD insertion are perceived as being a stressful encounter. In this model, stress is a negative emotional experience accompanied by predictable biochemical, physiological, cognitive and behavioural changes that are directed either towards altering the stressful event or accommodating to its effects (19). Quality of life can either improve or deteriorate after OHCA or ICD therapy. Physical, mental and social limitations are seen as reactions to having survived an OHCA (a stressful encounter). Also the insertion itself, as well as having to learn to live with having an ICD is a stressful (ongoing) encounter which influences the functional status, how one perceives his or her health, and overall quality of life.

The role of psychological factors on quality of life have also been included in the model. Depressive symptoms and (state) anxiety are indicators for psychological distress. These

factors have a casual relationship at every level of the model, most of the relationships are bidirectional (22). Decision making and/or handling stressful situations become impaired when confronted with psychological distress (22). In our model, psychological distress, is seen as a response to the stress encounter. Coping is a process of trying to manage demands that are appraised as taxing or exceeding one's resources (19). The impact of a stressful event is substantially influenced by how a person appraises it.

Social demographics, personal- and situational factors influence psychological distress and overall quality of life in our model. The following personal factors were studied: coping, and trait anxiety. Situational factors include social support and ICD shock delivery. In this model coping and social support may be viewed as interrelated: coping may be used to mobilize support and social support may determine coping (24).

The instruments that will be used to measure the above mentioned concepts will be described in paragraph **Measures** on page 23.

### **Quality of life and psychological distress of ICD recipients**

Despite obvious benefits like, improved patient survival and feelings of security of family members, ICD therapy also has adverse physical (25, 26), social and psychological effects (27, 28, 29, 30, 31, 32, 33, 34). Herrmann et al. found that ICD treatment primarily affects emotional adjustment (35). ICD has also major impact on cognitive functioning (25, 36). Cognitive processing has been found to be slower than normal (37). Furthermore, a reduction in energy levels (tiredness), and sleep disturbances have been reported (38,39).

According to Luderitz 47% of ICD recipients were unable to return to an active life (25). Sneed et al. concluded that 96% of all ICD recipients had to make alterations in their activities (40). Employment after implantation has been known to decrease to about 38 to 66% (26, 41) (42). Pycha et al (39) found that 75% of ICD recipients can be categorized as completely disabled. Some researchers found a decreased ability for sexual activity (29, 43), others found a decrease in social interaction, indicating isolation (39, 43, 44). Driving limits may also lead

to isolation. At the time of our study all ICD recipients by Dutch law were not allowed to drive a car or other motorised vehicle.

A large percentage of ICD recipients (60 to 70%) reported being anxious about their limited physical and recreational activities (25). After ICD implantation recipients remained anxious (32, 37). Concerns that may contribute to anxiety are: heart condition (45, 39); work and daily activities (46, 25); limited sexual activities (47); lack of social support (48); and, negative body image (46, 25).

Herbst et al (49), Keren et al (50), and Morris et al (31) reported that 15-50% of ICD-recipients were psychologically distressed and/or had psychiatric disorders. Depression may be a delayed reaction as it generally takes some time for patients to fully understand the implications of their condition.

Approximately 39% to 54% of all ICD recipients experience an ICD discharge (shock delivery) (51, 52). Those who experienced an ICD shock delivery were more susceptible to clinically relevant depression and anxiety (53, 54). The shock group (who experienced spontaneous conscious discharges) in Keren's study felt more anxious although this was not statistically significant compared to ICD recipients who did not experience discharges, and those without an ICD (treated with antiarrhythmic medication) (31). Dougherty reported significant differences in anxiety levels between the group who experienced a shock and the non-shocked group at one-year post-implantation (53). The anxiety levels of those ICD recipients who had no ICD delivery shocks throughout the first year post-implantation gradually decreased over time while those of ICD recipients who had received an ICD delivery shock remained unchanged. Similar trends were observed on measures of depression, however the differences were not significant. Hegel et al (34) found that ICD shock delivery was closely associated with the occurrence of depression. However, according to Pauli (55), Chevalier et al. (56) and Herbst et al. (49) the occurrence of ICD shock delivery has no influence on quality of life and psychological distress.

## **Aims of this thesis**

This is the first prospective study on quality of life of cardiac arrest survivors who either received an ICD or were treated otherwise in the Netherlands. By means of this study we aim to describe how patients perceive their quality of life throughout the first year after implantation and how they deal with having an ICD in their everyday life.

The aims of this thesis are :

- a. to determine which changes regarding quality of life, well-being, anxiety, and depression take place after admittance into the hospital and treatment for out-of-hospital cardiac arrest until 12 months post-discharge in a group of ICD recipients and a control group;
- b. to determine which factors account for the possible differences in quality of life between ICD-recipients and a control group of patients treated otherwise;
- c. to evaluate the differences between recipients who have experienced a ICD shock delivery with those who have not experienced shocks;
- d. to determine which variables during hospitalization and one-month post-discharge predict quality of life at 12-months post-discharge;
- e. to describe the relationship between continuity of care and quality of life.

## **Methods**

### ***Participants and procedure***

For this study we recruited 180 patients from three university hospitals and one large general hospital: University Medical Center Utrecht, University Hospital Groningen, University Hospital Maastricht and St Antonius Hospital Nieuwegein.

In total, 13 patients declined to participate in the study. Reasons given for not participating were 'lack of interest' (n =8), 'too tired' (n =1) , 'feeling depressed' (n = 1), 'language' (n=1), 'cognitive problems' (n = 1) and one person did not elaborate on the reason for not participating.

The sample consisted of 167 consecutive patients who were admitted to the hospitals after an out-of-hospital cardiac arrest. Of all 167 survivors, 132 (79%) received ICD treatment (ICD group) and 35 (21%) received other treatment, namely, antiarrhythmic drugs, revascularization, or surgery. The patients treated otherwise formed our control group.

The study was approved by the Committee for Ethics in Medical Investigations at all four hospitals. Patient consent was received shortly after being hospitalized. All patients completed a questionnaire shortly after admittance to the hospitals and before treatment. After discharge patients received a mailed questionnaire at 1, 6 and 12 months. The questionnaire items were based on issues regarding quality of life, depression, anxiety, coping, social support, continuity of care, unmet care demands and patient satisfaction with received patient education.

Patients were eligible for the study if they had a cardiac arrest outside the hospital. Other inclusion criteria were: no cognitive impairment, ability to understand and to read Dutch; older than 16 years and younger than 80 years.

Of the 132 ICD-patients who were recruited, 21 patients participated also in semi-structured interviews at 1, 6 and 12 months post-discharge. These patients were visited at their homes. After the interview the researcher received the filled-in questionnaire.

## **Measures**

Clinical data (type of treatment and cardiac history) were collected from the medical records. In the questionnaire at admittance patients were asked to report their age, gender, marital status, income, highest level of education, employment, and religion. In addition they completed questions on quality of life, anxiety, depressive symptoms, coping mechanisms, received social support, continuity of care, unmet care demands, and satisfaction with received patient education by means of the following questionnaires:

Quality of life was measured with a generic quality of life questionnaire and with a disease specific questionnaire. Generic quality of life was measured with the RAND-36 (57;58) which contains 36 items with a 4-point Likert scale. The Rand-36 comprises 9 subscales: physical and social functioning, role limitations due to physical problems and/or emotional problems, bodily pain, vitality, general mental health, general health perception, and health change. The higher the score on individual subscales, the better the quality of life.

The Heart Psychological Patient Questionnaire (HPPQ) was the disease specific quality of life questionnaire used. The HPPQ comprises of 52 items scored on a 3-point Likert scale. Four dimensions are measured: well-being, feelings of being disabled, displeasure, and social inhibition (59). A high score on the well-being dimension indicates a high degree of well-being, whereas high scores on the other three dimensions indicate a worse condition (60).

Anxiety is measured with the State Trait Anxiety Inventory (STAI) (61) which consists of 40 items with a 4-point Likert scale. The trait measure (20 items) reflects a more stable disposition to react anxious, while the state measure (20 items) reflects a transient characteristic (34). Spielberger et.al. suggested a cut-off score of 40 for both scales (ranges 20 - 80), all higher scores indicate that clinically significant anxiety should be suspected (62).

Depression is measured with the CES-D (Center for Epidemiological Studies Depression Scale) that consists of 20 items (range 0 - 60) scored on a 4-point Likert scale (63). A cut-off score of  $\geq 16$  is used to identify patients with a probable clinical depression (64).

Social support is measured with the Social Support List Interactions (SSL) (65). This

questionnaire contains 34 items with a 4-point Likert scale, measuring emotional support, support in stressful situations, instrumental support, appraisal support and informative support.

Coping was measured with a shortened version of the Utrecht Coping List (66). The 17-item version encompassed the following subscales: active problem solving, seeking support, religious coping, avoidance and palliative coping. This questionnaire measures coping as a trait, the way one copes with problems in general (67).

Social activities and sexuality were measured using two subscales of the EORTC (European Organization for Research and Treatment of Cancer) Quality of life Core Questionnaire-H&N35 (68). The subscale sexuality consisted of 2 items and social activities of 5 items with a 4-point Likert scale.

Satisfaction with patient education was evaluated with the Patient Education Questionnaire (69). This 29-item questionnaire is a combination of open-ended items and items on a 3-point Likert scale. The sub-scales are a) satisfaction with the patient education given by the physician and the nurse, b) satisfaction with the information received, and c) the need for improvement. Each subscale incorporates the following dimensions: time, clearness, attention, personal contact, and opportunity to ask questions.

The continuity of care in the post-hospitalization phase was evaluated with the Continuity of Care from the Clients' perspective Questionnaire (CCCPQ). The measure can be used to evaluate the care given by many different disciplines. Every discipline has a module comprised of the same questions. Every module incorporates 13 items with a 5-point Likert scale and measures four dimensions of continuity of care from the patients perspective (70): i) interpersonal continuity (provided care relates with the care-needs of the patient), ii) interdisciplinary continuity (general agreement among multi-disciplinary care-givers/facilities), iii) substitution of care, and iv) referral of care. In this study, four modules for the following disciplines were used: general practitioner care, cardiologist/specialist care, mental care (counseling), and patient education.

The 11 item questionnaire Received Care and Unmet-care Demand Survey (RC-UD

Survey) embodies three sections about the utilization of care. The first two sections measure the care given by a significant other and the care given by professional institutions. The third section measures the unmet-care demands. All sections were divided into three categories: (a) care services that support activities of daily living, (b) psychosocial support, and (c) aids (with device adjustments or financial resources). All the questions incorporate fixed alternative answers (yes or no).

The duration of filling in the questionnaire was approximately one hour. The interviews (for the qualitative data) took approximately 2 ½ hours.

### ***Statistical analyses***

To compare quality of life, depression and anxiety scores of our sample with that of a healthy Dutch population, the scores of the cardiac arrest survivors on the Rand-36, CES-D, STAI were compared to reference data using the independent-samples T-tests. To investigate relationships between the different variables assessed, correlational analyses were conducted. Multivariate analysis of variance for repeated measures were used to assess changes over time and/or within groups. To determine which variables influence quality of life one year post-discharge multiple regression analyses were carried out.

## **Outline of the thesis**

To address the research questions we conducted the following studies:

In **Chapter two** we examine continuity of care, unmet care demands, and patient satisfaction with patient education in survivors of cardiac arrest treated with an ICD or with other modalities.

Further we described the relationships between quality of life and these factors.

In **Chapter three** we compared quality of life and (psychological) well-being, over a 12 month period in cardiac arrest survivors who received an ICD and other treatment modalities (control group).

The aim of our study described in **Chapter four** was to determine whether depression, anxiety, and quality of life at 12 months can be predicted in ICD recipients by factors measured during hospitalization.

In **Chapter five** our goal was to determine the impact of receiving ICD shocks on depression, anxiety and quality of life during during the first 12 months after implantation. To examine the impact of shock delivery on quality of life, patients were categorized according to the period in which the shocks were received.

In **Chapter six** qualitative data from 21 ICD-recipients were analysed. In this study changes in quality of life and life experiences over a period of 1 year after ICD implementation were described .

**Chapter seven** contains the general discussion.

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Chapter 2

**Quality of Life and Satisfaction with Provided Care in Cardiac-arrest  
Survivors treated with or without an Implantable Cardioverter  
Defibrillator.**

## **Abstract**

Background: Sudden Cardiac Death (SCD) is major cause of death. Treatment with an implantable cardioverter defibrillator (ICD) has significantly improved survival, such that ICD therapy is no longer a last resort therapy but rather the treatment of choice for selected patients.

Objective: To examine continuity of care, received care, unmet-care demands, and patient satisfaction with patient education in survivors of cardiac arrest treated with an ICD (*ICD*<sup>+</sup>) or other modalities (*ICD*<sup>-</sup>), and to investigate possible relationships between these factors and quality of life.

Design: Patients (n = 180) were monitored for 6 months and completed a questionnaire during hospitalization (*t*<sub>1</sub>) and at 1 (*t*<sub>2</sub>) and 6 (*t*<sub>3</sub>) months after discharge.

Results: No significant differences were found between quality of life, well-being and satisfaction with patient education and continuity of care. Our results did not show continuity of care, and unmet care demands to be related with quality of life and well-being. Some associations between quality of life and received care were significant. With regard to quality of life, no significant differences were found between *ICD*<sup>+</sup> and *ICD*<sup>-</sup> patients. For both groups improvement took place over time.

The better the quality of life, the less care was consumed. Most patients were independent of care 6 months after discharge. A small group (5%) indicated that they did not receive the emotional care they needed. *ICD*<sup>-</sup> patients were more satisfied than *ICD*<sup>+</sup> patients with the patient education given by the nurse. Women were more satisfied than men with the 'substitution of care' given by the general practitioner and specialist.

Conclusions: We found no significant association between patient education, continuity of care and quality of life in either group of patients. Overall, patients were satisfied with patient education and continuity of care. Although quality of life improved over time, perceived health did not. This emphasizes the continuous impact of cardiac arrest and ICD therapy.

Implications: The methodology for evaluating continuity of care, satisfaction with patient education, and unmet care demands needs to be further researched.

## Introduction

Although in the past decades cardiovascular mortality has declined significantly in most industrialized countries, cardiovascular disease still remains one of the major causes of morbidity and mortality in Western societies (1, 2, 3, 4). In the Netherlands alone, but similar to other Western societies, cardiovascular disease accounts for 37% of all deaths. Of all cardiac mortality, 24% is due to conduction disorders and arrhythmias (3). In 1980, the implantable cardioverter defibrillator (ICD) was introduced for treatment of sudden cardiac death (SCD) (5, 6, 7). Although the list of indications for ICD therapy is expanding, in the Netherlands, ICD therapy is primarily used in cardiac arrest survivors.

Because the ICD has improved patient survival, it has also generated a new population of patients who may have different positive and negative attitudes, different scores in depression, anxiety, social support, and coping skills from those of a general cardiac population. While much is known about the ICDs' technical performance and its biophysical influence, little is known about the patient's subjective experience of treatment with an ICD. Survivors of cardiac arrest are often in hospital for a long time and undergo extensive diagnostic testing. Studies on post-hospitalization quality of life show that SCD and ICD have a major impact on psychological (8, 9,10,11,12,13,14,15), physical (16,17), and cognitive functioning (16,18). Quality of life has been defined as 'an individual overall satisfaction with life, and one's general sense of personal well-being' (19). Cella and Bonomi (20) give a slight different definition 'Health-related quality of life refers to the extent to which one's usual or expected physical, emotional and social well-being are affected by a medical condition or its treatment'.

Although many patients recover psychosocially after an acute cardiac event and their quality of life generally improves over time (21,17, 22), it is hypothesized that some SCD survivors experience persistent psychosocial distress. This is most likely true for ICD recipients because of the continuous presence of the ICD device in the body. We expect that

such patients will show multiple physical, social and psychological changes after treatment, which will affect their quality of life.

In the past decade there has been increasing interest in incorporating health-related quality of life aspects into the evaluation of different treatments (23). Little attention, however, has been given to the use of quality of life for monitoring the relative appropriateness of health care (24). In order to improve the process of care comprehensive evaluations of health care must involve assessment of outcomes and needs (24) (25). There are still many problems concerning the measurement of patient satisfaction with received care, unmet care needs, and patient education. The conceptualization and the methodology of evaluating continuity of care are in their infancy. There are no known international, reliable and validated measures, especially concerning research in the area of cardiological care. Moreover, the care given, patient satisfaction with the received care, patient satisfaction with patient education, and unmet care demands have not been evaluated in different care settings. This is probably why we know little about the continuity of care in the post-hospitalization phase.

The aim of the present paper is to examine continuity of care, unmet care demands, and patient satisfaction with patient education in survivors of cardiac arrest treated with an ICD or other modalities, and further to evaluate possible relationships between quality of life and these factors. Emphasis is on post-hospitalization phase because this is considered to be the last phase of the care continuum. It is presumed that when there is a discontinuity of care, it will have an adverse effect on the quality of care and therefore influence the quality of life.

## **Methods**

### *Study design*

In this prospective study, continuity of care, unmet care demands, patient satisfaction with patient education and quality of life are examined, over a 6-month period, in patients who survived a cardiac arrest due to ventricular tachyarrhythmia. Furthermore, the possible relationships between quality of life and continuity of care, unmet care demands and patient education are evaluated. After patients consented to participate, they all completed a questionnaire during hospitalization (baseline =  $t_1$ ) and at one ( $t_2$ ) and six ( $t_3$ ) months postdischarge.

### *Patient sample*

Participants were eligible for this study if they were older than 16 years and able to comprehend the Dutch language. A sample of 180 patients resuscitated from SCD was obtained from three university hospitals and one general hospital. The four hospitals are recognized by the Dutch government as being centers for the implantation of ICDs. The occurrence of SCD resulting from circulatory collapse that required resuscitation, ventricular fibrillation, ventricular tachycardia, or asystole was established from the patient records.

Thirteen patients declined to participate. Reasons given for not participating were 'lack of interest' ( $n = 8$ ), 'too tired' ( $n = 1$ ), 'feeling depressed' ( $n = 1$ ), 'language' ( $n=1$ ), 'cognitive problems' ( $n = 1$ ) and one person did not elaborate on the reason for not participating.

The sample consisted of 168 patients. About three quarters (79%) received an ICD and a small quarter (21%), our control group, was treated otherwise.

### *Instruments*

Both generic quality of life and psychological well-being were measured during hospitalization ( $t_1$ ) and after discharge ( $t_2$  and  $t_3$ ). Patient satisfaction with patient education was measured one month after discharge ( $t_2$ ), and continuity of care was measured at 6 months ( $t_3$ ). Unmet-care demands were measured at both  $t_2$  and  $t_3$ .

Generic Quality of life was measured with **The Rand-36 item Health Survey** (26) (27). This is a comprehensive measure of general health including physical and social functioning, role limitations due to physical problems and/or emotional problems, bodily pain, vitality, general mental health, general health perception, and health change. The higher the score on individual subscales, the better the quality of life.

Disease specific health-related quality of life was measured with the **Heart Patients Psychological Questionnaire** (HPPQ) (28). This questionnaire comprises of 52-items with a 3-point Likert scale and measures four dimensions: well-being, feelings of being disabled, displeasure, and social inhibition. A high score for well-being indicates a good psychological condition whereas a high score for the other three dimensions indicate a poor psychological condition.

Satisfaction with patient education was evaluated with the **Patient Education Questionnaire** (29). This 29-item questionnaire is a combination of open-ended items and items on a 3-point Likert scale. The sub-scales are a) satisfaction with the patient education given by the physician and the nurse, b) satisfaction with the information received, and c) the need for improvement. Each sub-scale incorporates the following dimensions: time, clearness, attention, personal contact, and opportunity to ask questions.

The continuity of care in the post-hospitalization phase was evaluated with the **Continuity of Care from the Clients' perspective Questionnaire**. The questionnaire consists of 13 items on a 5-point Likert scale and measures four dimensions of continuity of care from the patients perspective (30): i) interpersonal continuity (provided care relates with the care-needs of the patient), ii) interdisciplinary continuity (general agreement among multi-disciplinary care-givers/facilities), iii) substitution of care, and iv) referral of care. In this study, the modules general practitioner care, cardiologist/specialist care, mental care (counseling), and patient education were used.

The 11 item questionnaire **Received Care and Unmet Care Demand Survey** embodies three sections about the utilization of care. The first section measures the care

given by a significant other and the care given by professional institutions. The second section measures the unmet-care demands. All sections were divided into three categories: (a) care services that support activities of daily living, (b) psychosocial support, and (c) aids (with device adjustments or financial resources). All the questions incorporate fixed alternative answers (yes or no).

#### *Data analysis/Statistical methods*

Statistical analyses were performed with SPSS 10.0 for Windows (31). MANOVA for repeated measures was used to investigate the differences between the different treatment modalities ( $ICD^+$  and  $ICD^-$ ) over time.  $\chi^2$  test was used to identify differences in sociodemographic variables between  $ICD^+$  and  $ICD^-$  patients. Pearson's product-moment correlations were used to examine relationships between treatment modalities, quality of life and other outcomes variables. Cronbach's alpha coefficient was used as a measure of internal consistency.

### **Results**

Of the 168 survivors at  $t_2$ , 133 people received an ICD and 35 persons received other treatment (antiarrhythmic drugs, revascularization, and/or surgery). There were no differences between  $ICD^+$  and  $ICD^-$  patients regarding sex, religious beliefs, living situation, work, and education; however,  $ICD^+$  patients were younger than  $ICD^-$  patients (mean age 55.2 years, range 41.5 - 68.9 versus mean age 61.1 years, range 48.3 - 81,7) (Table 1).

No significant relationships were found between 'quality of life' (RAND-36), 'well-being' (HPPQ) and 'satisfaction with patient education' and 'continuity of care'. Some associations between 'quality of life', and 'received care' were significant. Eight sub-scales of the RAND-36 (physical functioning, social functioning, health change, physical role limitations, mental health, vitality, pain, and health perception) were associated with most of

Table 1

**Characteristics of patient population**

Patients who received an Implantable Cardioverter Defibrillator or other treatment

	n = 133		n = 35	
	ICD <sup>+</sup>		OT	
	n	%	n	%
<b>Gender</b>				
female	35	26.3%	8	22.9%
male	98	73.7%	27	77.1%
<b>Work status</b>				
employment	27	24.1%	7	20.0%
unemployment	32	20.3%	2	5.7%
retired	26	19.5%	10	28.6%
disability leave	19	14.3%	3	8.6%
unknown	29	21.8%	13	37.2%
<b>Marital status</b>				
married/living together	84	63.2%	23	65.7%
divorced	5	3.8%	1	2.9%
widowed	10	7.5%	3	8.6%
unmarried	9	6.8%	0	
unknown	25	18.8%	8	22.9%
<b>Education</b>				
primary education	28	21.1%	7	20.0%
secondary education	36	27.1%	7	20.0%
tertiary education	18	15.0%	3	8.6%
unknown	51	38.3%	18	51.4%
<b>mean age</b>	mean 55.24 / st.dev 13.7		mean 61.04 / st.dev 12.81	

the subscales of the questionnaire 'received care'. In addition, most of the subscales of the HPPQ correlated with the sub-scales of the 'received care' questionnaire (Table 2a). The pattern of correlations was different for 'quality of life' and 'unmet care demands' (Table 2b). The better the quality of life, the less care was consumed.

Table 2a Relationship between Quality of life (Rand-36 and HPPQ) and Received Care

	adl	eating/drinking	transference inside home	transference outside home	social activities	household	financial	aid- adjustment	preparing meals	emotional probl
<b>Rand-36</b>										
Physical functioning	-0.36			-0.34	-0.23					
social functioning		-0.25		-0.35				-0.22		-0.35
health change				-0.25						
physical role limitations				-0.37						-0.24
emotional role limitations										
mental health			-0.22	-0.27						-0.38
vitality		-0.24		-0.27				-0.23		-0.34
pain								-0.26		-0.34
health perception				-0.3						-0.24
<b>HPPQ</b>										
Well-being				-0.36	-0.22					-0.33
feelings of being disabled				0.29						0.26
displeasure				0.22			0.21	0.26		0.43
social inhibition				0.22						

Table 2b Relationship between Quality of Life (Rand-36 and HPPQ) and Unmet Care Demands

	adl	eating/drinking	transference inside home	transference outside home	social activities	household	financial	aid- adjustment	preparing meals	emotional probl
<b>Rand-36</b>										
Physical functioning					-0.26	-0.31				
social functioning	-0.22									
health change										
physical role limitations										
emotional role limitations								-0.63		
mental health										
vitality	-0.23									
pain	-0.25			-0.3	-0.29				-0.36	-0.34
health perception					-0.25					
<b>HPPQ</b>										
Well-being										
feelings of being disabled					0.24					-0.38
displeasure										
social inhibition										

correlation is significant at the level 0.01 (2-tailed)

With regard to quality of life, no significant differences were found between *ICD*<sup>+</sup> and *ICD*<sup>-</sup> patients. For both groups improvement took place over time on all the subscales of the Rand-36, except for health perception (Table 3). Well-being (HPPQ) improved significantly ( $p < 0.001$ ) over time in all patients, irrespective of the treatment received (Table 3). Furthermore, 'feelings of being disabled', 'displeasure' and 'social inhibition' did not improve significantly in all patients.

Table 3.

**Quality of life and well-being during (t1) and at 1 month (t2) and 6 months (t3) after discharge**

<b>RAND-36 scores</b>	<b>icd+</b>			<b>icd-</b>		
	<b>t1</b>	<b>t2</b>	<b>t3</b>	<b>t1</b>	<b>t2</b>	<b>t3</b>
physical functioning	57,5	61,2	68,4	62,3	69,8	73,3
social functioning	44,2	58,9	72,3	50,3	68,3	77,5
health change	36,5	38,8	53,0	36,0	43,1	59,8
emotional role limitations	44,8	56,4	65,2	59,1	65,4	73,5
physical role limitations	31,1	30,0	54,9	27,9	41,9	59,4
mental health	64,1	65,5	69,4	67,2	71,4	74,0
vitality	57,2	53,9	57,7	58,1	59,8	64,2
pain	78,7	25,0	86,5	81,1	26,4	85,6
health perception	58,2	57,8	58,0	63,0	66,5	61,4
<b>HPPQ</b>						
well-being	23,5	23,9	25,9	26,0	26,5	27,6
feelings of being disabled	24,7	25,6	25,4	24,6	24,3	23,9
displeasure	17,1	16,8	16,5	15,8	15,5	15,2
social inhibition	11,1	11,4	11,3	11,0	10,5	11,0

More than 50% of the patients indicated that they had received medical care in the past 6 months. Of this group more than 25% visited the general practitioner and a specialist (Table 4). Twenty-three percent of the whole sample had received care from a counselor (mental-health care). *ICD*<sup>+</sup> patients were slightly more satisfied than *ICD*<sup>-</sup> patients with the continuity of care provided by the general practitioner, specialist, and counselor. They also

were significantly ( $p < 0.01$ ) more satisfied with 'substitution of care by the specialist'. Women with an ICD were significantly ( $p < 0.05$ ) more satisfied than men with the interpersonal and interdisciplinary continuity of care by the specialist. Women who received other treatment (ICD-) were significantly ( $p < 0.01$ ) more satisfied than men who had received other treatment with the substitution of care by the specialist.

Table 4.

**Care received over 6 months in patients with an implantable cardioverter defibrillator (ICD+) and in patients who received other treatment (ICD-).**

<b>(Dis-)continuity of care over the past 6 months</b>		<b>ICD+</b>		<b>ICD-</b>	
Received medical care in the past 6 months		n = 75	56%	n = 19	54%
	<i>no response</i>		18%		11%
Reason for no medical care	did not need it	n = 21	15,8%	n = 9	25,7%
	other reason	n=5	3,80%		
	<i>no response</i>		80%		74%
Who gave the care	GP	n = 8	6%		
	specialist	n = 31	23,3%	n = 10	28,6%
	GP & specialist	n = 38	28,6%	n = 10	28,6%
	other	n = 3	2,3%	n = 2	5,7%
	<i>no response</i>		39,8%		37,1%
Received mental-health care in the past 6 months		n = 22	16,5%	n = 8	23%
	<i>no response</i>		19%		20%
Reason for no mental-health care	did not need it	n = 65	50%	n = 12	34,3%
	waiting list	n = 1	1%		
	other reason	n = 3	3,1%	n = 2	5,8%
	got care from significant other	n = 17	12,8%	n = 5	14,3%
	<i>no response</i>		35%		45,7%

There was no difference between the patient groups with regard to satisfaction with patient education. More than 65% of the patients in both groups indicated being 'satisfied' (score 7 or 8) with all four subdomains of patient education (clearness, attention, personal attention, and given time). The ICD- patients were more satisfied than ICD+ patients with the patient education given by the nurse (Table 4)

Most patients indicated that they had received the care that they needed, and a large proportion of the patients was independent and did not need any form of care. In table 5 an overview is given of the people who received care from a significant-other.

Table 5 **Care received from significant others and unmet care demands at 1 month (t2) and 6 months (t3) discharge**

<b>Received care from significant others</b>	<b>ICD+</b>		<b>ICD-</b>	
	t2	t3	t2	t3
ADL	18 (14%)	10 (7,5%)	7 (20%)	2 (8%)
eating/drinking	7 (5%)	3 (2,3%)	3 (9%)	
transference inside home	11 (8%)	5 (3,8%)	3 (9%)	1 (3%)
transference outside home	70 (52,6%)	50 (37%)	18 (51%)	10(29%)
preparing meals	31 (23%)	16 (12%)	11 (31%)	4 (11%)
household	48 (35%)	34 (26%)	13 (37%)	10 (29%)
social activities	60 (45%)	34 (26%)	13 (37%)	8 (23%)
emotional problems	20 (15%)	7 (5%)	9 (26%)	1 (3%)
aid adjustment	11 (8%)	4 (3%)	3 (9%)	
financial	11 (8%)	5 (4%)	1 (3%)	3 (9%)
<b>Unmet Care demands</b>				
ADL	1 (1%)			
eating/drinking				
transference inside home				
transference outside home	9 (6,8%)	2 (2%)	3 (9%)	
preparing meals	1 (1%)			
household	5 (4%)	1 (1%)		
social activities	5 (4%)	2 (2%)	1 (3%)	
emotional problems	22 (17%)	12 (9%)	8 (23%)	2 (6%)
aid adjustment	7 (5%)	4 (3%)	1 (3%)	3 (9%)
financial	7 (5%)	7 (5%)	2 (6%)	4 (12%)

A small number of patients indicated that not all care-demands were met. One month after discharge, nearly all patients received the care they wanted and had no unmet care demands. For both groups, activities of daily living, transference outside the home, meals, hous keeping, social activities, financial support, and aid adjustment improved significantly with time after treatment.

## Discussion

Coronary heart disease is a major cause of disability and the most common cause of death in the Netherlands and other Western countries. In most cases psychosocial recovery will ultimately take place after an acute cardiac event, but a minority of patients will experience persistent psychosocial distress, which can adversely affect their quality of life and work, social, leisure, sexual, or domestic activities.

This is the first study to examine the quality of life and its relationship with continuity of care, unmet care demands, and patient satisfaction with patient education. Moreover, quality of life was measured three times (at baseline, and twice during the 6-months follow-up). Other researchers have noted that a single measure of quality of life may underestimate or overestimate the quality of life and well-being.

Generic quality of life (as measured with the RAND-36) did not change differently in the two groups over time. An explanation for this can be that SCD has a greater impact on a person's quality of life than the treatment modality. For both *ICD*<sup>+</sup> and *ICD*<sup>-</sup> patients, we found an improvement over time in most subscales of the Rand-36 and HPPQ. This is inconsistent with the findings of May et al. (17), who found a deterioration in the quality of life at 6 months, in ICD recipients using the Sickness Impact Profile. We found that social functioning and physical role limitations improved with time. This is also not in accordance to that what others reported (32, 16, 33, 15, 34).

'General health perception', as an indicator for overall quality of life, did not improve or decline over time in both groups (*ICD*<sup>+</sup> and *ICD*<sup>-</sup>). However, the *ICD*<sup>-</sup> patients had a better perceived health than the *ICD*<sup>+</sup> patients. *ICD*<sup>+</sup> patients had on all subscales poorer scores except for physical role limitations. This emphasizes the continuous impact of surviving cardiac arrest and ICD therapy.

Both groups, irrespective of the treatment received, had a poor psychosocial condition. The three subscales of the HPPQ: feelings of being disabled, displeasure, and social inhibition did not improve or deteriorate over time.

Those patients who had received medical care in the 6 months after discharge were satisfied with the care received. This was also true for the patient education received. Most patients were independent of care at 6 months after discharge. Van den Bos and Triemstra (24) proposed that a discontinuity of care would have an adverse effect on the quality of life. In our study, patient education and continuity of care were not significantly associated with quality of life.

Patient education and continuity of care are multidimensional concepts that are receiving more attention in research. Evaluation of these concepts is in its early stages, and it can be questioned whether we really assessed satisfaction with patient education and continuity of care because our results showed little variance (because all patients scored high, indicating they were very satisfied). When looking at continuity of care, patient education, and received care, we were unable to detect areas that needed improvement. However, a small group of patients indicated that they needed more assistance with emotional care and wanted more aid adjustment. Thus not all care-needs were met. Results did not show continuity of care, received care, and unmet care demands to be related with quality of life and well-being.

When patients were asked whether they received medical care in the past 6 months, it transpired that some people who had had a check-up (only an ICD reading was done) did not consider this to be receiving medical care. This might be the reason for the low response on the continuity of care questionnaire.

A likely reason for not finding a relationship between all these concepts is that we were looking for differences between two treatment modalities, and possibly the study lacked sufficient power (there were only 35 people in the *ICD* group). Moreover, the presence of an informal caregiver would reduce the probability of receiving professional care (35) and perceiving unmet care demands (36). The small number of people receiving care from significant others and reporting unmet care demands may also have reduced the power of the study.

Overall, we can conclude that quality of life and well-being improved during the first 6 months after treatment, irrespective of the treatment received. However, general health perception did not change, emphasizing the continuous impact of the therapy received. Additionally, it is also possible that having experienced a cardiac arrest has a greater impact on a person than the treatment he or she receives.

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Chapter 3

**A 12-month quality of life assessment of cardiac arrest survivors  
treated with or without an implantable cardioverter defibrillator**

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## **Abstract**

Background: Previous studies indicate that the implantable cardioverter defibrillator (ICD) has a large impact on the quality of life of patients. The effects of having an ICD over longer periods of times has been less studied.

Objective: To assess the quality of life and well-being of cardiac arrest survivors who have received an (ICD) or other treatment.

Methods: 168 patients were monitored for 1 year.

Results: No differences were found between the two treatments regarding quality of life (except for pain: ICD patients perceived less pain) and well-being. A significant improvement in physical and social functioning, and in mental health was found in the first six months. Older patients (60 years or older) perceived less improvement in their health than younger patients. Women indicated having a poorer social functioning. The prevalence of anxiety and probable depression was high irrespective of the treatment received: anxiety and depressive symptoms did not change significantly between 1 and 12 months after discharge. Patients with higher anxiety scores experienced less improvement of health and patients with more depressive symptoms experienced poorer social functioning.

Conclusions: The prevalence of anxiety and probable depression was high in cardiac arrest survivors. Probable depression affected social functioning. Those patients who felt anxious experienced less health improvement. Quality of life and well-being were not affected by the type of treatment. We conclude that surviving an out-of-hospital cardiac arrest has a greater impact on patients than the treatment received.

**Keywords:** out-of-hospital cardiac arrest, arrhythmia, implantable cardioverter defibrillator, quality of life, well-being, anxiety, depression

## Introduction

One of the major health problems in the Netherlands is cardiac disease. Thirty-seven percent of all deaths are due to cardiovascular disease and in 1997 24% of all cardiac deaths were related to conduction disorders and arrhythmias (1). Approximately 20% to 30% of patients survive cardiac arrest as a result of cardiopulmonary resuscitation (2, 3). In 1980, the implantable cardioverter defibrillator (ICD) was introduced in the United States of America as treatment for sudden cardiac death. The device was introduced in the Netherlands in 1984 (4). Although indications for ICD therapy are expanding, in the Netherlands ICD therapy is primarily used in survivors of sudden cardiac arrest.

Evaluation of quality of life in patients and in ICD recipients in particular, has become necessary because it provides information on how patients adjust psychologically to disease and its treatment. Quality of life assessment is often included as secondary treatment outcome in medical trails, in descriptive studies of patient groups, and in population studies. However, there is still no clear and broadly approved definition of quality of life. The consensus is that it is a multidimensional concept that not only includes physical, psychological and social functioning but also economic and cultural aspects, cognition, spiritual well-being, and structural functioning. The World Health Organization has defined health as total physical, psychological and social well-being. Following the WHO definition of health, three dimensions are considered relevant for patient perceived quality of life: physical, emotional and social functioning. In quality of life studies of ICD recipients, quality of life is usually seen as a series of separate constructs. In this study, quality of life refers to subjective health and well-being and the ability to function in day-to-day activities. Appropriate measures have been designed to quantify such subjective experiences (5).

Studies (see table 1) on the quality of life of cardiac arrest survivors who received an ICD often lack pretreatment data, so that it is not clear whether patients differed in psychological profile before treatment. In studies in which quality of life and psychological well-being are

measured prospectively, researchers examine presumed causes and go forward in time to observe presumed effects. Unfortunately, most studies have used different tools to measure quality of life, psychological well-being, anxiety, and depression (*Table 1*). Consequently, the results of these studies cannot be compared. Moreover, most studies are limited by the small number of patients and the lack of control groups.

The aim of this prospective study was to assess and compare quality of life and (psychological) well-being, using well-validated instruments, in cardiac arrest survivors who received an ICD or other treatment.

**Table 1 Quality of Life assessment**

<b>Author</b>	<b>Questionnaire</b>	<b>Design</b>	<b>Characteristics</b>
Hermann et al (6)	- Hospital Anxiety and Depression Scale - Quality-of-life Profile for the Chronically Ill	- cross-sectional - administration of questionnaire 1.4 years after implantation	ICD patient, n = 63 CAD patients, n = 112 (control group)
May et al (7)	Sickness Impact Profile	- prospective longitudinal - 14 month follow-up	ICD patients, n = 21
Herbst et al (8)	- Medical Outcome Study 36-item Short Form health survey - Brief Symptom Inventory - New York Heart Association Classification	cross-sectional - administration of questionnaire for the four groups is different (22 - 32 months follow-up) (no pre-treatment measure)	drugs only, n = 35 ICD only, n = 24 ICD + drugs, n = 25 control*, n = 73 (* composed of cardiac patients who had not experienced a major coronary event or coronary surgery)
Lüderitz et al (9)	- State Trait Anxiety Inventory - Specific developed questionnaire by Vlay & Olson 1989	prospective (regarding anxiety) and longitudinal	ICD patients, n = 57
Dubin et al (10)	- Medical Outcome Study 36-item Short Form health survey	- cross-sectional - administration of questionnaire, 3 years after ICD implantation	ICD patients ≤ 40 years, n = 16

<b>Author</b>	<b>Questionnaire</b>	<b>Design</b>	<b>Characteristics</b>
Carroll et al (11)	<ul style="list-style-type: none"> <li>- Medical Outcome Study 36-item Short Form health survey</li> <li>- Ferrans and Powers Quality of Life Index</li> <li>- Mishel Uncertainty in Illness Scale</li> </ul>	<ul style="list-style-type: none"> <li>prospective &amp; longitudinal</li> <li>- 6 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>drugs only, n = 36</li> <li>ICD patients, n = 41</li> </ul>
Bolles Vitale & Funk (12)	<ul style="list-style-type: none"> <li>- Nottingham Health Profile</li> <li>- Funk &amp; Edwards Index of Subjective Concerns for People with ICDs</li> <li>- Heart Rhythm Profile</li> </ul>	<ul style="list-style-type: none"> <li>- prospective &amp; descriptive</li> <li>- follow- up 3 to 6 months after implantation</li> </ul>	<ul style="list-style-type: none"> <li>ICD patients <math>\leq</math>50 years, n = 9</li> </ul>
Jessurun et al (13)	<ul style="list-style-type: none"> <li>- Medical Outcome Study 36-item Short Form health survey</li> </ul>	<ul style="list-style-type: none"> <li>- prospective</li> <li>- administration of questionnaire 1 year after implantation</li> </ul>	<ul style="list-style-type: none"> <li>ICD patients, n = 44</li> </ul>
Craney et al (14)	<ul style="list-style-type: none"> <li>- Duke Activity Status Index</li> <li>- Psychosocial Adjustment to Illness Scale</li> <li>- Ways of Coping Checklist</li> <li>- Charlson Comorbidity Index</li> </ul>	<ul style="list-style-type: none"> <li>- cross-sectional</li> <li>- time with ICD (mean = 4.5 years)</li> </ul>	<ul style="list-style-type: none"> <li>ICD patients, n = 80</li> </ul>
Dougherty (15)	<ul style="list-style-type: none"> <li>- Profile of Mood States Questionnaire</li> <li>- State Trait Anxiety Inventory</li> <li>- Distancing Subscale of the Ways of Coping Checklist (Revised)</li> <li>- Trailmaking A and B tests</li> </ul>	<ul style="list-style-type: none"> <li>prospective &amp; longitudinal (1,3,6 and 12 months after discharge)</li> </ul>	<ul style="list-style-type: none"> <li>ICD patients, n = 15</li> <li>Family members, n = 15</li> </ul>
Bainger & Fernsler (16)	<ul style="list-style-type: none"> <li>- Ferrans and Powers Quality of Life Index</li> </ul>	<ul style="list-style-type: none"> <li>- retrospective</li> <li>- period of assessment 4 to 82 months after ICD implantation</li> </ul>	<ul style="list-style-type: none"> <li>ICD patients, n = 70</li> </ul>
Chevalier (17)	<ul style="list-style-type: none"> <li>- Hamilton Anxiety Scale</li> <li>- Beck Depression Inventory</li> <li>- Minnesota Multiphasic Personality Inventory</li> <li>- Specific developed quality of life questionnaire for ICD patients</li> </ul>	<ul style="list-style-type: none"> <li>cross-sectional</li> <li>- time of assessment: 2 to 54 months after ICD implantation</li> </ul>	<ul style="list-style-type: none"> <li>ICD patients (nonshocked), n = 17</li> <li>ICD patients (shocked), n = 15</li> </ul>

## **Methods**

### *Design*

In this prospective study, quality of life and well-being were examined in patients surviving an out-of-hospital cardiac arrest due to ventricular tachyarrhythmia. Over a 12-month period, consecutively patients who had experienced an out-of-hospital cardiac arrest and who had received an ICD were compared with patients who had received other modes of treatment were admitted to the study. The other treatment modalities were: antiarrhythmic drugs, revascularization, and surgery. Approval for this study was obtained from the institutional review boards at the participating hospitals. After patients consented to participate they completed a questionnaire during hospitalization (baseline = T<sub>1</sub>) and at 1 (T<sub>2</sub>), 6 (T<sub>3</sub>) and 12 (T<sub>4</sub>) months postdischarge. Self-administered forms were given personally to patients a couple of days before ICD implantation or other treatment-therapy (OT). Once patients were discharged from the hospital all questionnaires were sent by post. Patients filled in the forms at home. Reminders were sent to those individuals who did not respond. Other data that were collected came from patient-medical records.

### *Study Sample*

Patients were recruited from four hospitals in the Netherlands. Participants were eligible for this study if they were older than 16 years, able to comprehend Dutch, and had survived a out-of-hospital cardiac arrest. In total, 179 patients met the enrollment criteria; 11 patients declined to participate, resulting in 168 patients (26% were women and the median age was 60 years). During the study there was no crossing over between the groups. Within 12 months of discharge, 11 people had died and 22 had not returned the last questionnaire, resulting in 133 patients who completed all (four) questionnaires. Cardiac arrest as a result of circulatory collapse that required resuscitation was established from medical records. The same applied for the presence of ventricular fibrillation, ventricular tachycardia, or asystole.

## ***Dependent Measures***

Quality of life was measured with the Rand 36-item Health Survey (Rand-36) and psychological well-being was measured with the Heart Patients Psychological Questionnaire (HPPQ). Depression was measured with the Center for Epidemiological Studies Depression Scale (CES-D) and anxiety was measured with the State-Trait Anxiety Inventory (STAI).

The **Rand-36** (18, 19) is a generic health-related quality of life instrument. The 9, 4-point Likert, subscales are physical and social functioning, role limitations due to physical problems and/or emotional problems, bodily pain, vitality, general mental health, general health perception, and health change. The higher the score on individual subscales, the better the quality of life.

The **HPPQ** (20) comprises 52 items score on a 3-point Likert scale and measures four dimensions: well-being, feelings of being disabled, displeasure, and social inhibition. A high score on the well-being dimension indicates a high degree of well-being, whereas high scores on the other three dimensions indicate a poor psychological condition.

The **State-Trait Anxiety Inventory** (STAI-DY) (21) consists of 40 items scored on a 4-point Likert scale. Trait measures (20 items) reflect a personality characteristic, while the state measures (20 items) reflect a more transient characteristic (22). The scores of state-anxiety can be divided into 3 categories: low anxiety (scores 20-39), medium anxiety (scores 40 - 59) and high anxiety (scores 60 - 80) (23), although usually a cut-off score  $< 40$  and  $\geq 40$  is used (21). The **Center for Epidemiological Studies Depression Scale** (CES-D) consists of 20 items scored on a 4-point Likert scale (24). In this study the total score of the CES-D was used as a measure of depressive symptoms (range from 0 to 60); higher scores indicate more depressive symptoms (25). A cut-off score of  $\geq 16$  identifies patients with probable clinical depression (26).

Clinical and demographic data, such as age, marital status, income, gender, education, employment, religion and type of treatment, were collected from the medical records and by subject interview.

### **Statistical Analyses**

The data were analysed using the statistical package SPSS for Windows, version 10 (27). Chi-square ( $\chi^2$ ) test was used to assess whether there were any differences between the treatment modalities regarding age, marital status, income, gender, education, employment, and religion. MANOVA for repeated measures was used to investigate differences between the two treatment modalities over time (28, 29). The independent variables were treatment (implantation of an ICD or no ICD implantation), anxiety or depressive symptoms measured at baseline. To distinguish between the two treatment groups with regard to the effect of therapy, pre-treatment scores were used as covariates. We used the Helmert contrast to look at differences between 1 (T<sub>2</sub>) and 6 months (T<sub>3</sub>), and between 6 months (T<sub>3</sub>) and 12 months (T<sub>4</sub>).

### **Results**

Of all 168 cardiac arrest survivors, 133 (79%) received an ICD treatment and 35 (21%) received other treatment (OT patients). There were no differences between ICD patients and OT patients regarding gender, religion, education, work, and income (Table 2). ICD patients were significantly ( $p = 0.03$ ) younger than OT patients (mean age  $\pm$  SD 55.2  $\pm$  13.7 years versus 61  $\pm$  12.8 years).

The results of the MANOVA (the mean values and standard deviations) are shown in table 3; the pre-treatment scores (T1) are not depicted because they were used as covariates. The prevalence of high anxiety and probable depression (CES-D score  $\geq$  16) is given in table 4.

Table 2

**Characteristics of patient population**

Patients who received an Implantable Cardioverter Defibrillator or other treatment

	n = 133		n = 35	
	ICD <sup>†</sup>		OT	
	n	%	n	%
<b>Gender</b>				
female	35	26.3%	8	22.9%
male	98	73.7%	27	77.1%
<b>Work status</b>				
employment	27	24.1%	7	20.0%
unemployment	32	20.3%	2	5.7%
retired	26	19.5%	10	28.6%
disability leave	19	14.3%	3	8.6%
unknown	29	21.8%	13	37.2%
<b>Marital status</b>				
married/living together	84	63.2%	23	65.7%
divorced	5	3.8%	1	2.9%
widowed	10	7.5%	3	8.6%
unmarried	9	6.8%	0	
unknown	25	18.8%	8	22.9%
<b>Education</b>				
primary education	28	21.1%	7	20.0%
secondary education	36	27.1%	7	20.0%
tertiary education	18	15.0%	3	8.6%
unknown	51	38.3	18	51.4%
<b>Deaths during study period</b>	9	6.7%	2	5.7%
<b>Comorbidity</b>				
myocardial infarction	64	48.2%	21	60.0%
hypertension	14	10.5%	5	14.3%
diabetes	4	3.0%	1	2.9%
COPD	6	4.5%	0	
<b>Ejection fraction</b>				
< 20	9	6.8%	1	2.9%
20 - 39	33	24.8%	9	25.7%
40 - 59	21	15.8%	2	5.7%
60 - 79	9	6.8%	1	2.9%
unknown	61	45.9%	22	62.9%
<b>Mean age</b>	mean 55.24 / st.dev 13.7		mean 61.04 / st.dev 12.81	

Table 3

**Adjusted means and standard deviation for the quality of life, psychological well-being, anxiety and depression in patients who received an Implantable Cardioverter Defibrillator or other treatment**

	ICD patients						OT patients											
	t2	mean	SD	t3	mean	SD	t4	mean	SD	t2	mean	SD	t3	mean	SD	t4	mean	SD
<b>RAND-36 scores</b>																		
physical functioning	62,3	25,1	68,2	25,0	69,6	26,2	67,9	21,7	74,6	15,5	79,2	20,6	68,2	23,5	79,1	26,2	76,5	25,3
social functioning	57,8	29,7	72,5	23,2	73,4	25,5	68,2	23,5	79,1	26,2	76,5	25,3	39,1	25,6	58,6	28,8	70,6	27,8
health change	38,7	25,6	54,6	27,1	67,8	26,6	39,1	25,6	58,6	28,8	70,6	27,8	63,3	44,4	71,6	36,3	75,0	41,7
emotional role limitations	55,1	46,0	68,4	42,4	68,6	42,6	46,0	46,5	55,2	45,3	75,0	34,3	28,1	37,6	53,9	45,4	53,6	43,3
physical role limitations	28,1	37,6	53,9	45,4	53,6	43,3	46,0	46,5	55,2	45,3	75,0	34,3	66,1	21,0	70,1	19,0	70,9	19,6
mental health	66,1	21,0	70,1	19,0	70,9	19,6	72,6	21,0	74,7	20,1	75,6	20,3	54,7	21,6	58,4	20,5	59,5	21,9
vitality	54,7	21,6	58,4	20,5	59,5	21,9	60,6	19,7	65,8	23,9	66,8	21,8	24,9	13,0	86,1	20,9	86,3	21,6
pain	24,9	13,0	86,1	20,9	86,3	21,6	25,8	12,9	84,9	20,6	95,8	9,6	57,6	16,0	57,4	15,7	58,6	14,5
health perception	57,6	16,0	57,4	15,7	58,6	14,5	65,2	14,9	61,0	18,2	64,7	21,2						
<b>HPPQ</b>																		
well-being	23,9	6,7	25,9	6,2	25,0	3,4	26,5	6,0	27,6	6,0	25,5	2,3	25,6	5,4	25,4	6,0	25,5	2,6
feelings of being disabled	25,6	5,4	25,4	6,0	25,5	2,6	24,3	5,1	23,9	5,9	24,5	2,4	16,8	5,5	16,5	4,9	16,7	5,1
displeasure	16,8	5,5	16,5	4,9	16,7	5,1	15,5	5,5	15,2	4,9	15,8	4,8	11,4	2,8	11,3	2,7	11,3	2,6
social inhabitanacy	11,4	2,8	11,3	2,7	11,3	2,6	10,5	3,0	11,0	2,8	11,1	2,3						
<b>STAI</b>																		
trait-anxiety	38,9	13,1	38,0	13,2	37,5	12,6	34,9	11,9	35,0	11,4	35,0	11,8	41,6	12,2	40,2	11,7	39,2	11,3
state-anxiety	41,6	12,2	40,2	11,7	39,2	11,3	37,1	11,3	35,7	9,0	37,2	11,7						
<b>CES-D</b>																		
depressive symptoms	13,3	11,0	12,2	10,3	11,6	10,4	9,7	7,9	8,5	8,1	9,6	8,2						

t2 = 1 month after discharge; t3 = 6 months after discharge; t4 = 12 months after discharge

Table 4 **Prevalence of anxiety and depression in patients who received an Implantable Cardioverter Defibrillator or other treatment (OT patients)**

	ICD patients				OT patients			
	t1	t2	t3	t4	t1	t2	t3	t4
STAI >= 40	61%	49%	49%	42%	47%	34%	28%	31%
CES-D >= 16	37%	37%	38%	32%	35%	31%	24%	27%

t1 = before treatment; t2 = 1 month after discharge; t3 = 6 months after discharge; t4 = 12 months after discharge

With regard to all subscales of generic quality of life (RAND-36), the two treatments differed significantly ( $p = 0.05$ ) only for the subscale “pain”, and nearly significantly ( $p = 0.06$ ) for the subscale “physical role limitations”. Physical functioning ( $p = 0.04$ ), mental health ( $p = 0.02$ ), and social functioning ( $p < 0.001$ ) improved with time in both treatment groups. Vitality, emotional role limitations, and health perception did not change substantially over time. Physical functioning, mental health, and social functioning did not improve further after 6 months.

Between 6 and 12 months, ICD patients perceived significantly less pain than OT patients over the same period, ICD patients did not feel limited by their physical limitations (physical role limitations stabilized) whereas OT patients felt more limited by their physical functioning.

Gender and age were used as extra independent variables in the MANOVA procedure. Results showed there was an interaction between gender and time ( $p = 0.03$ ). Women had a poorer social functioning over time than men. An interaction was also found between age and time (for the subscales health change,  $p = 0.03$ ; and vitality,  $p = 0.01$ ). Patients older than 60 perceived less improvement in health than did patients younger than 60 ( $p = 0.03$ ). Vitality improved in patients older than 60 and deteriorated in patients younger than 60.

In general, OT patients achieved a better quality of life than ICD patients. Compared with normative data for a healthy Dutch population, the ICD group scored worse at 12 months after discharge on all subscales, except for health change and pain. Hardly any differences were found when the scores of the OT group were compared with those of a healthy Dutch population: OT patients did less well on social functioning and vitality, but better on health

change and pain. The significant improvement in health change and pain is to be expected because survivors of a cardiac arrest have a different frame of reference from that of a healthy population.

The psychological well-being questionnaire (HPPQ) did not establish any differences between the two treatment modalities. However, there was a significant improvement in psychological well-being, except for 'displeasure'. Well-being improved significantly ( $p < 0.001$ ) from 6 to 12 months, but only tended to improve from 1 to 6 months ( $p = 0.08$ ). 'Feelings of being disabled' decreased significantly ( $p < 0.001$ ) from 6 to 12 months. The same applied for 'social inhibition' ( $p = 0.02$ ). Psychological well-being was not influenced by gender. However, an interaction was found between age and time for the subscale 'displeasure'. With time, people younger than 60 years felt less pleasure whereas people older than 60 perceived more pleasure.

Anxiety and depressive symptoms did not change significantly between 1 and 12 months after discharge. The cut-off scores  $< 16$  and  $\geq 16$  of the CES-D and  $< 40$  and  $\geq 40$  of the STAI were used as two extra independent variables in the MANOVA procedure, to examine the effect of the different levels of depressive symptoms and anxiety on the quality of life. A significant three-way interaction ( $p = 0.03$ ) was found between treatment, level of depressive symptoms, and social functioning with time (figure 1). We also found a significant three-way interaction ( $p = 0.003$ ) between treatment, level of anxiety, and health change with time (figure 2).

Figure 1. High and low depressive symptoms and social functioning of ICD and OT patients over time.

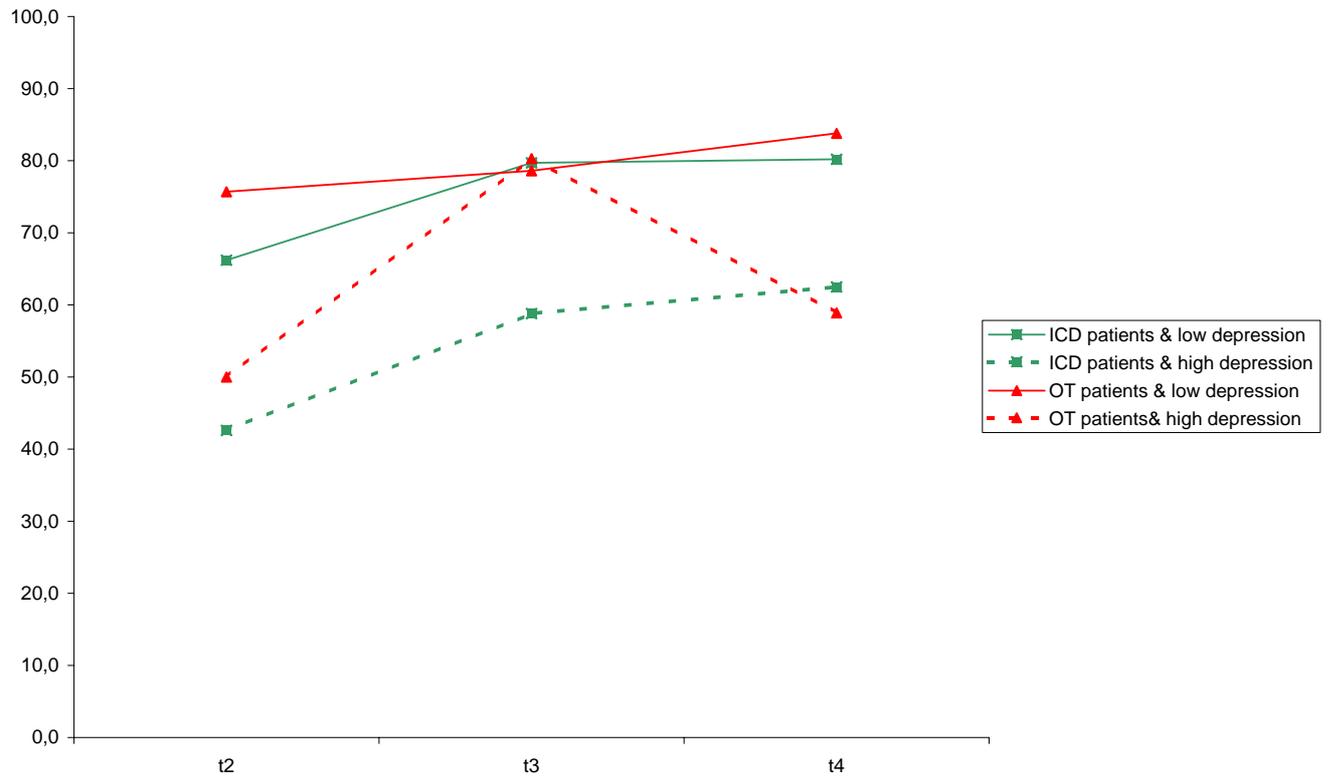
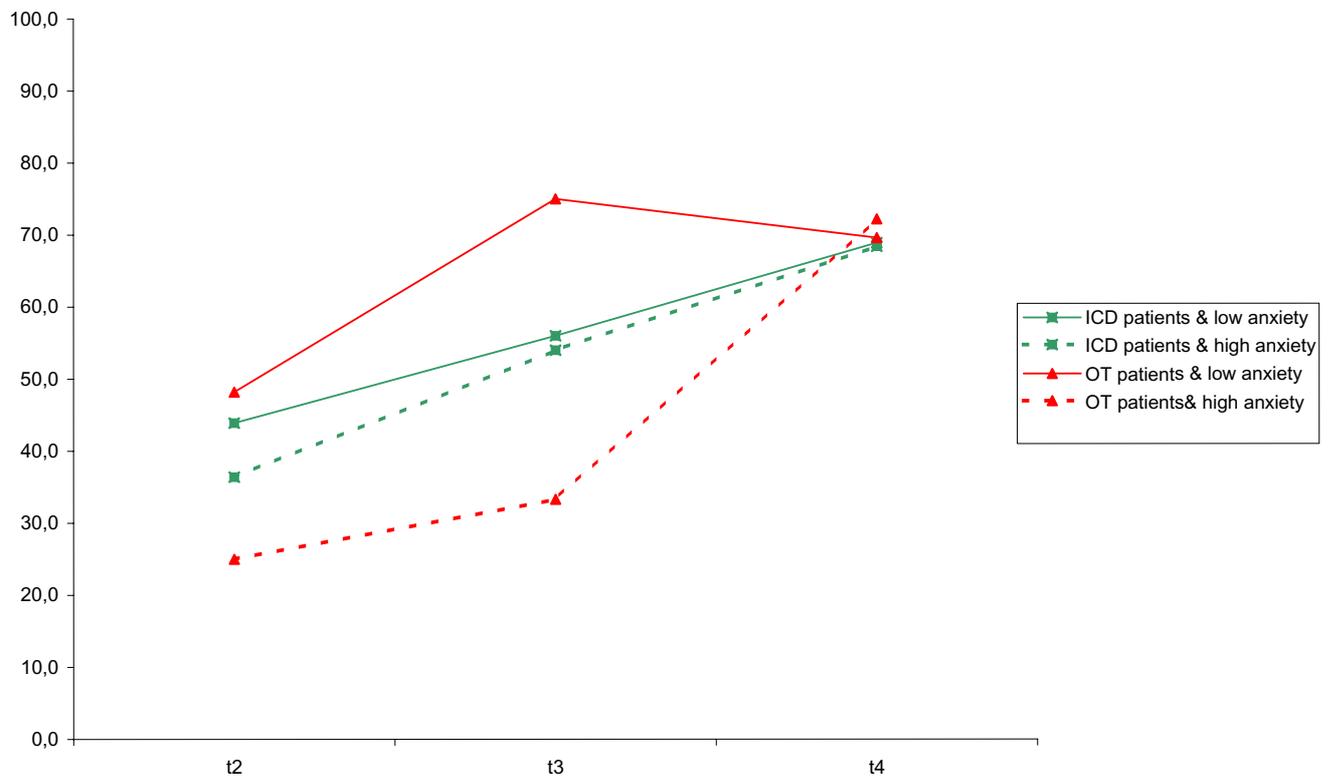


Figure 2. High and low anxiety scores and health change in ICD and OT patients over time



## Discussion

A few studies have investigated quality of life issues in patients who have received an ICD. To our knowledge, there are no other prospective studies that evaluated patients over 12 months and which had pre-treatment baseline data. Lüderitz et al (15) and Dougherty et al (30) both focussed on the expectance of the ICD, like our study, but they did not have pre-treatment baseline measures. Furthermore they both examined other variables (Dougherty concentrated on anxiety, depression, and coping, while Lüderitz used a specifically designed questionnaire and the STAI (measuring anxiety)). This makes it difficult to compare our results with those of other studies.

In general, OT patients achieved a better quality of life than ICD patients. Compared with normative data for a healthy Dutch population, the ICD group scored worse at 12 months after discharge on all subscales, except for health change and pain.

The quality of life improved significantly in all patients in the first 6 months but did not improve further in the next 6 months. Physical functioning, mental health, social functioning, physical role limitations, and pain did not improve further in the last six months. Cooper et al. (31) and Dubin et al. (10) reported a similar decrease in social interaction. Carroll et al. (11), using the SF-36, found an improvement in the first 6 months regarding physical health and mental health, but they did not study later time points. May et al (7), came to another conclusion: using the Sickness Impact Profile (SIP), quality of life declined initially but then improved, and at 12 months returned to pre-implant levels. Like Herbst et al (8), we found no significant decrease in the quality of life (except for pain) of patients with and without an ICD.

The improvement in quality of life in the first six months after hospitalization may be explained by the long hospitalization admission. Most of the patients studied were admitted for as long as 2 and in some cases even 3 months. It is most likely that quality of life declined during the long hospitalization phase and after 6 months returns to pre-resuscitation levels. To further improve the study design quality of life assessment should take place very shortly after admittance. Another explanation for the quality of life improvement during the first six months

is that patients feel relieved to have survived the cardiac arrest and feel more safe due to the treatment they have received.

Anxiety and depression are related concepts and together are an indication of the level of distress. Both our groups were relatively distressed, with significantly higher scores than those of a healthy population, and this did not change after discharge. Dougherty (15) reported a decrease in anxiety and depression after a year; we did not find this. Lüderitz et al. (30) reported that anxiety before and after ICD implantation decreased slightly, but non-significantly, during the follow-up period of 12 months. Herbst et al. (8) found no significant differences in psychological distress between patients with or without an ICD. Our findings were similar. This is most likely because both groups had survived a life-threatening event, and the distress they experienced may be of more influence on quality of life and well-being than the treatment received.

It is presumed that ICD-therapy delivery (shocks) elicits negative affective reactions such as anxiety and depression (32) (33). A subanalysis of the incidence and influence of ICD-therapy delivery (shocks) on quality of life was carried out. Quality of life was not influenced by ICD-therapy delivery except that ICD recipients who received shocks felt significantly ( $p = 0.051$ ) more limited in their physical functioning.

Probable depression had a substantial influence on social functioning. Patients from both treatment groups who had high levels of depressive symptoms showed an improvement in social functioning in the first 6 months but this improvement disappeared in the next 6 months. The level of anxiety appeared to influence the perceived change in health. While in ICD patients health improved over time regardless of the level of anxiety, in the OT patients with low anxiety health improved more, but diminished 6 to 12 months after discharge, whereas in the OT patients with high anxiety health improved over time. One year after implantation all patients had similar scores.

The influence of gender and age on quality of life and psychological well-being were marginal. Women felt limited in their social interaction but this was not influenced by the type

of treatment. Older patients indicated that they felt more vital. Vitality improved significantly in the 12 month follow-up period. Comparison of older and younger patients over the 12-month period, showed a greater, but non-significant, improvement in mental health, emotional role limitations, social functioning, pain, and health perception in the older patients.

The data of those who died during the study were not analysed as most of the patients died during the first six months of the study, and therefore only pre-treatment and 1-month postdischarge data was available. The medical cause of these deaths was not documented. The reason for this is that the patients died in other hospitals than where ICD implantation took place.

The principal goal of the present investigation was to determine if there are any differences in changes in quality of life and psychological well-being between patients who received an ICD and patients who received other treatment. All patients had survived a life-threatening event. In an earlier study, Kolar and Dracup (34) recognized that sudden cardiac death survivors feel stronger for having lived through the worst thing that would probably ever happen to them. Our results suggest that survival had a greater impact on quality of life and well-being than the type of therapy received after the event.

### ***Limitations of the study***

There are several potential limitations of this study. The influence of social support, (psychological & medical) evaluation of cognitive and physical performance, mobility (such as the effect of driving restrictions), and drug therapy were not taken into account. As far as we know no information exists about the influence of treatment-related aspects, such as side effects of drug-therapy, ICD-related restrictions of activities of daily living (ADL-activities), on quality of life in the area of cardiac arrest survivors. We did not collect information on these variables. In future research these variables should be studied, especially the influence of drug-therapy influencing mental health (e.g. depression). Both our groups are relatively distressed therefore the role of mental health should receive more attention in future studies. As clinical and

population based studies indicate that depressive symptoms have significant effect on daily functioning and ability to work (21).

Another limitation is the small size of the control (OT) group. The reason for this small group is that during the data collection period ICD-therapy became the first-choice therapy for cardiac arrest survivors. The control group primarily received drug-therapy and in some cases received revascularisation and surgical treatment. We did not analyse the quality of life within this small group of patients as the focus of our study was to assess and compare quality of life and (psychological) well-being in cardiac arrest survivors who received an ICD with those who did not receive a ICD.

A larger number of patients would have enabled us to take the diversity of therapies for life-threatening arrhythmias into account. To be able to assess the effect of therapy on quality of life, we believe that a comparison with myocardial infarction patients should be considered. An infarction can also be considered to have a great impact on a person's life and is perceived as life-threatening even though it does not lead to out-of-hospital cardiac arrest in the majority of cases.

The focus of our study was on patient perceived quality of life and (psychological) well-being rather than on the impact of disease-related variables. We acknowledge that we assessed patient perceived quality of life. We did not evaluate disease-related variables and their effect on quality of life. Even though it is debatable, the patient is the only appropriate person to assess his or her own quality of life. The outcome of our study indicates that from a patient perspective quality of life is not influenced by the choice of treatment but rather by having survived a cardiac arrest.

As we found that quality of life did not improve further 6 months after discharge, which we think might be a temporary effect, we recommend that the time period over which quality of life is assessed in longitudinal studies should be extended to 2 to 5 years after discharge. The medical and nursing profession should give attention and support to those with probable depression, female patients, and those younger than 60 years because these groups appear

to be susceptible to impaired well-being and quality of life after treatment.

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Chapter 4

**Predictors of quality of life in survivors of cardiac arrest treated  
with an Implantable Cardioverter Defibrillator.**

Submitted British Journal of Health Psychology

## **Abstract**

Background: This study focuses on predicting quality of life at 12 months in ICD recipients. Quality of life may be compromised in ICD recipients. It is therefore important to determine which factors predict quality of life and depression in ICD recipients.

Objective: To examine whether depression and quality of life at 12 months can be predicted by factors measured before ICD implantation during hospitalization.

Methods: Patients (n = 128) completed a questionnaire before ICD implantation and 1, 6 and 12 months post-discharge measuring quality of life, psychological well-being, anxiety, depression, coping, and social support.

Results: Recipients with a poor physical functioning and feelings of displeasure during hospitalization were more likely to experience a poorer general quality of life at 12 months. Appraisal support and good mental health at baseline were associated with less depressive symptoms at 12 months. Neither gender, age, coping, or having had a myocardial infarction were predictors of quality of life, or depression.

Focusing only on recipients who experienced ICD discharges we found that a poor appraisal support and emotional role limitations during hospitalization predicted depressive symptoms one year after implantation. We found the prevalence of possible clinical depression to range from 31 to 37%.

Conclusions: Mental health, appraisal support, feelings of displeasure, and physical functioning were predictors of poor quality of life and depressive symptoms in ICD recipients at 12 months. Pre-treatment assessment can be used to identify patients at risk for poor quality of life and depression.

## **Keywords:**

ICD, arrhythmia, cardiac arrest, quality of life, depression, anxiety, coping and social support

## Introduction

In the Netherlands more than 50.000 deaths a year are due to cardiovascular disease alone, accounting for 37% of all death causes. In 1997 about 24% of all cardiac mortality was related to conduction disorders and arrhythmias (1). An ICD is a device designed to treat malignant ventricular arrhythmia by defibrillation and provides antitachycardia pacing to prevent sudden cardiac death. Although the list of indications for ICD therapy is expanding, to date in the Netherlands ICD therapy is primarily used in survivors of sudden cardiac arrest.

The ability to prevent cardiac arrest by using ICD therapy has significantly improved survival (2) (3). Learning to live with an Implantable Cardioverter Defibrillator (ICD) is a dynamic process which might affect individuals differently. In this study, we will examine which factors can predict health-related quality of life and depression 1 year after discharge from the hospital.

In recent years, more studies have focussed on the quality of life of ICD recipients. Results of these studies are however often contradictory. A decline in quality of life has been described when comparing ICD recipients with those patients who were treated with anti-arrhythmic drugs (3, 4, 5, 6) . While others found an improvement in quality of life when compared to drug therapy (7, 10). May (11) found a decline in quality of life in ICD recipients in the first six months where after it improved to pre-treatment levels. Two studies indicated that quality of life is not affected by having an ICD, as quality of life and psychological distress are maintained (12, 13). However, some researchers have shown increased psychological distress among ICD recipients (8, 9).

Typically, ICD patients are marked by mood-destabilizing events such as surviving cardiac arrest, long hospitalization and invasive electrophysiologic testing (14). During hospitalisation, patients are often confronted with their mortality, sometimes for the first time, and the future becomes uncertain. Further, the patients are confronted with the unpredictability of the reoccurrence of malignant arrhythmias (15).

After a long diagnostic phase, some patients will receive an ICD, and are usually

discharged from hospital within three days after implantation. At home, patients are faced with psychological and social adjustment to a new situation and find themselves dependent on an implanted device to keep them alive, should they experience recurrence of life-threatening ventricular arrhythmias. Some ICD patients will eventually experience appropriate or inappropriate ICD discharges (shocks).

Despite increasing interest in quality of life as an endpoint in medical research, still little is known about the factors which determine quality of life, and depression one year after ICD implantation. Yet it is important to be able to predict quality of life in ICD recipients so that patients who need support and/or psychosocial care can be targeted. Research on predicting quality of life in survivors of cardiac arrest treated with an ICD is limited to a few studies. A cross-sectional study on the long-term physical and psychosocial adaptation of ICD recipients showed that emotional responses to distress were predictive of little physical activity and psychological distress. Men and young ICD recipients who used a problem-focussed coping style in contrast to emotion-focussed coping style reported a better physical functioning (16). Likewise patients with an ICD who tend to be emotion-focussed were likely to experience psychological distress, and have poorer social and domestic adaptation. In other words, the use of problem-focussed coping was predictive of better physical and psychosocial functioning. A longitudinal study done by Dunbar et al (17) revealed that age, sex, optimism, functional status, and history of sudden cardiac arrest accounted for 47% of the variance in total mood disturbance (as measured by the Profile of Mood States questionnaire). Predictors for a poorer functional status (as measured by the Heart Failure Functional Status Inventory) and mood disturbances were female sex, less optimism, higher threat appraisal and more use of evasive coping behaviour. Burgess found that psychological distress (as measured by the Symptom Check List-90 revised) was associated with diminished physical activity (38% of the variance). In this study the number of (appropriate) ICD discharges was not statistically related to psychological distress, however the number of inappropriate ICD firings was a significant predictor of psychological distress accounting for 19% of the variance (18).

Depression and anxiety may interfere with good emotional and social functioning (19) (11) (20) (21) (22) (23). Between 15-58% of ICD recipients are found to be psychologically distressed and/or had psychiatric disorders (13), (24), (8), (25). It is believed that depression may be a delayed reaction to cardiac arrest and ICD implantation because it generally takes time for patients to fully understand the implications of their condition (17).

Although the ICD may prolong survival and prevent a re-occurrence of a cardiac arrest, quality of life may be compromised in ICD recipients and it is therefore important to know more about the factors that determine quality of life, and depression in ICD recipients. The aim of our study was to determine whether depression and quality of life at 12 months can be predicted by factors measured before ICD implantation. Once these factors are identified, this knowledge may help to identify which patients need additional support and psychosocial care.

## **Methods**

### Study population

The study sample consisted of cardiac arrest survivors who had an ICD implanted at the University Hospital Groningen, University of Maastricht, and Heart Lung Center Utrecht (a collaboration of the University Medical Center Utrecht and St. Antonius Hospital, Nieuwegein) in the Netherlands.

Participants were eligible for this study if they were older than 16 years, comprehended Dutch, and were given an ICD after having survived an out-of-hospital cardiac arrest. In total 133 patients met the inclusion criteria, of whom 128 participated at all four measurements. Five patients died during the study: four died during the first 6 months and one patient died during the last 6 months of this 12-month study.

## Study design

All patients completed a questionnaire before extensive cardiac evaluation, and at 1, 6, and 12 months postdischarge. The questionnaire contained questions about: sociodemographic characteristics (age, marital status, children, living situation, religion, educational level, previous myocardial infarction), medical history, quality of life, well-being, coping, depression, anxiety, and social support. At follow-up patients were asked about changes in marital status and living situation.

## Measures

Generic quality of life was measured with the Rand-36 (26) (27), which contains the following 9 subscales: physical and social functioning, role limitations due to physical problems and/or emotional problems, bodily pain, vitality, general mental health, general health perception, and health change. The higher the score on individual subscales, the better the quality of life.

Well-being is measured with a disease specific questionnaire. The Heart Psychosocial Patient Questionnaire (HPPQ) (28) comprises 52 items scored on a 3-point Likert scale. The HPPQ was devised specifically for cardiac patients. Four dimensions are measured: well-being, feelings of disability, displeasure, and social inhibition. A high score on the well-being dimension indicates a high degree of well-being, whereas high scores on the other three dimensions indicate a poor psychological condition.

Anxiety was measured with the State-Trait Anxiety Inventory (STAI-DY) (29), which consists of 40 items with a 4-point Likert scale. The trait measure (20 items) reflects a more stable personality characteristic, while the state measure (20 items) reflects a transient characteristic (30). Applying Spielberger's recommended cut-off of 39/40 on the STAI sum score (31), we can identify patients with significant anxiety symptoms.

Depression was measured with the Center for Epidemiological Studies Depression Scale (CES-D), which consists of 20 items scored on a 4-point Likert scale (32). In this study the total score of the CES-D was used as a measure of depressive symptoms (33). A score of  $\geq 16$  on

the CES-D is used as an indication for depression, with the recommendation that respondents scoring  $\geq 16$  should be screened for a diagnosis of major depression (34).

Social support was measured with the Social Support List Interactions. This questionnaire contains 34 items with a 4-point Likert scale, measuring emotional support, support stressful situations, instrumental support, appraisal support, and informative support. These five subscales can be combined in one overall measure of social support (35). The total score for social support indicates the social support received in general and in stressful situations.

Coping was measured with a shortened version of the Utrecht Coping List (36). The 17-item version encompasses the following subscales: active problem solving, seeking support, religious coping, avoidance and palliative coping. This questionnaire measures coping as a trait, the way a person copes with problems in general (37).

Social activities and sexuality were measured using two subscales of the EORTC Quality of Life Core Questionnaire-H&N35 (38). The subscale 'social activities' consists of 5 items with a 4-point Likert scale and the subscale 'sexuality' contains two items with a 4-point Likert scale.

### Statistical Analyses

The data were analysed using the statistical package SPSS for Windows, version 10 (39). Both the Rand-36 and the HPPQ do not have a total/overall score for quality of life. For the purpose of this study we therefore performed a factor analysis. The factor analysis was used as a reduction scheme indicating which variables cluster together allowing us to get an overall score for quality of life (40). The 9 subscales of the Rand-36 and the 4 subscales of the HPPQ were grouped to form two new constructs. We are simply transforming the original variables into a new set of linear combinations. In table 1 we provide an overview of the sub-scales belonging to the two constructs. They are: general quality of life (GqoL) and perceived health change (PHC). As the number of variables per component are important we only used those components with four or more loadings above .60 (40). For Gqol the following variables (sub-scales) were disregarded: health change and well-being. Four loadings meet the criteria to

make up the second construct. However, as two of the loadings , social functioning and vitality, also loaded for Gqol we choose not to use this new construct as only two components were left to predict perceived health change at 12-months.

**Table 1. Deriving factors and assessing overall fit of the rand-36 and HPPQ at 12 months**

	component 1	component 2
<b>Rand-36</b>		
physical functioning	0,71	
social functioning	0,68	0,60
health change		0,88
emotional role limitations	0,75	
physical role limitations	0,62	
mental health	0,69	
vitality	0,68	0,62
pain	0,70	
health perception	0,68	
<b>HPPQ</b>		
well-being		0,65
feelings of being disabled	-0,73	
displeasure	-0,70	
social inhibition	-0,67	

Multivariate analyses of variance for repeated measures were used for the comparison of the average scores of the Rand-36, the HPPQ, the CES-D, and the STAI over time (40, 41).

In order to determine predictors of depression and quality of life at 12-months a stepwise multiple regression analysis was performed. The total score of the CES-D, and the new construct, Gqol, were used as dependent variables. The first set of variables entered were all the subscales of the Rand-36 and HPPQ. The next set contained: gender, age, previous myocardial infarction, ICD discharges, emotional support, support stressful situations, instrumental support, appraisal and informative support, active problem solving, seeking support, religious coping, avoidance and palliative coping, and sexuality. The above described procedure was repeated for those patients who had experienced shocks during the first year after implantation.

## Results

The mean values at baseline, and at 1, 6 and 12 months of all scales of the questionnaire are shown in Table 2. At 12 months, all the sub-scales of the Rand-36, except for health perception, had significantly improved. The improvement mostly occurred in the first 6 months after discharge. For the HPPQ only well-being improved over time.

**Table 2. Mean values of scales and single items of questionnaires**

Manova					
	baseline	1 month	6 months	12 months	
<b>RAND-36 scores</b>	mean	mean	mean	mean	p-value <sup>5</sup>
physical functioning	59.8	62.3	68.8 <sup>2,4</sup>	69.9	p < 0.001
social functioning	44.0	58.2	73.0 <sup>2,4</sup>	74.0	p < 0.001
health change	37.3	38.9 <sup>1</sup>	54.5 <sup>2,4</sup>	68.2 <sup>3</sup>	p < 0.001
emotional role limitations	46.9	55.7	68.8 <sup>2,4</sup>	69.0	p < 0.001
physical role limitations	32.0	29.4	55.2 <sup>2,4</sup>	54.9	p < 0.001
mental health	64.8	66.2	70.7 <sup>2,4</sup>	71.9	p < 0.001
vitality	58.3	55.0	58.8 <sup>2</sup>	60.6	p < 0.001
pain	79.1	25.2 <sup>1</sup>	86.8 <sup>2,4</sup>	86.6	p < 0.001
health perception	59.3	58.1	57.1	59.2	N.S
<b>HPPQ</b>					
well-being	23.5	24.1	26.1 <sup>2,4</sup>	25.0 <sup>3</sup>	p < 0.001
feelings of disability	24.6	25.4	25.2	25.4	N.S
displeasure	17.0	16.7	16.3 <sup>4</sup>	16.5	N.S
social inhibition	11.1	11.4	11.3	11.3	N.S
<b>STAI</b>					
State anxiety	44.4	41.2	39.8 <sup>2,4</sup>	38.9	p < 0.001
Trait anxiety	38.1	38.6	37.6	37.1	N.S
anxious personality					
Percentage with total score >= 40	40%	41%	42%	41%	
<b>CES-D</b>					
totale score	13.5	13.0	11.8 <sup>4</sup>	11.3	N.S
depressive symptoms					
Percentage with total score >= 16	36%	36%	37%	31%	

<sup>1</sup> p < 0.01 1 month post discharge compared to baseline (paired t-test)

<sup>2</sup> p < 0.01 6 months post discharge compared to 1 month (paired t-test)

<sup>3</sup> p < 0.01 12 months post discharge compared to 6 months (paired t-test)

<sup>4</sup> p < 0.01 6 months post discharge compared to baseline (paired t-test)

<sup>5</sup> MANOVA for repeated measures is used for comparison of the means scores at all time points

N.S = Not Significant

A large percentage of patients were anxious and depressed at all measurement times (see Table 1). Approximately 40-42% of all ICD patients were suffering from significant anxiety symptoms (STAI cut-off score 39/40) and 31-37% have a probable depression (CES-D  $\geq$  16). Compared to a healthy population, ICD recipients had significantly higher scores on both the CES-D and the STAI (32) (29).

In the stepwise multiple regression analyses, the focus was on whether depressive symptoms, and quality of life at 12 months could be predicted by variables measured at baseline. As shown in Table 3a, two variables (mental health and appraisal support) measured before treatment accounted for 41% of the variance in depressive symptoms reported at 12 months. General quality of life 1 year after ICD implantation can be predicted by physical functioning and displeasure measured during hospitalization (explaining 41% of the variance).

Neither gender, age, coping style, ICD discharges or having had a myocardial infarct were predictors of quality of life and depression at 12-months.

Table 3a.

**Multiple regression analyses: variables measured at baseline, predicting depressive symptoms, and general quality of life at 12 months post-discharge of ICD-recipients (n = 128)**

	R <sup>2</sup>	R <sup>2</sup> -change	B*	p-value	* Standardized regression (coefficient of the last mode)
depressive symptoms					
mental health	34%		-0,54	<0.0001	
appraisal support	41%	7%	-0,28	0.017	
general quality of life					
physical functioning	32%		0,45	0.002	
displeasure	41%	9%	-0,35	0.013	

In the second phase of this analysis (table 3b) we only focussed on those patients who had experienced ICD discharges during the first year after implantation. According to Schron et. al. an ICD can have an adverse effect on both physical functioning and mental well-being (42),

we therefore tried to see whether we could predict Gqol and depression at 12 months. We found no factors that could predict Gqol at 12 months post-discharge.

Table 3b.  
**Multiple regression analyses: variables measured at baseline, predicting depressive symptoms at 12 months post-discharge of ICD-recipients who have experienced a shock (n = 35)**

	R <sup>2</sup>	R <sup>2</sup> -change	B*	p-value
depressive symptoms				
emotional role limitations	58%		-0,87	<0.0001
appraisal support	90%	32%	-0,57	0.004

\* Standardized regression (coefficient of the last mode)

We, however, did find that emotional role limitations and appraisal support were predictors for depressive symptoms. Emotional role limitations and appraisal support as measured during hospitalization accounted for 90% of the variance in depressive symptoms in recipients who had experienced a shock.

**Discussion**

In this study we examined whether it was possible to predict quality of life of ICD recipients 12 months after ICD implantation using variables measured before ICD implantation. Mental health, appraisal support, displeasure and physical functioning were significant predictors of different aspects of quality of life in ICD recipients. Recipients with a poor physical functioning and feelings of displeasure during hospitalization were more likely to experience a poorer general quality of life at 12 months. Regarding physical functioning this is in accordance with the study of Burgess (18). Appraisal support and good mental health were associated with less depressive symptoms. Neither gender, age, coping, or having had an myocardial infarct

were predictors of quality of life, or depression at 12 months.

Although physical functioning improved over time, ICD recipients had a poor physical functioning compared to a healthy Dutch population at 12 months (26). Whether this prevents a person from having an active lifestyle is hard to conclude from our data. However, Luderitz et al, (43) reported that 47% of ICD recipients were unable to return to an active life and Psychas and Calabrese (20) found that 75% were categorized as completely disabled. Recipients with poor physical functioning during hospitalization may need to receive special attention. A rehabilitation-program may encourage ICD recipients with poor physical functioning to discover new limits, to optimize/improve their physical condition and therefore improve their general quality of life.

Appraisal support was associated with less depressive symptoms and was not associated with a better general quality of life at 12 months. This finding highlights the role that significant others may have in helping the ICD recipient in coping with a stressful event. It may be suggested that future studies should focus on the participation of significant others and the effect of significant others on quality of life of ICD recipients. In our study we were unable to conclude which effect significant others have on the quality of life of ICD recipients.

Depression and low perceived social support are prominently linked to morbidity and mortality in coronary heart disease (44). We however, found no studies that examined the influence of social support and psychological distress in ICD recipients. Our results reveal that people who experienced depressive symptoms at 12 months post discharge were more likely to have experienced less appraisal support during hospitalization. It would be interesting to investigate whether the experience of a stressful event (having survived an cardiac arrest, undergoing a long hospitalization period and receiving an ICD), interferes with the ability to use social support effectively.

Depressive symptoms are common in ICD recipients (13) (24) (8) (25). The researchers reported a prevalence between 17 - 58%. We found the prevalence of possible clinical depression to range between 31 and 36% (one and 12 months post-discharge). A limitation in

this study is that we have no knowledge of psychological distress prior to cardiac arrest. Goodman and Hess (45) found that there was a relationship between the number of ICD discharges and current depression. Although Goodman and Hess did not find a relationship regarding prior history of psychological distress and ICD discharges others have found a relationship between psychological distress and life-threatening arrhythmias (46-49). We did measure psychological distress during hospitalization and prior to ICD implantation. We found that probable depression at 12 months is not explained by depressive feeling measured during hospitalisation but rather by poor mental health. However, these two concepts are related, measuring mood-destabilization.

For future research it would be interesting to see whether psychological distress before cardiac arrest has an effect on perceived quality of life, feelings of depression and ICD discharges. Also the effect of medication should be further studied. As antiarrhythmic drugs may exert either direct or indirect an effect on the central nervous system which may result in producing depressive symptoms in a person. Also the adverse effects of antiarrhythmic drugs, such as drowsiness and fatigue, may impact on the patients moods and sense of well-being (13)

Depressive symptoms did not change over time much (table 2). ICD recipients remain relatively distressed during the first year after implantation, having significantly higher scores than those of a healthy population (29). Dougherty et al (50) reported a decrease in depression 12 months postimplantation, our outcome supports this conclusion. Although compared to normative data for a health population our population is very depressed 12 months postdischarge (32).

We found an improvement in quality of life on all subscales of the Rand-36 except for health perception. This result is in accordance with results of Chevalier et al. (7), Heller et al. (8), Luderitz et al. (9), and Irvine et al. (10). However, compared with normative data for a healthy Dutch population, ICD recipients still had a poorer quality of life at 12 months after discharge (26).

In contrast to our expectations that coping would have a prominent role in explaining

psychological distress at 12 months. In our study, coping did not predict depression and Gqol at 12 months.

In total 133 patients met the inclusion criteria, of whom 128 participated at all four measurements. As compared with other studies (6, 7, 13, 18, 42, 10, 9) where the participation rates lay between 50 - 68 %, we had a high participation rate.

## **Limitations**

The small sample of patients who experienced ICD discharges made the analysis less powerful. The results should therefore be interpreted carefully. Future prospective studies may consider a larger sample of cardiac arrest survivors, with ICD recipients and comparable control group with a comprehensive assessment of premorbid psychological symptoms, physical functioning before cardiac arrest, and the New York Heart association classification criteria to assess disease severity, as these factors may account for the relationship between ICD discharges, psychological distress and quality of life in the first year after implantation.

The focus of our study was on patient perceived quality of life and (psychological) well-being rather than on the impact of disease related variables. We did not evaluate the influence of disease-related variables on quality of life, but we acknowledge that in future research these variables should also be included.

Our measure of depression was based on a self-report measure . We do not know what proportion of patients with an high CES-D score would have been classified as having a major depression according to current psychiatric criteria.

There are many measures (questionnaires) that measure the concept quality of life, one of them being the Rand-36. The Rand-36, however, does not allow for a reduction of variables like the SF-36. In order to get one over-all outcome-measure of quality of life at 12-months we performed a factor analysis. This new construct allows us to say something about the possible predictors of general quality of life at 12-months . However, it still does not make comparison with other studies possible.

## **Conclusions**

Recipients with a poor physical functioning and feelings of displeasure during hospitalization were more likely to experience a poorer general quality of life at 12 months. Appraisal support and good mental health at baseline were associated with less depressive symptoms at 12 months. Neither gender, age, coping, ICD discharges or having had a myocardial infarction were predictors of quality of life and depression.

In recipients who experienced ICD discharges, emotional role limitations and poor appraisal support during hospitalization were an indicator for depressive symptoms one year after implantation.

Received appraisal support, poor physical functioning, poor mental health and feelings of displeasure need to get more attention from healthcare professionals as attention/care for these factors might decrease psychosocial morbidity and improve quality of life after ICD implantation. This needs to be further studied. Pre-treatment assessment during hospitalization can be used to identify people at risk of poor quality of life and depression. Once these persons are identified special attention should be given to this group in out-patient clinics and rehabilitation programs to prevent further psychosocial morbidity.

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Chapter 5

**Implantable Cardioverter Defibrillator recipients: Quality of Life in recipients with and without ICD shock delivery.  
A prospective study.**

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## **Abstract**

Aims: The experiences of patients who experience firing of their Implantable Cardioverter Defibrillator (ICD) and how these events affect their overall adjustment are poorly understood. Our goal is to evaluate quality of life and psychological well-being, and the prevalence of, and changes in, depression and anxiety of patients who did or did not experience defibrillatory shocks in the first 12 months after ICD implantation. In total 167 patients were monitored after discharge. Four self-administered questionnaires were used. The first assessment took place before ICD implantation, the remaining three at 1, 6 and 12 months after discharge.

Results: We classified patients into three shock groups and one no shock group. A small group of ICD recipients (26%) received ICD shock delivery, usually during the last 6 months of the study. Significant differences were found within the groups over time regarding physical role limitations ( $p < 0.051$ ). Those who experienced shocks throughout the year (group 1) felt more limited in their daily activities due to physical or mental problems. All groups reported an improvement in their health ( $p < 0.001$ ). Overall quality of life did not change significantly after 6 months. Anxiety and depression did not change significantly over time. In total 11% - 66% of patients reported clinically significant depressive symptoms throughout the first year, and 31%-83% clinically significant symptoms of anxiety. ICD recipients who had experienced a shock were significantly more anxious one-year postdischarge than those who had not received a shock.

Conclusions: Overall quality of life and psychological well-being did not change in ICD recipients, irrespective of whether they experienced defibrillatory shocks. The high prevalence of depression and anxiety can be interpreted as a response to the perceived physical and mental problems regarding daily activities. Our data indicate that patients who have experienced an ICD shock do not adapt well to living with an ICD, they are more anxious than ICD recipients who received no shocks. However, the anticipation to have another shock after having experienced a shock is less stressful than the first shock experience. We conclude that the lasting psychological distress will not dissipate spontaneously or naturally and that psychosocial interventions may be warranted.

## Introduction

The experiences of those who are faced with the unpredictable firing of their Implantable Cardioverter Defibrillator (ICD) and how these events affect their overall adjustment has hardly been studied. In the Netherlands more than 50,000 deaths a year are due to cardiovascular disease alone, accounting for 37% of all deaths (1). In the past years treatment after a cardiac arrest event has significantly improved survival during follow-up. The AVID (Antiarrhythmics Versus Implantable Defibrillators) Clinical Trial investigators concluded after comparing antiarrhythmic-drug therapy with ICDs in patients resuscitated from near-fatal ventricular arrhythmias that the ICD is superior to antiarrhythmica drugs for increasing overall survival. In a period of three years 36% of the patients who had received antiarrhythmic-drug therapy had died, as opposed to 25% in the ICD group (2) Although the number of indications for ICD therapy is increasing in the Netherlands, ICD therapy is currently used primarily for survivors of cardiac arrest due to life-threatening arrhythmias.

The average ICD recipient has typically been exposed to mood-destabilizing experiences such as surviving sudden cardiac arrest, undergoing long hospitalization and invasive electrophysiologic testing (3). Moreover, the patient is confronted with the unpredictability of the reoccurrence of malignant arrhythmias. During hospitalization the patient is probably confronted with his/her mortality, sometimes for the first time, and the future becomes more uncertain (4).

The World Health Organization (WHO) has defined health as total physical, psychological and social well-being. Following the WHO definition of health, three dimensions are considered relevant for patient perceived quality of life: physical, emotional and social functioning. In this study we chose to zoom in on psychological well-being but did not consider it as a separate entity. Although quality of life after ICD implantation is reported to remain unchanged (5, 6, 7, 8) or to improve after ICD implantation (9), little is known about the long-term effect of having an ICD and how patients' perceive their quality of life. Negative emotions are associated with the unpredictability, and frequency of ICD shock delivery, and depressed mood, anger, anxiety

and uncertainty are common feelings reported by patients with an ICD (10, 11, 12, 13, 14, 15). According to Heller et al (10), 20% - 58% of ICD recipients are depressed, although relatively few patients receive psychiatric medication either before (13%) or after (17%) ICD placement. Pycha and Calabrese, found that approximately 15 to 35 percent of ICD patients were anxious and depressed during the first few years following implantation (16). Other studies showed that the occurrence of ICD shock delivery has no influence on quality of life and psychological distress (5, 17, 18). Most patients adapt well to living with an ICD (19). In the late nineties, Hegel (20) and Dougherty (21) suggested that more research should target the psychological reactions and adjustments to ICD implantation.

The above results suggest that additional evidence from a longitudinal perspective is needed. Our goal is to evaluate quality of life, depression and anxiety in patients who did or did not experience an ICD shock delivery in the first 12 months after ICD implantation.

## **Methods**

### *Study design and questionnaires*

A 12-month longitudinal study was carried out over 48 months at three major university hospitals and one general hospital. The study was approved by the Committee for Ethics in Medical Investigations in all hospitals. For this study 180 patients were approached during 1998 and 1999. During the data collection period 13 patients refused to participate in the study. The sample consisted of 167 consecutive patients who were admitted to the hospitals after an out-of-hospital cardiac arrest. Of all 167 cardiac arrest survivors, 132 (79%) received ICD treatment and 35 (21%) received other treatment, namely, antiarrhythmic drugs, revascularization, or surgery. As we also wanted to examine whether the treatment as such had an effect on quality of life we included the control group in our comparison.

All patients completed a questionnaire shortly after admission (before extensive cardiac evaluation), and at 1, 6 and 12 months after discharge. Information regarding patients' quality of life and psychological well-being was collected by using the RAND-36, HPPQ (Heart Patient

Psychological Questionnaire), STAI (State-Trait Anxiety Inventory), and CES-D (Center for Epidemiologic Studies Depression Scale). The questionnaire also contained items about sociodemographic characteristics and medical history.

Generic quality of life was measured with the RAND-36 (22),(23), which contains 36 items with a 4-point Likert scale. For all 9 subscales, low scores indicate poor physical functioning, social limitations (due to physical and mental problems), physical and mental limitations (due to problems with work or other daily activities), nervousness, depression, tiredness, exhaustion and pain.

Well-being was measured with a disease-specific questionnaire. The Heart Patients Psychological Questionnaire (HPPQ) is a questionnaire developed for heart patients in general. The HPPQ (24),(25),(26), comprises 52 items scored on a 3-point Likert scale. Four dimensions are measured: well-being, feelings of being disabled, displeasure, and social inhibition. A high score on the well-being dimension indicates a high degree of well-being, whereas high scores on the other three dimensions indicates a worse condition (27).

Anxiety was measured with the STAI (28), which consists of 40 items with a 4-point Likert scale. The trait measure (20 items) reflects a more stable personality characteristic, while the state measure (20 items) reflects a transient characteristic (20). Spielberger et.al. suggested a threshold value for the sumscore of 40 for both scales, all higher scores indicating that clinically significant anxiety should be suspected (29).

Depression was measured with the CES-D, which consists of 20 items scored on a 4-point Likert scale (30). A cut-off score of  $\geq 16$  is used to identify patients with probable clinical depression (31).

## Statistics

The data were analysed using the statistical package SPSS for Windows, version 10 (32). Multivariate analyses of variance for repeated measures were used for the comparison of the average scores of the Rand-36, the HPPQ, the CES-D, and the STAI over time (33),(34). The independent variable was whether or not the patient had received an ICD shock delivery. To determine the effect of the independent variable, pre-treatment scores and the scores 1-month after discharge were used as covariates, as patients could only report whether they had experienced an ICD shock delivery retrospectively, at 6 and 12 months after discharge.

## Results

Patient characteristics are given in table 1. ICD recipients were primarily male, married, received secondary education, and were either unemployed or retired (thus having no employment). Slightly less than half of all ICD recipients had a myocardial infarction before their cardiac arrest.

Table 1  
**Characteristics of patient population**  
 Patients who received an Implantable Cardioverter Defibrillator or other treatment

	n = 132		n = 35	
	ICD <sup>+</sup>		no ICD	
	n	%	n	%
<b>Gender</b>				
female	35	26.5	8	22.9
male	97	73.5	27	77.1
<b>Work status</b>				
employment	28	21.2	6	17.1
unemployment	32	24.2	2	5.7
retired	26	19.7	10	28.6
disability leave	17	12.9	5	14.3
unknown	29	22.0	12	34.3
<b>Marital status</b>				
married/living together	84	63.2	23	65.7
divorced	5	3.8	1	2.9
widowed	10	7.5	3	8.6
unmarried	9	6.8	0	
unknown	25	18.7	8	22.9
<b>Education</b>				
primary education	28	21.1	7	20.0
secondary education	36	27.1	7	20.0
tertiary education	18	15.0	3	8.6
unknown	51	38.3	18	51.4
<b>Comorbidity</b>				
myocardial infarction	64	48.2	21	60.0
hypertension	14	10.5	5	14.3
diabetes	4	3.0	1	2.9
COPD	6	4.5	0	
<b>Ejection fraction</b>				
< 20	9	6.8	1	2.9
20 - 39	33	24.8	9	25.7
40 - 59	21	15.8	2	5.7
60 - 79	9	6.8	1	2.9
unknown	61	45.8	22	62.8
	mean	(SD)	mean	(SD)
<b>mean age</b>	55.24	13.7	61.04	12.81

No significant differences were found between the ICD group and the no ICD group, except for age. Patients with an ICD were significantly ( $p = 0.04$ ) younger than patients without an ICD (respectively; mean age 55.24, range 41.5 - 68.9, versus mean age 61.04 range 48.2 - 73.8). When comparing those who had shocks ( $n=35$ ) with those who experienced no shocks ( $n = 97$ ) we found no significant differences regarding age, gender, work, marital status and education.

To examine the impact of shock delivery on quality of life, patients were categorised according to the number of shocks received (table 2).

Table 2

**Patients categorized according to the number of ICD shocks received**

	n	%
group 1 = shocks at both time intervals*	6	4
group 2 = shocks exclusively during the first 6 months (t3)	9	6
group 3 = shocks exclusively during the last 6 months (t4)	20	15
group 4 = no shocks during first year	97	75
total	132	

\* ICD recipients had both shock during the first time span (0 to 6 months postdischarge) and second time span (6 to 12 months)

Those who experienced shocks before the 6 and 12 month assessments were allocated to group 1. ICD recipients in group1 experienced shocks during both time intervals. Group 2 consisted of those patients who only experienced shocks during the first time span of this study (0 to 6 months post-discharge). Those in group 3 experienced ICD shock delivery only during the last 6 months of the study (second time span: 6 to 12 months postdischarge). The fourth group consisted of those patients who did not experience ICD shock delivery. Of all ICD recipients, 26% received ICD shock delivery at some time during the first year after discharge from the hospital of whom 6% had more then 3 shocks. Most of them received an ICD shock between 6 and 12 months after discharge.

The mean values and standard deviations of the quality of life parameters are shown in table 3. As the pre-treatment scores and the scores at one-month postdischarge were used as

covariates, the focus of the MANOVA was primarily on the period from 6 to 12 months postdischarge. With regard to generic quality of life (RAND-36), differences in physical role limitations occurred over time in all patient groups ( $p = 0.051$ ). Patients who experienced ICD shock delivery during both time spans (0 to 6 months and 6 to 12 months) (group 1) felt more limited in their daily activities (a decrease in physical role limitations), whereas patients who had not had ICD shocks (group 4) experienced no change. Physical role limitations improved with time in the other groups. All groups reported a significant ( $p < 0.001$ ) improvement in health (subscale health change) and experienced less pain between 6 and 12 months postdischarge ( $p = 0.067$ ).

Table 3 - a Means and standard deviation for the quality of life, psychological well-being, anxiety and depression in patients

RAND-36 scores	group	pre-treatment scores		1 month		6 months		12 months	
		mean	(SD)	mean	(SD)	mean	(SD)	mean	(SD)
physical functioning	1	51,2	(22,0)	57,4	(27,7)	71,9	(24,4)	65,0	(23,9)
	2	59,6	(30,4)	53,7	(26,5)	60,7	(29,4)	60,7	(37,9)
	3	60,3	(28,1)	68,3	(23,5)	62,8	(24,9)	66,0	(24,9)
	4	60,6	(31,0)	62,2	(25,4)	70,9	(24,4)	72,3	(25,7)
	5	67,3	(26,6)	66,2	(22,7)	71,8	(18,3)	77,4	(20,6)
social functioning	1	35,4	(35,7)	50,0	(30,6)	66,7	(23,3)	66,7	(29,2)
	2	35,9	(36,9)	45,3	(22,1)	65,6	(23,8)	75,0	(28,3)
	3	44,5	(40,6)	66,4	(23,1)	68,0	(27,7)	72,7	(22,5)
	4	45,4	(35,7)	58,5	(32,4)	76,0	(22,1)	75,2	(26,1)
	5	48,5	(37,7)	65,0	(23,7)	75,0	(27,0)	74,0	(24,9)
<u>health change*</u>	1	37,5	(25,0)	37,5	(43,3)	37,5	(14,4)	56,3	(12,5)
	2	28,6	(22,5)	21,4	(22,5)	71,4	(17,2)	64,3	(31,8)
	3	42,2	(28,5)	40,6	(25,6)	48,4	(30,9)	65,6	(28,6)
	4	37,3	(24,3)	40,4	(24,9)	55,4	(28,1)	70,4	(26,4)
	5	34,8	(23,5)	38,0	(21,1)	56,5	(27,4)	68,5	(27,4)
emotional role limitations	1	66,7	(57,7)	0,0	(0)	88,9	(19,2)	55,6	38,5)
	2	46,7	(44,7)	53,3	(50,5)	80,0	(29,8)	60,0	(43,4)
	3	48,7	(50,2)	53,9	(48,1)	71,8	(44,8)	74,4	(41,1)
	4	44,4	(47,1)	58,6	(45,3)	65,4	(43,9)	68,8	(43,9)
	5	53,3	(43,8)	63,3	(44,5)	71,7	(36,3)	75,0	(41,7)
<u>physical role limitations**</u>	1	39,6	42,7	0,0	(0)	56,3	(51,5)	37,5	(43,3)
	2	20,0	44,7	10,0	(13,7)	30,0	(44,7)	55,0	(37,1)
	3	26,8	42,1	34,5	(37,4)	48,2	(42,1)	55,4	(47,2)
	4	32,7	43,3	32,9	(40,7)	60,6	(45,7)	57,2	(43,2)
	5	27,5	40,5	38,8	(45,5)	47,5	(45,8)	66,3	(39,9)
mental health	1	62,4	(26,3)	64,8	(17,3)	64,0	(26,6)	68,8	(21,8)
	2	61,0	(19,9)	64,0	(21,9)	77,5	(16,1)	70,0	(21,7)
	3	62,1	(20,6)	60,5	(21,8)	61,7	(21,3)	66,1	(17,6)
	4	66,4	(22,1)	67,9	(22,1)	72,8	(17,4)	74,0	(19,1)
	5	68,0	(22,8)	70,3	(21,2)	71,8	(20,7)	72,0	(22,4)
vitality	1	45,0	(28,9)	55,0	(20,0)	62,0	(16,0)	61,0	(20,4)
	2	55,0	(19,3)	49,4	(18,2)	55,0	(17,1)	53,1	(27,4)
	3	55,0	(26,5)	52,3	(23,0)	51,2	(24,4)	58,2	(21,6)
	4	61,1	(23,9)	56,4	(21,9)	61,4	(20,2)	62,3	(22,3)
	5	62,2	(24,9)	58,5	(20,7)	63,4	(23,4)	63,3	(21,6)
pain	1	70,1	(34,8)	26,9	(12,9)	72,8	(27,1)	75,9	(30,2)
	2	90,6	(13,5)	23,0	(9,3)	94,6	(11,6)	92,4	(14,2)
	3	74,2	(34,0)	25,8	13,6)	80,2	(26,5)	85,7	(21,6)
	4	79,6	(25,8)	25,0	(13,5)	88,6	(18,1)	87,0	(21,7)
	5	81,1	(27,5)	25,2	(13,0)	82,9	(22,6)	94,7	(11,0)
health perception	1	47,5	(9,6)	58,8	(17,9)	62,5	(21,7)	60,0	(12,2)
	2	53,8	(15,5)	48,1	(11,0)	51,9	(11,0)	51,9	(12,2)
	3	58,8	(13,3)	53,5	(12,9)	56,5	(14,1)	58,2	(11,8)
	4	61,1	(16,5)	61,8	(17,1)	57,9	(16,8)	60,7	(15,3)
	5	62,8	(13,8)	63,6	(14,7)	60,8	(17,2)	61,6	(21,9)

**Group definition**

n = 6 / group 1 = shocks at both time intervals\*\*\*  
n = 9 / group 2 = only shocks during the first 6 months (t3) postdischarge  
n = 20 / group 3 = only shocks during the last 6 months (t4) postdischarge  
n = 81 / group 4 = no shocks during first year postdischarge  
n = 35 / group 5 = treated otherwise (no ICD)

Data in *italic* were used as covariates

\* = changes are significant over time

\*\* = significant changes within the group over

\*\*\* ICD recipients had both shock during the first time span (0 to 6 months postdischarge) and second time span (6 to 12 mc

Table 3 - b

Means and standard deviation for the quality of life, psychological well-being, anxiety and depression in patients

group	pre-treatment scores		1 month		6 months		12 months	
	mean	(SD)	mean	(SD)	mean	(SD)	mean	(SD)
<b>HPPQ</b>								
well-being								
1	24,0	(8,5)	21,5	(7,6)	25,5	(7,1)	25,0	(4,8)
2	22,1	(5,6)	19,8	(4,0)	26,1	(5,2)	24,9	(3,8)
3	23,1	(6,5)	22,2	(6,6)	24,3	(7,1)	24,8	(3,4)
4	23,5	(6,4)	25,0	(7,1)	26,9	(6,5)	25,4	(3,7)
5	26,0	(5,9)	26,3	(6,3)	27,1	(6,3)	25,3	(2,4)
feelings of being disabled								
1	26,7	(8,4)	28,7	(7,1)	26,0	(7,1)	26,2	(3,4)
2	23,6	(7,3)	27,4	(3,6)	27,6	(3,6)	27,0	(2,5)
3	25,1	(6,3)	25,9	(6,0)	26,6	(6,1)	25,9	(2,6)
4	24,3	(6,6)	25,0	(5,7)	25,0	(6,7)	25,3	(2,8)
5	24,9	(7,0)	24,9	(4,9)	24,6	(5,9)	24,9	(2,4)
displeasure								
1	16,0	(5,0)	18,0	(5,5)	16,8	(3,7)	16,7	(4,0)
2	14,4	(4,4)	15,8	(3,6)	13,1	(2,2)	15,2	(5,2)
3	18,9	(5,3)	18,4	(5,8)	17,5	(5,5)	17,9	(5,1)
4	17,1	(4,9)	16,0	(5,7)	15,8	(5,1)	15,8	(5,1)
5	16,0	(4,1)	15,8	(5,0)	15,7	(5,4)	16,1	(5,2)
social inhibition								
1	9,8	(2,3)	11,7	(3,0)	11,0	(2,5)	9,8	(3,5)
2	11,3	(2,6)	10,4	(2,1)	11,3	(2,9)	11,4	(3,5)
3	12,3	(3,2)	12,6	(2,9)	12,4	(3,3)	12,2	(3,0)
4	11,2	(2,9)	11,1	(2,9)	11,0	(2,9)	11,1	(2,7)
5	11,0	(2,8)	10,8	(2,9)	11,1	(2,7)	11,3	(2,2)
<b>STAI</b>								
trait-anxiety								
1	39,1	(17,4)	47,2	(17,2)	40,5	(11,9)	40,7	(14,5)
2	40,5	(13,3)	42,9	(14,6)	35,9	(8,5)	40,9	(9,6)
3	41,7	(10,4)	40,6	(12,9)	42,1	(13,1)	40,0	(12,1)
4	36,8	(11,6)	37,0	(12,4)	36,5	(13,3)	35,7	(12,5)
5	35,0	(11,7)	36,4	(12,2)	37,3	(13,3)	37,1	(12,7)
state-anxiety								
1	44,3	(16,6)	48,5	(14,6)	44,8	(10,9)	43,3	(15,1)
2	44,3	(11,6)	44,9	(11,4)	39,5	(8,4)	42,8	(11,3)
3	47,2	(11,3)	44,3	(11,3)	43,8	(11,4)	43,4	(10,6)
4	43,6	(11,1)	39,5	(12,1)	38,4	(11,7)	37,1	(10,7)
5	41,6	(12,7)	38,8	(11,8)	38,0	(10,7)	39,1	(12,1)
<b>CES-D</b>								
depressive symptoms								
1	16,2	(18,7)	20,2	(12,6)	13,7	(7,5)	13,8	(9,4)
2	13,7	(10,6)	17,4	(11,0)	10,9	(7,7)	13,5	(7,6)
3	16,0	(10,4)	15,3	(11,7)	14,7	(11,2)	13,4	(10,1)
4	12,7	(10,3)	11,5	(10,3)	11,1	(10,2)	10,4	(10,6)
5	11,5	(8,3)	11,2	(9,4)	10,4	(10,2)	11,1	(9,2)

**Group definition**

n = 6 / group 1 = shocks at both time intervals\*  
n = 9 / group 2 = only shocks during the first 6 months (t3) postdischarge  
n = 20 / group 3 = only shocks during the last 6 months (t4) postdischarge  
n = 81 / group 4 = no shocks during first year postdischarge  
n = 35 / group 5 = treated otherwise (no ICD)

Data in *italic* were used as covariates

\* ICD recipients had both shock during the first time span (0 to 6 months postdischarge) and second time span (6 to 12 months)

Mental health did not change significantly over time in any group, however it decreased in group 2 between 6 and 12 months post-discharge. Although health perception also did not change significantly over time and there were no differences between the groups, patients in group 1 reported a diminished perceived health 6 to 12 months after discharge whereas the other groups reported a slight improvement. The same applied for physical functioning.

The psychological well-being questionnaire (HPPQ) did not reveal differences between groups. Well-being deteriorated in all groups over time ( $p < 0.001$ ) whereas there was an improvement in feelings of disability ( $p < 0.001$ ). A further refinement: patients in both group 1 and group 4, indicated that they felt more handicapped than patients in the other groups.

Overall anxiety and depressive symptoms did not change significantly over time in any group. The prevalence of clinically relevant anxiety and depression is shown in table 4. Patients in groups 1 and 3 were more susceptible to clinically relevant depression and anxiety.

Table 4.

**Prevalence of clinical relevant anxiety and depression in shocked versus non-shocked patients.**

	n	pre-treatment	one month	6 months	12 months	missing data
total STAI sumscore > 40						n
group 1	6	50%	83%	66%	66%	
group 2	9	78%	62%	44%	44%	
group 3	20	75%	63%	65%	58%	
group 4	78	59%	42%	44%	35%	3
group 5	34	50%	34%	31%	37%	1
total CES-D sumscore >= 16						
group 1	6	33%	66%	50%	33%	
group 2	9	11%	50%	22%	22%	
group 3	20	60%	52%	50%	47%	
group 4	78	33%	30%	35%	28%	3
group 5	34	38%	31%	24%	30%	1

**Group definition**

- group 1 = shocks at both time intervals\*
- group 2 = only shocks during the first 6 months (t3) postdischarge
- group 3 = only shocks during the last 6 months (t4) postdischarge
- group 4 = no shocks during first year postdischarge
- group 5 = treated otherwise (no ICD)

\* ICD recipients had both shock during the first time span (0 to 6 months postdischarge) and second time span (6 to 12 months)

## Discussion

There are few prospective studies addressing quality of life and psychological recovery over time in ICD recipients who have experienced ICD shock delivery. The principal goal of the present prospective study was to determine the effect of receiving ICD shock delivery on quality of life and psychological well-being, by comparing patients who received an ICD shock with those who did not.

This is the first study in which the group who received ICD shocks was differentiated and a control group of patients who had no ICD was included. We distinguished between patients who had received early or late ICD shocks or shocks at both stages because we believe that the time of ICD shock delivery influences the quality of life. ICD recipients who experienced ICD shock delivery were more depressed and anxious than those who did not experience a shock (group 4 and control group). Interestingly, patients who experienced ICD shock delivery during the first 6 months (group 2) of the study were more depressed and anxious between 6 and 12 months postdischarge, than were patients in the other groups.

Our study took into account that patient-perceived quality of life during hospitalization and 1-month postdischarge could influence quality of life at 6 and 12 months. Patients were not able to report on their experience with ICD shocks until 6 months after they were discharged. But, as we did not want to lose the impact of the quality of life outcome during hospitalization and 1-month postdischarge, we used the data as covariates in a multivariate analysis. This distinguishes our study from all previous studies. We also tested whether our research-design influenced the outcome by repeating the multivariate analysis of variance incorporating all measuring points. No significant differences were found between the groups over time.

Although patients who experienced an ICD shock had a poorer quality of life, especially those patients who experienced a shock during the two times spans (group 1), overall quality of life did not change significantly between 6 and 12 months postdischarge in any group, Schron et al (35) found that shocks were associated with reduced quality of life in ICD recipients. We found a significant change over time within the groups regarding physical role limitations.

Those patients who experienced shocks during both time spans (group 1) felt more limited in their daily activities (a decrease in physical role limitations) compared to the other groups. This is consistent with the findings of Reid et al (36) and Schron et al (35, 37).

All patients in our study reported a significant improvement in their health (subscale health change), but this was not perceived as such (subscale health perception). The subscale health perception comprises five questions and mainly focuses on how patients compare their health to that of others. One retrospective question assesses health status (health change): the patient is asked to compare his/her health at the time of assessment to that of a year earlier. The different outcomes may be due to a response shift, in that perceived quality of life changes due to experiences and comparisons patients make. In future research we need to focus more on this possible response shift.

We found that most of the improvement occurred during the first 6 months postdischarge. With regard to quality of life, this may be because patients were often hospitalized for a long time, 2 to 3 months, and were glad to be back home. All patients groups reported extreme low scores indicating poor quality of life on all subscales of the Rand-36 except for pain. Baseline quality of life measures were *worse* than the mean values in the general healthy adult population in the Netherlands (22). It is most likely that quality of life declined during the long hospitalization as hospitalization and the medical diagnostic period is a very stressful time for patients. After 6 months post discharge, quality of life did not improve further. A limitation of this study is that we were unable to assess quality of life directly after resuscitation. A possible explanation for the improvement reported in the first 6 months is that patients feel relieved to have survived the cardiac arrest and feel safer due to the treatment they have received. Before conclusions can be drawn about whether patients adapt well to their new situation in the long run, quality of life should be assessed for a longer period, up to 2 to 5 years after discharge.

Physical functioning did not change in any group 6 to 12 months after discharge in our study. Schron et al.(38) using the Medical Outcomes Short Form 36-item questionnaire (SF-36), which is comparable to the Rand-36 (22), found that physical functioning and mental well-being

reduced over time in those who experienced an ICD shock delivery. We found that mental health (a sub-scale of the Rand-36) got worse for those patients who experienced a shock during the first six months after discharge.

Our study sample was relatively large compared with that of earlier studies. Of our sample, 26% experienced a shock in the first year after implantation, which is less than reported in other studies (Schron et al.:39% [ICD recipients n = 373]; Reid et al.: 54% [ICD recipients n = 87]) (38),(35). Furthermore, those who had received a shock felt more limited in their daily activities and were more susceptible to depression and anxiety. This finding is in agreement with results from previous studies in which ICD shock delivery showed to be associated with increased psychological distress (15),(39). However, Chevalier et al (9) did not find any association between ICD shock delivery and psychological well-being.

In our study, between 11% and 66% of patients could be diagnosed having possible clinical depression (using the cut-off score  $\geq 16$  on the CES-D) from discharge till 12 months after implantation. This outcome is consistent with that of Heller (40) and Pycha (16). Many of our patients (31% - 83%) both shock and non-shocked groups reported clinically relevant anxiety, a percentage similar to that reported by Herbst et al.(5). This is most likely because all groups had survived a life-threatening event. All patients who had experienced ICD shock delivery were more anxious than those who had no shocks. The prevalence of depression shows another picture: the anticipation of having another shock is less stressful than the anticipation of experiencing the first shock.

Like Dougherty (15) we found that ICD recipients became less anxious with time when they had not experienced an ICD shock delivery in the first year after implantation. However, in our study ICD recipients who had received an ICD shock became more anxious with time. We found that one year postdischarge, ICD recipients who had received an ICD shock were significantly ( $p = 0.046$ ) more anxious than those who had not received a shock. In another study, patients who experienced ICD discharge, were more anxious than ICD recipients who did not experience ICD discharges or patients without an ICD (treated with antiarrhythmic

medication)(12).

Sears et al (41) reported on health care providers' (physicians and nurses) perceptions of the psychosocial impact of having an ICD. They found that health care providers felt less comfortable in managing the emotional concerns of ICD recipients than more traditional health care and lifestyle concerns. The outcome of our study indicates health care providers should pay attention to the emotional concerns of ICD recipients and especially to those who have experienced ICD shock delivery during the return visits to the out-patient clinics. Our results indicate that psychological distress will not dissipate naturally over time. Psychosocial interventions by healthcare professionals may be warranted six months after discharge from the hospital. Whether psychological distress can be managed and/or decreased by psychosocial interventions should be studied in future research.

More needs to be learned of the emotional reactions to having an ICD and of receiving ICD shocks. Strong emotional reactions to having survived cardiac arrest and to having an ICD are to be expected. The emotions expressed are likely to hold clues to how individuals adapt to their situation. Our data suggest that people who have experienced an ICD shock do not adapt well to living with an ICD. To further understand how patients adapt to their new situation, more attention should be paid to personality structure, coping skills, past psychopathology, and life experiences.

There were several limitations of this study. The influence of social support, evaluation of cognitive and bio-medical performance, ICD complications, mobility (such as the effect of driving restrictions), and drug therapy were not taken into account. In future research these variables should be studied. At the time of data-collection little was known of the possible cerebral effects (like memory loss or brain damage) on perceived quality of life. Also it was not standard practice to test cognitive performance of cardiac arrest survivors either during hospitalization or during the first year after ICD implantation. Therefore the effect of cognitive performance on quality of life could not be studied.

In future research we need to specify the necessity of reporting the functional status,

severity of heart disease, whether the ICD shock discharge was appropriate, and ICD related complications in the patients' medical record to healthcare professionals. During the patient record review we found that not all records were complete. The influence of these variables on patients perceived health and well-being could therefore not be included in the analysis of the data. In future research the assessment of quality of life of ICD recipients by healthcare professionals, and the medical status of the patient compared to how patients perceive their quality of life should be studied.

Another limitation was that the control group remained small. This was because we only allowed patients with an out-of-hospital cardiac arrest due to life-threatening arrhythmias to participate in the study. We wanted a homogeneous patient group. At the start of the data-collection we expected that more patients would be treated otherwise, like receiving medication as therapy, however, during the data collection period ICD-therapy became the first-choice therapy for cardiac arrest survivors, therefore the control group remained small.

It is difficult to compare our findings with other studies because of differences in study methodology: most studies are cross-sectional. Moreover, studies with quality of life scores measured before ICD implantation are rare. Additionally, the studies reviewed have used different instruments (questionnaires) to measure quality of life, making it hard to compare our outcome with that of other studies. In future studies the emphasis should be on using the same instruments to measure quality of life, depression and anxiety. Furthermore the use of a homogeneous definition of quality of life would be practical.

Our study concentrated on patient-perceived quality of life and (psychological) well-being, rather than on the impact of disease-related variables (like functional status, ICD complications and severity of heart disease). We can conclude that from a patient's perspective quality of life is not influenced by the choice of treatment; however, quality of life is influenced by ICD shock delivery. It can be concluded that having survived cardiac arrest and having had an ICD shock has a major impact on the quality of life.

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Chapter 6

**The first year after implantation of an ICD**

A qualitative study defining the patient experience

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## **Abstract**

Background: The experiences of how patients live with an ICD are still poorly understood. So far only a few qualitative studies have studied this phenomenon. The study presented in this paper was undertaken as part of a larger on-going project to evaluate quality of life and psychological well-being in those survivors of cardiac arrest who have received an ICD.

Aims and objectives: The aim of this qualitative study was to explore and gain insight into how ICD recipients perceive their lives during the first year after implantation of the device.

Methods: A sample of 21 patients who received an ICD were interviewed during 3 consecutive periods: 1, 6 and 12 months post-discharge from the hospital. The semi-structured interviews were based on insights gained from a review of literature. The transcripts were subjected to content analysis.

Results: Analysis of the data revealed seven major categories: physical deterioration, cognitive changes, perceived social support, dependency, contact with the physician, confrontation with mortality, and uncertainty surrounding having a shock. Anxiety, uncertainty, disappointment, frustration, unexpected barriers, acceptance of and dependency on the ICD played a major role in the lives of ICD recipients. Well-being improved throughout the year. During the first months after discharge from the hospital the focus was on regaining physical health. During the early post-implantation period both the ICD recipient and family members had adapted to the situation. Reflection on the impact and consequences of the cardiac arrest was reported more often in the late post-implantation period.

Conclusions: Content analysis is a resourceful approach giving answers to questions that have hardly been addressed within the domain of cardiology. ICD recipients face a complex first year, especially the first six months. Cognitive deterioration and confrontation with mortality are problems that need to be researched further.

Relevance to clinical practice: Care givers are able to explain to future patients what they can expect in the first year after implantation. Care givers may become more receptive to physical, psychological and social limitations and to emotional and social problems that occur in ICD recipients, enabling them to act upon them.

**Keywords:** cardiac arrest, implantable cardioverter defibrillator, content analysis, qualitative analysis, life perception

## Introduction

A third (37%) of all deaths in the Netherlands can be attributed to cardiovascular disease. A quarter (24%) of those deaths is related to arrhythmias and conduction disorders (Konings-Dalstra & Reitsma, 1999). Survivors of cardiac arrest have a high chance (70-90%) of clinical recurrence if a suitable regimen capable of suppressing the arrhythmias cannot be found (de Vreede-Swagemakers et al., 1998). In 1984 the first ICD was implanted in a patient in the Netherlands (Wever, 1995). The ICD, at time of print, has become a device smaller than a matchbox that recognises life-threatening heart-arrhythmias (malignant ventricular dysrhythmias) and ends these by means of pacing, converting and/or defibrillating. The device has dramatically improved survival rates, although the underlying cause of the arrhythmia still exists (AVID investigators, 1997). The ICD is implanted below the collarbone on the left or right side of the chest (pectoral implant), in a specially prepared pocket.

Little has been done to attempt to document the experiences of patients who live with an ICD in the Netherlands. Worldwide only seven qualitative studies have been conducted so far to study the personal experiences of living with an ICD, and five of these were carried out in the USA. The remaining two were carried out in Europe, of which one in the Netherlands. As Dutch culture is very different from the American and Swedish culture, ICD recipients may have other experiences with living with an ICD than American and Swedish recipients. Only one qualitative Dutch study has been found in the course of this research. This study was conducted in the early years of ICD implantation in the Netherlands. In this study, all ICD recipients (51) were interviewed only once, focussing on the pre and post implantation phase (Weustink, 1994). Although Weustink concluded that the reactions to having an ICD were diverse, she reported that most ICD recipients functioned normally. However, feelings of anxiety and uncertainty did have an impact on their daily functioning; ICD recipients valued autonomy and control over their own body highly (Weustink, 1994).

In contrast to all studies mentioned in the previous paragraph, where ICD recipients were interviewed only once, our research focusses on the changes over time incorporating three interviews per ICD recipient.

Most of the studies conducted during the last two decades on quality of life are of a quantitative nature. By doing research based on a qualitative approach we hope to provide insights that cannot be gained by using the quantitative approach. We aim to assess the ICD recipients' own experiences and perspectives and the way these change during the first year after implantation.

## Literature review

### *Psychological, social changes and physical changes because of the ICD*

The emphasis of this study and the literature review is on the post-implantation period. This last period can be subdivided into an *early post-implantation* period (the first three months after implantation) and the *late post-implantation* period (four months onwards).

Recovery after ICD implantation is predominantly described in terms of psychological reactions of the ICD recipient and his perception of quality of life. The literature examined shows that the ICD is well accepted as the treatment of choice for cardiac arrest survivors due to life-threatening heart arrhythmias. However, it remains unanswered whether a "return to normal living" takes place. ICD therapy can have adverse physical, social and psychological effects. For example, when consideration is given to the emotional reaction of ICD recipients, research has shown that ICD recipients can be irritable and dissatisfied with themselves. Emotional adjustments have to be made (Herrmann et al., 1997). With regard to cognitive functioning forgetfulness is apparent; the ICD wearer has difficulties with activities that require concentration and thinking. Cognitive processing has been shown to become slower (Dougherty, 1994).

As a result of this, the ICD recipient's social interaction diminishes and there is a raise in irritability towards family and friends. This irritability can surface in the shape of an aggressive attitude towards loved ones (May, Smith, Murdock, & Davis, 1995). A decrease in social interaction is found, causing isolation from family, friends and coworkers (Cooper & Luceri, 1986) (Dubin, Batsford, Lewis, & Rosenfeld, 1996) (Pycha & Calabrese, 1990).

Apart from the aspects mentioned above, a feeling of loss of independence may start to play a role. The ICD recipient is dependent upon an electronic device and feels he has partially lost control of himself (Cooper & Luceri, 1986).

Apart from the psychological and social problems that accompany the implantation of an ICD there are physical discomforts for the ICD recipient (Reid, McKinley, & Nagy, 1999). ICD recipients find that their normal physical and intellectual activities are affected. There is an overall reduction in physical activity, which is due to the fear of receiving shocks, and dysfunction and/or pain of the shoulder and arm as a result of the operation. ICD recipients have reported a decline in vitality, they feel listless (Luderitz, Jung, Deister, & Manz, 1994). There is also a decrease in or total loss of sexual activity (Dubin et al., 1996) (Heller, Ormont, Lidagoster, Sciacca, & Steinberg, 1998). Sleeping disorders were also reported (Cooper et al., 1986a) (Pycha et al., 1990). After more than one year only half the ICD recipients state that they are in good to excellent physical health (Chevalier, Verrier, Kirkorian, Touboul, & Cottraux, 1996). Many of those can return to an active life, provided that they incorporate some changes,

e.g. with regard to participating in sporting activities (Gallagher et al., 1997).

### *Stress*

The changes that result from the ICD have to be incorporated into the life of the ICD recipient. This results in a certain amount of stress. A number of stressors can be identified for ICD recipients:

- the battery: on the one hand there is fear that the battery might fail without prior warning; on the other hand people worry about the future operation necessary to replace the battery (Sneed, Finch, & Leman, 1994);
  - shocks: fear of the pain caused by a shock and the fear of the reaction of bystanders when the ICD discharges (Dougherty, 1995);
  - dependence upon an electronic device for survival: self-control is partially lost and ICD recipients have surrendered to an electric device (Sneed et al., 1994);
  - worries about the future: 'how long will I live?', 'what are my capabilities in a year's time?' (Kuiper, 1991);
  - failure of the ICD: the fear that the system will not be able to gain control over the arrhythmia (Burke, 1996).
- the unpredictability of the occurrence of the shocks is a major contributing factor towards most ICD recipients' psychological distress/tension (Gallagher et al., 1997) (Herrmann et al., 1997). The unfamiliarity with regard to where and when the shock will occur produces feelings of insecurity in a number of ICD recipients.

For many ICD recipients these aspects can be regarded as chronic stressors. In the perception of the ICD recipient they are confronted with these stressors daily.

In summary: the most common stress reactions for ICD recipients are both psychological and behavioural: deteriorated physical activity and decreased social activity (Burgess, Quigley, Moran, Sutton, & Goodman, 1997), insecurity and anxiety (Burke, 1996), feelings of depression (Sneed et al., 1994), sleep disorders and decreased sexual activity (Burke, 1996).

### *Social support*

The ICD recipient has an increased need for social support from hospital admittance until one year after discharge. Family and friends want to respond to this need, but unfortunately their help is viewed as disproportionate concern by the ICD recipient. The amount of support that is offered is greater than the amount of support that is needed, resulting in over-protectionism. This phenomenon is mostly found in relationships with persons very close to the ICD recipient (Schuster, Phillips, Dillon, & Tomich, 1998).

The social network is used by ICD recipients as a source of security in case the ICD might fail. Family and friends are instructed on how to act if the ICD does not function adequately, thereby increasing their chances of survival (Burke, 1996).

Despite all the changes that may result from the implantation of the ICD, the majority of ICD recipients are satisfied with the ICD and convinced that it increases their life expectancy. A large proportion of the ICD recipients resume their normal pattern of activities over the months following the operation and integrates the ICD successfully into their body image / self-concept (Gallagher et al., 1997). After one year most ICD recipients have returned to their normal way of life and estimate the quality of their life to be at the same level as before the implantation (Chevalier et al., 1996) (Hegel et al., 1997) (Schuster et al., 1998).

### **Research question**

The aim of this study was to answer the following question: How do ICD recipients experience life during the first year after implantation of the device?

The following subquestion is answered:

- What developments in the perception of the ICD recipient take place over time during the first year after the implantation?

### **Research design and method**

Due to the nature of the research question a qualitative approach was used. Qualitative research is eminently suited to shed more light on the ICD recipients' perception of his life situation. This method of research can stimulate informants to actively think about a subject. Moreover, the qualitative method is suitable for areas where knowledge is scarce, as is the case with ICD recipients.

The qualitative approach described in this article examines the experiences and perceptions of ICD recipients participating in a larger quantitative study assessing quality of life of recipients that have survived cardiac arrest and have received an ICD. We opted for a mixed model; a combination of quantitative and qualitative methodologies. The scope of this paper is restricted to presenting the outcome of the qualitative study. The study was approved by the Committee for Ethics in Medical Investigations from the participating hospitals.

#### *Data collection*

All respondents had a out-of-hospital-cardiac arrest, followed by an ICD implantation. Patient consent was received shortly after being hospitalized. Semi-structured interviews were conducted with 21 persons (12 males and 9 females) at their home at 3 consecutive moments: 1, 6 and 12 months post-discharge from the hospital. Every interview focussed on the experiences of the ICD recipient in the preceding period. The motivation for choosing these intervals is that we expected many changes in the early post-implantation period. The second reason is that we want to assess changes that take place over time during both the early and

late post-implantation period.

The average age of the ICD recipient was 58.3 years (47.2 - 69.4). Ten respondents lived together with a partner, 7 respondents lived together with partner and children, one respondent lived with only her children, and three lived alone. Most of the men had a job, in contrast to the women, none of whom had a job. Other ICD recipient characteristics are given in table 1.

**Table 1. Characteristics of patient population**

<b>Gender</b>		
male	12	
female	9	
<b>Age</b>		
mean	58.3	
sd	11.1	
<b>Age categories</b>		
< 20	0	
20-39	3	
40-59	9	
60-69	7	
> 70	2	
<b>Work status</b>		
	male	female
non	1	5
full-time	6	0
part-time	0	0
disability leave	1	1
retired	2	1
unknown	2	2
<b>Living situation</b>		
with partner	10	
partner + children	7	
with children only	1	
alone	3	
<b>Marital status</b>		
married	17	
widowed	3	
unmarried	1	

## **Data processing and data analysis**

A semi-structured interview was conducted to address experiences of living with an ICD. The interviews were audio-recorded and transcribed verbatim. To process and analyse the data the method of "content analysis" was used. This method was used to identify key themes. Starting point for this identification process was four themes that were derived from literature review: stress, social support, physical condition and personal well-being. The aim of the content analysis was to restructure the collected data (interviews) in such a way that the communicative message (text) could be translated into structured datasets, using WinMax (Ridder de, 1994) (Kuckartz, 1995). The analysis of the data was performed by two researchers. During the content analysis various questions were asked that were deemed relevant, in order to be able to describe the complex phenomena studied. The topics that were derived from insights gained by studying relevant literature (Coffey & Atkinson, 1996) formed the building blocks for the so-called categorizing system. This system, where related concepts are grouped, is an often-used tool within the field of content analysis to restructure texts by grouping and encoding text fragments based on their content (Albinski, 1981). The material was analysed step by step, following rules of procedure. The encoding breaks down the text into smaller, manageable fragments, simplifying and reducing it to equivalent classes/subcategories.

Once all interviews were ordered, a transformation of the structured categories to meaningful information took place. Patterns, contrasts, paradoxes and irregularities were contrived (Coffey et al., 1996) within interviews at one time point and between interviews over all three time points.

## **Results**

With regard to the experiences of ICD recipients a distinction must be made between situations caused by the ICD on the one hand, and how the ICD recipient experiences these situations on the other hand. Due to the implantation of an ICD the following situations arise:

### *Physical deterioration*

Some ICD recipients were disappointed by the rate of recovery and found it hard to accept the physical deterioration. Confrontation with their physical limitations yielded somberness or anger:

*'The feeling that my body let me down. Because my head keeps saying "let's just do this too, and then we'll do that." But now your body says "No. Time for a break!"'*

Some other ICD recipients perceived these limitations in a positive way: they tried to enjoy the opportunities they still had. They tried to improve their physical condition as much as possible, but accepted the limitations that remained.

#### *Cognitive changes*

A deterioration of cognitive abilities is experienced as a limitation in daily life. Hence ICD recipients found this very hard to accept. In addition to acceptance of this limitation, cognitive changes also result in insecurities because it is uncertain to what extent the cognitive abilities will be regained:

*'It is as if things go this far and there's a wall. If I have to remember something or do something I am apprehensive, because I know that I won't be able to look over that wall. It's as if I say "until here"; here I see everything clearly and beyond that everything is vague or there is nothing there.'*

This person used the wall as a metaphor in order to describe his short-term memory dysfunction that prevented him performing simple cognitive tasks. Cognitive disturbances can be affected permanently. When this happens ICD recipients became irritated and angry because they found it hard to perform tasks that were accomplished easily before the ICD, such as remembering a name, getting coffee etc.

#### *Social support*

The home and family was viewed as a safe haven. Family-members felt more secure knowing that the ICD recipient is safe because of the ICD. For the ICD recipient this knowledge was an important factor in the decision process.

*'Had I been alone in this world then I would not have decided to have the ICD implanted. If I had no wife or children I really wouldn't have had the implantation'*

The social support given by the family was mostly in the form of listening and being empathetic. From the interviews we found that ICD recipients were very satisfied with the support they received from their family. The children were more supportive than before and offered more help; the relationship with the children had improved in most situations. The bond was stronger. However, sometimes the ICD recipient was disappointed with the support and empathy given by the children who still lived at home. The children expected that now the parent (ICD recipient) is back home things would get back to normal. In most cases the ICD recipient could understand this reaction.

ICD recipients valued it highly if good relationships continued or improved after the operation. In these relationships ICD recipients often felt that they were understood and that they were taken seriously. Unfortunately some relationships weakened or discontinued. This development and a lack of understanding from the environment were experienced as serious disappointments. This lack of understanding by significant others (family and friends) of their situation was perceived throughout the first year by ICD recipients:

*'I sometimes feel that people don't understand. At first sight you look fine, if I may say so, because you're basking in good health. And yet you have limitations. And I think that they don't understand that very well. Someone who's in a wheelchair doesn't have to say that he isn't well all the time. And if they say, when I meet them, "how are you?" and I say "well, could be better", then they say "but you look fine!"*

During the first months this lack of understanding by family and friends was experienced by some as a disappointment. After a while however, it became less important: ICD recipients accepted that others cannot see the changes they had gone through.

Some ICD recipients perceived that the bond with their family was strengthened during the first year due to the radical events that had taken place. This was experienced as very pleasurable. Attention and interest during the first few weeks/months after implantation from family and circle of acquaintances were appreciated to a certain extent, but later in the year too much attention resulted in increasing irritation. The attention was experienced as stifling, it blocked the path to independence and freedom.

#### *Contact with the physician*

The insecurities / doubts that ICD recipients had regarding the ICD and living with an ICD were not topics which were easily discussed with the physician. Contact with the physician was limited and restricted by the time factor during hospitalization. This did not change during out-patient-clinic visits. During the consultations in the out-patient-clinic there was limited time for conversations that go beyond the necessary physical check-up (reading of the ICD device and heart functions). It was the ICD recipient's experience that hardly any attention was paid to questions and/or problems the ICD recipient had, especially issues regarding sexuality, mortality, medication and the side-effects, tiredness, and feelings of depression. These issues were hard for the ICD recipient to bring up by himself.

#### *Confrontation with mortality*

This issue is not covered in the literature reviewed. However, in our study, it was a recurring theme in the interviews. The confrontation with death is a theme that impressed ICD

recipients very much. It takes a prominent place in the perception of ICD recipients. The 'meeting' with death was experienced as something that happens to you, as something you do not notice. Respondents had expected that death would be bleak, and needed to be seen as a threat. In contrast to this general image of death, meeting death was described by most respondents as 'positive'. As a result they no longer regard death as a threat:

*'You float away slowly and unnoticed.'*

The confrontation with the finiteness of life resulted in a changed approach to life in some respondents. The confrontation with death made people realise that they were lucky and that life is not self-evident. ICD recipients felt they have to enjoy every moment. Life was appreciated more than before. However, the confrontation with their own mortality was not always perceived as positive. ICD recipients experienced having less grip on their lives in general. Everything that was important to them before the cardiac arrest had become less important: values, friendships and activities were reassessed. Although they appreciated the continued life that was given they focussed less on the future:

*'I live more in today than that I think of the future. I try to, but you often encounter things that make you think "Why am I doing this?" I have taken up an old hobby and am in the process of putting together a new collection for next year. Then you get to the point where you think "you're doing that, but will you be alive then?"'*

#### *The possibility of receiving a shock*

With regard to this concern uncertainty and fear took a prominent place in the perception of the ICD recipient. If no shock had yet been received, fear of the unknown played a major role because he or she did not know what to expect.

The anxiety may have to do with the possibility of receiving a shock while out of the house, receiving a shock without familiar people in the vicinity, fear of the shock itself, or the period after having received an ICD shock delivery. Receiving the shock was experienced as a disappointment by a number of people because it proved that the body cannot function autonomously anymore but has to rely on this device (the ICD):

*'I still have to wait and see how I'll experience it when this little machine does its job, how will it go? Where am I? And will it work correctly? My main concern is not whether the ICD will function, but how I'll experience it.'*

If people had assumed beforehand that receiving a shock would be a terrible experience, the actual occurrence was not as bad as they had feared. Those that had not lost consciousness felt dizzy, breathing became more rapid and were anxious. Those that lost consciousness reacted emotionally afterwards.

*'I had this illusion that this would not happen, I never expected it to happen. There goes my illusion and that is a big disappointment to me. Damm, why did this have to happen?'*

The feeling of uneasiness could remain for some days. Some even refrained from doing certain activities they believed enhanced the arrhythmia.

### *Changes over time*

The themes mentioned above take a prominent place in the perception of the ICD recipient. During the first year a positive development takes place. People feel more and more secure, have more faith in themselves and the ICD. In general people indicate that they started feeling happier during the year, and that they dare to undertake more activities.

A small group was very happy to have gained this 'extra time' and experienced life to its fullest.

*'I can't explain to anyone how terribly happy I am. I'm living my 'extra time' ..... Sometimes I say: Dear Lord, that I'm allowed to experience all this'*

Certain situations that occurred during the first year, such as the termination of friendships, were accepted. Unfortunately the positive change was not discernable in all ICD recipients. Especially people who had to deal with complications took on a more negative outlook. The complications reinforced the uncertainty about the body and the future. These people asked themselves "why me?" and regularly "see no way ahead".

During the first six months ICD recipients perceived a larger improvement physically than in the next six months. After 12 months most recipients reported similar levels of fitness as prior to the cardiac arrest.

The implant location was sensitive, which is experienced as a discomfort during the first 6 months. In men the level of discomfort decreased significantly after 6 months. Women however still reported some discomfort in the following 6 months.

In the area of cognitive abilities, memory and concentration was back to an acceptable level 6 months after the implant for most ICD recipients. A few ICD recipients perceived hardly any improvement in their cognitive abilities.

Socially, both the need for social support and the amount of support received was highest in the first six months. Most ICD recipients perceived a decrease during the following 6 months. A month after discharge most ICD recipients indicated that they lived day by day. Over time their planning horizon increased slowly. At 6 months a few ICD recipients were able to make plans for the future. After a year most were able to make plans for the future.

ICD recipients were more emotional one month after discharge than before the cardiac arrest. Those confronted with complications during the first six months remained emotional throughout the year. In general, ICD recipients reported a decline in the number and intensity of their mood swings.

In general, well-being improved during the first year. During the first months the focus was on regaining physical health. After the first 6 months the family and ICD recipient had adapted to the situation. More than in the first 6 months, ICD recipients reflected on the impact and consequences of the cardiac arrest during the last 6 months.

## **Conclusions and discussion**

This study shows that the implantation of the ICD changes many things in a ICD recipient's life: psychologically, socially and physically. These findings are similar so those studies conducted by others (Dickerson, 2002; Fridlund & Lindgren, 1999; Dunbar, Warner, & Purcell, 1993; Burke, 1996; Dougherty, 1997; Weustink, 1994). All studies describe a complex life situation after ICD implantation. Anxiety and uncertainty play an important role in the way people experience these changes. Uncertainty is related to the future, recovery, and how receiving a shock will be experienced. Anxiety is mostly related to receiving a shock, both because of the uncertainty of the location and time of the shock, as well as the experience of the shock itself or the recovery from the shock. Gallagher et al and Dunbar et al arrived at similar conclusions (Gallagher et al., 1997; Dunbar et al., 1993).

Apart from these two aspects, disappointment and frustration play a role. Disappointment is largely caused by changing relationships within their social network. ICD recipients are very disappointed when 'friends' let them down unexpectedly or do not understand the situation. There is further disappointment because the ICD recipient's own body cannot function autonomously anymore, but needs an ICD.

There are limitations felt in a large number of ICD recipients both physically and cognitively. These are hard to accept and therefore yield many frustrations. Our study shows that cognitive deterioration influences many aspects of a person's life. In the light of these results it is surprising that so little attention has been paid to cognitive deterioration in other

studies.

ICD recipients feel more and more secure as time moves on. They become less anxious and indicate that they feel happy again one year after implantation of the ICD. Fridlund et al (1999) reported that ICD recipients gain a feeling of safety and make the best of their lives.

From our literature review hardly any information can be found regarding the physical and cognitive constitution of ICD recipients. Only Chevalier et al. (1996) concludes that after a year only 50 percent of ICD recipients have a good physical condition. ICD recipients that suffered physical complications or setbacks are an exception to this. These setbacks cause some level of depression and negative feelings. People start to doubt the future and the final stages of recovery.

Confrontation with mortality is described by Dickerson (2002) and Fridlund (1999). This is an important theme that reoccurred in all three interviews throughout the first year.

During the analysis of the interviews a suspicion was raised that there is a difference between the perception of men and women. It seems as if women encounter more problems during recovery and dealing with the situation than men. Many of the interviewed women do not have a job. They therefore do not have an official period of sick leave. They fulfil the role of housewife and re-assume this role quickly once discharged from hospital. The majority of male respondents are in paid employment and therefore have an official period of sick leave. During this period, they stay at home and have the opportunity to recover fully in a restful situation before returning to their job. Perhaps the difference between the perception of male and female respondents is due to these factors.

## **Limitations**

With regard to the results, a point of criticism needs to be raised: this research shows the perception of ICD recipients in general. It is impossible to prove that these perceptions can be ascribed to the ICD; these perceptions may also be ascribed to having survived a cardiac arrest.

A limitation with this kind of research method is the impracticality of using large samples to obtain data. However, 63 interviews of approximately 90 minutes each were documented. Each ICD recipient participated in 3 interviews. This provided us with a large amount of data and enabled us to focus on the specific time periods as well as document changes over time. This makes our study unique compared to other qualitative studies.

With this qualitative approach we were able to get more insight in the changes in perceived quality of life, allowing us to categorise the topics, describing the ICD recipients'

experience with living with an ICD. This insight can and should be further studied from a quantitative perspective to confirm and further refine our conclusions.

### **Relevance to clinical practice**

There are some concrete points worthy of attention for caregivers who are involved with ICD recipients. These are: the cognitive changes that take place and their influence on family relationships; the confrontation with life and death; the uncertainty associated with receiving shocks; the acceptance of dependency on the ICD; the presence and/or lack of presence of social support, and the physical and cognitive limitations. This study shows that the cardiac arrest followed by the implantation of an ICD is an event of a large magnitude, with a big influence on the ICD recipients' quality of life.

Our research shows that in order to provide ICD recipients with adequate care and improve early return to 'normal' life, attention must be paid to the psycho-social aspects of life. It is of the utmost importance that health caregivers are aware of the problems that play a role in the perception of ICD recipients. If the caregiver has insight into the life of the ICD recipient and the associated (potential) problems, the care demand can be recognised quickly and appropriate interventions can be initiated. It is important both during admittance and after discharge from the hospital that a situation is created in which it is self-evident that psycho-social problems can be discussed too, apart from physical problems.

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## Chapter 7

### **General discussion**



## **Introduction**

This study was conducted to provide a better understanding of quality of life of patients who have survived cardiac arrest due to ventricular tachycardia and/or ventricular fibrillation (VT/VF) followed by Implantable Cardioverter Defibrillator (ICD) therapy. Up till today little is known about how ICD recipients who have survived a cardiac arrest perceive their quality of life. Quality of life can be seen as an overall satisfaction with life regarding physical, emotional and social well-being. The studies about quality of life in ICD recipients conducted before 1997 were usually small, lacked adequate control groups and pre-morbid assessment, and did not provide information about changes regarding quality of life over time. For the period before 1997 we found 53 publications (Medline search from 1980-1997). Since 1997 approximately 75 research articles focussed on different aspects of quality of life, however in most of these studies not all the domains of quality of life were assessed. Although there is more attention for the views and experiences of ICD patients in the last decade, we conclude that today there is still little attention for the implementation of results and recommendations from research on quality of life of ICD recipients.

Knowledge about the impact of ICD therapy helps caregivers to explain to future patients what they can expect in the first year after implantation. It may also helps the caregiver to be receptive to anxiety, depression, social isolation, physical and mental limitations as a result of ICD treatment, and act upon them. Furthermore, insight is important as it directs attention to the informational, support and care needs of ICD recipients.

In this thesis, the following research questions regarding quality of life are addressed:

- which changes occur after ICD implantation regarding quality of life? Furthermore, which changes take place regarding specific aspects of quality of life, such as anxiety and depression?
- which factors account for the differences in quality of life between patients receiving an ICD

after cardiac arrest and those who have received other forms of treatment?

- what is the influence of shock delivery on quality of life in patients with an ICD?

- what are the predictors of quality of life one year post-implantation?

- which relationships exist between continuity of care and quality of life in patients treated with an ICD?

In this chapter we will discuss our main findings and we will reflect on the implications and perspectives for future research and clinical practice.

### **Discussion on the quality of life of ICD recipients**

ICD implantation not only has an effect on patients' life expectancy (improved survival after and cost-effectiveness of ICD implantation have been documented) but also on quality of life. By introducing the concept of quality of life in medical research prominence has been given to the views and experiences of patients. We found only 2 longitudinal descriptive studies (between 1980 and 2004) which gave prominence to the views and experiences of ICD recipients (1, 2). May et al. (1) followed 21 ICD recipients for 12 months. In this study, functional capacity was unchanged in all but one of the survivors. Overall quality of life was significantly worse at 6 months follow-up but returned to pre-implant levels by 12 months. May et al. (1) did not use a control group. In the study of Carroll et al. (2), 70 ICD recipients were followed for one year after ICD implantation. They found a significant improvement over time regarding physical functioning, vitality and social functioning. General quality of life revealed no significant changes over time. Psychological states improved within the first 6 months compared to the baseline measure.

Some trials (3, 4) have been conducted to compare the ICD therapy with anti-arrhythmic drugs. The AVID trial (n=905) and SID study (n=178) primarily focussed on demonstrating survival benefits between the two therapy options (ICD and medication). As a secondary

endpoint, the investigators also collected quality of life data. Both trials are very similar in design to our study: the AVID trial collected data prior to randomization and then at 3, 6 and 12 months. In the SID study quality of life data was assessed around the time of randomization (either immediately before or after) and at 2, 6 and 12 months of follow-up (5). The difference with our study is that in our study no randomization took place, assessment of quality of life took place one month after discharge, and our sample was smaller in contrast to the trials mentioned. Similarity with the AVID trial is that they used the SF-36 to measure quality of life which is derived from the Rand-36 which we used in our study.

The outcomes of both trials are contradictory to each other. The AVID trial found no quality of life advantage of ICD therapy compared with anti-arrhythmic therapy, while the SID study demonstrated a better quality of life outcome in ICD therapy than with amiodarone treatment. Like the outcome of our study, physical functioning and mental well-being were significantly impaired in both groups at baseline (6). The AVID trial also reported no significant time trend regarding mental well-being. The differences in outcome may be due to the fact that both studies used different quality of life measurements and quality of life was measured at different time periods. Last but not least, in the SID study the focus was only on amiodarone treatment while in the AVID trial anti-arrhythmic therapy in general was assessed and compared with ICD therapy.

We found that quality of life hardly changed after treatment in both groups and there were no significant differences regarding quality of life and well-being between ICD recipients and patients treated otherwise (control group) one year after discharge from the hospital. The other treatment modalities were: anti-arrhythmic drugs, revascularization and surgery. For both groups most of the improvement regarding quality of life was gained in the first 6 months after discharge. In addition, we found that women compared to men had a poorer social functioning over time. When taking age into account, we found that older patients (> 60 years) perceived less improvement in health over time, even though they reported an increase in vitality.

Patients' perception of quality of life is very much influenced by having experienced ICD shock deliveries. Patients who have experienced a ICD shock reported poorer quality of life one year after discharge, especially those patients who had experienced a shock during both time spans (1-6 months and 6-12 months). Overall, quality of life did not change after six months. This outcome is supported by the AVID trial and SID study.

Prevalence of depressive symptoms (CES-D score  $\geq 16$ ) in the general population at any point of time is 12.8 (7). In our study sample, 32-38% of the ICD recipients scored  $\geq 16$  on the CES-D. A significant percentage of our sample experiences depressive symptoms that persist for a long time. We can even consider this a high percentage when we compare it to populations that were treated for cancer (19.7%) and myocardial infarction (14.4%) (7).

Other studies (8, 9, 10, 11, 12, 13) support our outcome that the ICD implantation exerts a negative effect on psychological functioning of ICD recipients. The ICD recipient faces a host of unique device-related problems, such as device dependency and fear of shocks. As shown in our study, ICD recipients are vulnerable to anxiety and depression. We believe that this outcome should get more attention within psychological research.

The outcomes of our qualitative and quantitative studies point in the same direction but there is a small discrepancy. In our qualitative study, according to the ICD recipient, well-being improved during the first year. The quantitative data shows that well-being hardly changes throughout the first year.

The ICD recipients, compared with normative data from a healthy Dutch population, had a significantly poorer quality of life one year after inclusion in the study. Quality of life hardly improved over time in our study. These findings are consistent with that of other studies (2, 6). Possible explanations for the lack of improvement in quality of life may be related to the number of patients who have had a myocardial infarction previous to cardiac arrest. Since the type of heart disease may be related to the outcome, additional analysis was performed. When we compared patients who had a myocardial infarction to those who did not, we found no

differences between these groups except for health perception. Infarct patients and those patients who had experienced an ICD shock delivery perceived their health less positive than non-infarct patients with an ICD who had not received any shocks throughout the first year after implantation.

Another explanation for not finding any changes over time regarding quality of life of ICD recipients may be due to the adaptation process that takes place over the course of the illness trajectory. An important mediator to this adaptation process is 'response shift' which involves changing internal standards, values and the conceptualization of quality of life (14) over a period of time. This response shift may not always be within the individual's own awareness (15). The questionnaires we used are not receptive to measuring this possible response shift.

We were unable to describe the factors that account for the possible differences in quality of life between ICD recipients and the control group. The control group was very small and not homogeneous in respect to the treatment received. Patients with an ICD are generally younger than the control group. The control group experiences more pain over time than those who received an ICD. The control group also reported more positive changes in health.

Having survived a cardiac arrest may be the most important denominator for how one qualifies the quality of his life. Granja et al. (16), found no significant differences between cardiac arrest survivors and other Coronary Care Unit (CCU) patients regarding quality of life during the first 6 months after discharge. Cardiac arrest survivors, however, did report more problems in some dimensions (especially in the domains of pain/discomfort and anxiety/depression). In a retrospective study 50 cardiac arrest survivors were compared with a healthy control group (17). No significant differences in anxiety, depression, vitality, general well-being or self-control were found between the groups. However, a significant decrease in physical mobility, energy levels, emotional reactions and sleep patterns were found in arrest patients. This most likely has an effect on perceived quality of life.

## **Risk factors for maladjustment**

It was examined which aspects measured before treatment could be used to predict poor quality of life one year after implantation.

Risk factors for maladjustment in ICD recipients identified in this study were: incidence of psychological distress, young age, frequent shocks, and being female.

In ICD recipients attention for depression and anxiety should be part of the overall treatment strategy. Little attention has been given to these risk factors, while data from two studies using the CES-D have indicated that the prevalence of depression in a cardiac population (12%) and our ICD population (38%) differ greatly (7). We believe that this high prevalence (38%) is due to the fact that ICD recipients have survived a cardiac arrest. These survivors revalue their lives which may be the cause of the depressive and anxious feelings. Another reason for the high prevalence throughout the year is that depressive symptoms are usually not diagnosed by primary care physicians and cardiologists (18).

It is surprising that only a few studies have been conducted to identify psychological treatments in ICD recipients that can reduce distress and psychological disorders (19, 20, 21, 22).

## **The relationship between continuity of care and quality of life**

We found that those patients that had received medical care during the first 6 months after discharge were satisfied with the care they had received. This was also true for patient education. A very small group of patients (9%) indicated that they needed more emotional support from professional caregivers and needed more aid assistance. Continuity of care and patient education were not significantly associated with quality of life. We did find a association between received care and quality of life.

Patient education and continuity of care are multidimensional concepts. At the start of data collection there were not many instruments available to assess the 'care needs' and/or the

'care received'. We used the most effective measures available. Results regarding satisfaction with patient education and continuity of care have to be interpreted carefully, because we found little variance in the reports patients made. There are still many problems concerning the measurement of patient satisfaction with received care, unmet care needs, and patient education. The conceptualization and measurement evaluating continuity of care continue to be in their infancy. There are no known international, reliable and validated measures, especially concerning research measuring continuity of care in general. Moreover, the care given, patient satisfaction with the received care, patient satisfaction with patient education, and unmet care demands have not been evaluated in different care settings. This is probably why we know so little about the continuity of care in the post-hospitalization phase in ICD recipients.

### **Limitation of our study**

At the start of the study our aim was to have two homogeneous patient groups. The study design was quasi-experimental. The study group consisted of ICD recipients and a control group of patients treated otherwise. During data-collection the ICD-therapy became frequently the first-choice therapy for cardiac arrest survivors, as other studies had shown that ICD's are often more successful than drug therapy in reducing mortality from malignant ventricular arrhythmias. Therefore, only a minority of cardiac arrest survivors were recommended to get other forms of treatment. Thus, our control group remained small (n= 21) and was of a heterogeneous compilation. As we only had a small control group, we were unable to take the diversity of therapies for life-threatening arrhythmias, anti-arrhythmic drugs, revascularization, and surgery, into account.

The baseline measure used in our study might not be an adequate time point. The first assessment of quality of life in our study took place just after diagnosis and before treatment allocation. Most patients within our study had already been hospitalized for a long time (6 to 8 weeks) in another hospital waiting for recovery after the cardiac arrest episode and admittance

to a hospital allocated for arrhythmia analysis and ICD implantation. To be able to evaluate quality of life in cardiac arrest patients, assessment should take place as soon as possible after hospital admittance.

### **Recommendations for future research**

Reflecting on our data we can conclude that the first year after discharge is aimed at getting life back to 'normal'. Our main objective in this study was to assess quality of life in ICD recipients. Instead of a single measurement, we suggest that future studies incorporate several measurements during hospitalization: the first questionnaire needs to be answered within the first two days after admittance, the second questionnaire just before ICD implantation and the last questionnaire during the hospitalization period just before discharge.

We do know that quality of life hardly changes throughout the first year after implantation. We, however, don't know whether quality of life changes after one year. Future research should span a larger time frame to examine whether quality of life in ICD recipients changes after 12 months. We suggest the measuring points after discharge to be extended to measurements at 2 and 3 years after discharge. In the suggested time span changes in quality of life may be found. Once the lives of ICD recipients are back to normal, one can focus on improving quality of life. Confirmation of this hypothesis is needed.

From our qualitative study we found that memory loss and brain damage can have an impact on family life and employability. These changes and their effects on quality of life should be studied in the future.

The functional status of the patient, severity and type of heart disease, ICD complications, the appropriateness of the ICD shock delivery and number of shocks deliveries at one time point could be important predictors of quality of life. To be able to determine the effectiveness of the treatment on quality of life, future research should also measure these variables.

During our study we discovered that social support and bio-medical performance, mobility and effects of drug therapy may have some influence on patients' quality of life. These variables and their impact on quality of life need to be studied in future research.

We concluded that having an ICD was not the reason that psychological distress did not change over time for both the ICD recipients and the control group. An explanation might be that a percentage of these persons were already depressed before cardiac arrest. Our data does not allow us to verify this hypothesis. We would like to have had more insight in the phase preceding the cardiac arrest, as we would like to know if these patients were anxious and/or depressed before the cardiac arrest episode. However, a prospective analysis of cardiac arrest survivors requires participation of an enormous number of subjects which will be hard to realize considering that cardiac arrest is an unforeseeable event with low survival rates.

According to Denollet (23) we should focus on the potential role of personality as a determinant of emotional distress. The tendency to experience negative emotions combined with inhibitory self-expression in social interaction designates a personality sub-type, known as type D. An association has been found of this personality type with depression and incidence of cardiac arrest (23). Others have shown that the interaction between vital exhaustion (characterized by unusual tiredness, lack of energy) and inhibition of emotions (increased irritability and feelings of demoralization) is a significant antecedent of cardiac arrest (24). Future research should examine whether the phase before cardiac arrest is associated with depression and anxiety in ICD recipients.

From the qualitative interviews we found that having an ICD predominately changes how one looks at life and death. Future research should try to analyse this phenomenon and its effect on quality of life further.

### **Implications for clinical practice**

There are some concrete points worthy of the attention of caregivers who are involved

with ICD recipients. These are: the cognitive changes that take place and their influence on family relationships; the impact of the confrontation with life and death; the uncertainty associated with receiving shocks; the acceptance of dependency on the ICD; lack of presence of social support, and the physical limitations.

Our research shows that in order to provide ICD recipients with adequate care and to improve early return to 'normal' life, attention must be paid to the psychosocial aspects. We established that there were hardly any differences between ICD recipients and the control group. It is important that health caregivers are aware of the problems that play a role in the perception of cardiac arrest survivors concerning quality of life, physical functioning, depressive feelings, anxiety and lack of appraisal support. From our qualitative data (n = 21) the following problems were identified in ICD recipients:

- the implantation location can remain sensitive during the first few months
- memory and concentrations problems can occur in some ICD recipients
- slow wound recovery and infection due to ICD implantation can make ICD recipients feel more vulnerable emotionally.

The impact and consequences of the cardiac arrest need to get more attention during the first six months from caregivers.

If the caregiver has insight into the quality of life of the ICD recipient, probable needs regarding support can be recognised and interventions can be developed to improve quality of life and decrease depressive and anxious feelings. It is important both during admittance and after discharge from the hospital that a situation is created in which it is self-evident that psychosocial problems can be discussed, next to physical problems.

## **Conclusions**

The present longitudinal descriptive study is one of the few studies documenting how cardiac arrest and ICD affects physical, psychological and social functioning. Only two other

longitudinal descriptive studies on quality of life in ICD recipients have been performed. It appears that the impact of the cardiac arrest episode on quality of life is greater than the effect of the type of treatment given. Quality of life is very much affected in ICD recipients that have experienced ICD shock delivery. Recipients with poor physical and mental functioning, feelings of displeasure, and limited appraisal support before ICD treatment are at risk for psychological distress and poor quality of life afterwards.

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## Summary



Quality of life is increasingly being recognized as an important outcome within the domain of cardiology. Quality of life is a heterogeneous entity that can be measured in many ways. In this thesis we choose to combine different questionnaires covering the domains of quality of life: physical, mental and social well-being. The main purpose of this study was to investigate quality of life in patients' who had survived a cardiac arrest and were treated with an implantable Cardioverter Defibrillator (ICD). Two groups were compared, those that had received an ICD with those that were treated otherwise. The patient population for this study were contrived from three university hospitals and one large general hospital.

This thesis comprises several studies on cardiac arrest survivors and especially those that received an ICD therapy. Cardiac disease is one of the major health problems in the world. In the Netherlands alone, 37% of all death causes are related to cardiac disease. Of all cardiac mortality, 24% is due to conduction disorders and arrhythmias. Since the early eighties the ICD has become the treatment of choice for cardiac arrest survivors.

In **Chapter 1** the research questions of this thesis are introduced. Furthermore, we introduced the concepts Out-of-Hospital Cardiac Arrest (OHCA), ICD, and the significant characteristics preceding cardiac arrest or ICD shock.

In this chapter we also described quality of life and the determinants of quality of life. For this study we incorporated Wilsons and Cleary's conceptual model on health-related quality of life. The main purpose of this conceptual model was to described expected associations between pre-stressor factors, the stressor itself and the emotional response to the stressor, contributing to the outcome quality of life.

The study design is described in this chapter. The study started in 1998. Between 1998 and 1999, 180 patients were included. The sample consisted of 168 consecutive patients who were admitted to the hospital after OHCA. The patients completed a questionnaire at baseline, and at one, six and 12 months. The questionnaire contained items on quality of life (Rand-36 and HPPQ), depressive symptomatology (CES-D), anxiety (State Trait Anxiety Inventory), coping

(Utrecht Coping List), social support ( Social Support List Interactions), social activities (subscale EORTC), sexuality (subscale EORTC), satisfaction with patient education (patient education questionnaire), continuity of care (CCCpQ) and utilization of care (RC-UD survey). Five research questions were derived from the main research question. We aimed to describe how patients perceive their quality of life throughout the first year after implantation and how they deal with having an ICD in their everyday life.

In **Chapter 2** the results are presented on the relationship between continuity of care and quality of life. In the past decade there has been an increasing interest in incorporating quality of life aspects into the evaluation of treatment and care. We found that there are still many problems concerning the measurement of continuity of care, patient satisfaction with received care, unmet care needs and patient education. The conceptualization and measurement of these concepts are in their infancy. The emphasis of our study was to examine these concepts in relation to survivors of cardiac arrest and evaluate the possible relationships between quality of life and continuity of care, patient satisfaction with received care and patient education. We found no significant association between patient education, continuity of care and quality of life in either groups. We, however, did find an association between patient satisfaction with received care and quality of life. The two groups studied were ICD patients and control group (which comprised of patients treated otherwise). Overall, patients were satisfied with the patient education received and with the continuity of care.

**Chapter 3** reports on a 12 month quality of life assessment of cardiac arrest survivors treated with or without an implantable cardioverter defibrillator. The effects of having an ICD over longer periods of time has been less well studied. Evaluation of quality of life in ICD recipients has become necessary because it provides information on how patients adjust psychologically to disease and treatment. The aim of this prospective study was to assess and compare quality of life in ICD recipients and patients who were treated otherwise. Of all 168 cardiac survivors,

133 (79%) received an ICD and 35 (21%) received other treatment. The other treatment modalities are: antiarrhythmic drugs, revascularization or surgery. No differences were found between the ICD group and control group regarding quality of life and well-being. A significant improvement in physical and social functioning, and mental health were found in the first six months. Older patients perceived less improvement in their health than younger patients. The prevalence of anxiety and probable depression was high irrespective of the treatment received: anxiety and depressive symptoms did not change significantly between 1 and 12 months after discharge. Patients with higher anxiety scores experienced less improvement of health. Patients with more depressive symptoms experienced poorer social functioning.

Quality of life and well-being were not affected by the type of treatment. When comparing quality of life of both groups with those of a healthy Dutch population, those that survived a cardiac arrest had a poorer quality of life. We concluded that surviving a cardiac arrest has a greater impact on patients than the type of treatment received.

**Chapter 4** details the factors that predict quality of life and depression in ICD recipients. The outcome of the literature review shows that despite the increasing interest in quality of life, still little is known about the factors which determine quality of life and depression one year after ICD implantation. Mental health, appraisal support, feelings of displeasure and physical functioning measured at baseline (before treatment) were significant predictors of quality of life in ICD recipients at 12 months. Recipients with poor physical functioning and feelings of displeasure during hospitalization were more likely to experience poorer general quality of life. Focussing only on recipients that had received an ICD shock we found that less appraisal support and emotional role limitations during hospitalization predicted depressive symptoms one year after implantation. We concluded that these factors need to get more attention during hospitalization. Further, we advice caregivers to perform pre-treatment assessment enabling them to identify patients at risk for poorer quality of life and depression.

In **Chapter 5** we assessed quality of life, depression and anxiety in ICD recipients who did and did not experience an ICD shock delivery. A small group of ICD recipients (26%) received ICD shock delivery, usually during the last 6 months of the study. Significant differences were found within the groups over time regarding physical role limitations ( $p < 0.051$ ). Those who experienced shocks throughout the year (group 1) felt more limited in their daily activities due to physical or mental problems. All groups reported an improvement in their health ( $p < 0.001$ ). Overall quality of life did not change significantly after 6 months. Anxiety and depression did not change significantly over time. In total 11% - 66% of the patients had a probable depression throughout the first year, and 31% - 83% were anxious. ICD recipients, who had experienced a shock, were significantly more anxious at one-year postdischarge than those who had not received a shock.

We concluded that overall quality of life and psychological well-being did not change in ICD recipients, irrespective of whether they experienced defibrillatory shocks. The high prevalence of depression and anxiety may be interpreted as a response to the perceived physical and mental problems regarding daily activities. Our data indicate that patients who have experienced an ICD shock do not adapt well to living with an ICD, they are more anxious than ICD recipients who received no shocks. However, the anticipation to have another shock after having experienced a shock is less stressful than the first shock experience. Furthermore, we conclude that the psychological distress will not dissipate spontaneously and that psychosocial interventions may be warranted to improve quality of life and decrease anxious and depressive feelings.

**Chapter 6** describes the content of the qualitative study. Worldwide seven qualitative studies have been conducted so far to study the personal experiences of living with an ICD, and five of these were carried out in the USA. In all of these studies ICD recipients were only interviewed once. Our research focusses on the changes over time and incorporates three interviews. A semi-structured interview was conducted to address experiences of living with an ICD. The interviews were audio-recorded and transcribed verbatim. Data were analysed using content analysis. Seven major categories were derived from the analysis: physical deterioration, cognitive changes, perceived social support, dependency, contact with the physician, confrontation with mortality, and uncertainty surrounding having a shock. Anxiety, uncertainty, disappointment, frustration, unexpected barriers, acceptance of and dependency on the ICD played a major role in the lives of ICD recipients. Well-being improved throughout the year. During the first months after discharge the focus was on regaining physical health. Reflection on the impact and consequences of the cardiac arrest were reported more often during the second half of the study (last six months). During the analysis of the interviews a suspicion was raised that there is a difference between the perception of men and women. It seems that women encounter more problems during recovery and dealing with the situation than men. It may be suggested that this is due to the fact that most women in this study fulfil the role of housewife and re-assume their role quickly once discharged, while the majority of male respondents are in paid employment and have therefore an official period of sick leave. They have the opportunity to recover fully in a restful situation before returning to their job. We concluded, that ICD recipients face a complex first year, especially the first six months. Cognitive deterioration and confrontation with mortality needs to be further assessed in future studies.

Finally, in the **General Discussion** we discussed the outcome to the research questions and the limitations of our study. Last but not least we considered the possible clinical implications and future directions for research.

The main problems ICD recipients encounter are: poor quality of life, poor physical functioning, depressive feelings, anxiety (especially for the next shock), acceptance of and dependency on the ICD, disappointment, frustration, poorer social functioning due to depressive feeling and high age. Our research shows that in order to provide ICD recipients with adequate care and to improve early return to 'normal life', attention must be paid to the psychosocial aspects of life. Future research should focus on functional status, type of heart disease, left ventricular ejection fraction, drug therapy, social support, depression and cognitive (and memory) functioning. Also we believe more attention should be paid to personality characteristics of ICD recipients. We suggest that future studies assess a longer period but also incorporate more time points during hospitalization.

This study leads us to believe that survival of cardiac arrest has a greater impact on quality of life than the type of therapy received after the event. We furthermore conclude that having survived a cardiac arrest is most probably the most important denominator for how one perceives his life. During the first months after ICD implantation all attention is focussed on getting back into rhythm.

## **Nederlandse samenvatting**



Kwaliteit van leven is afgelopen jaren een belangrijkere uitkomstmaat geworden binnen het domein van cardiologie. Kwaliteit van leven is een heterogene entiteit die op vele verschillende wijzen gemeten kan worden. Binnen dit proefschrift is ervoor gekozen om verschillende vragenlijsten, die de drie domeinen van kwaliteit van leven afdekken samen te voegen. De drie domeinen zijn: fysiek, psychisch en sociaal welzijn. De voornaamste doelstelling van dit onderzoek was de kwaliteit van leven bij patiënten die een hartstilstand hebben overleefd, en behandeld zijn met een implanteerbare cardioverter defibrillator (ICD) te onderzoeken. Twee groepen werden vergeleken: patiënten met een ICD en patiënten die op een andere wijze zijn behandeld. De patiëntenpopulatie was afkomstig van drie universiteitsziekenhuizen en één algemeen ziekenhuis.

Dit proefschrift bevat meerdere studies die gericht zijn op patiënten die een hartstilstand (cardiac arrest) hebben overleefd, maar concentreert zich voornamelijk op patiënten die een ICD behandeling hebben ontvangen. Hartziekte is een van de belangrijkste gezondheidsproblemen die voorkomt in onze wereld. In Nederland alleen, is 37% van de sterftegevallen toe te wijzen aan hartkwalen. Van de 37% is 24% toe te wijzen aan geleidings- en ritmestoornissen. Sinds begin jaren '80 is de ICD een de eerste keus behandeling geworden.

In **hoofdstuk 1** worden de onderzoeksvragen gepresenteerd. Daarnaast introduceren wij de concepten Out-of-hospital Cardiac Arrest (OHCA) en ICD, en veelvoorkomende kenmerken voorafgaand aan een hartstilstand of ICD schokken. In dit hoofdstuk wordt verder kwaliteit van leven en factoren bepalend voor de kwaliteit van leven beschreven. Voor deze studie hebben wij Wilson en Cleary's conceptuele model van gezondheidsgerelateerde kwaliteit van leven gebruikt. De voornaamste bedoeling van dit model is associaties tussen pre-stressoren, stress en emotionele reactie op stress te beschrijven. Tevens worden de relaties tussen kwaliteit van leven beschreven in dit model.

Het type onderzoek dat wij hebben uitgevoerd wordt in dit hoofdstuk toegelicht. In 1998 is het

onderzoek gestart. In 1998 en 1999 zijn 180 patiënten geïncludeerd. De steekproef bestond uit 168 opeenvolgende patiënten die opgenomen werden met een OHCA in de genoemde periode. Alle patiënten hebben een vragenlijst ingevuld tijdens opname, voorafgaand aan de operatie. Vervolgens hebben alle patiënten één maand, zes maanden en 12 maanden na ontslag een vragenlijst ingevuld.

De vragenlijst behelsde de volgende domeinen: kwaliteit van leven (Rand-36 en HPPQ), depressieve symptomen (CES-D), angst (STAI), coping (UCL), Sociale steun (SSL-I), sociale activiteiten (subscale van EORTC), seksualiteit (subscale EORTC), satisfactie met patiëntenvoorlichting, continuïteit van zorg (CCCpQ), zorggebruik en gepercipieerd zorgtekort (RC-UD survey).

Vijf subvragen werden afgeleid uit de hoofdonderzoeksvraag. Onze voornaamste doelstelling was de kwaliteit van leven te beschrijven in het eerste jaar na implementatie van een ICD. Daarbij wordt nagegaan hoe de door de patiënt ervaren kwaliteit van leven wordt beïnvloed door de behandelmethode na een doorgemaakte onverwachte circulatiestilstand (hartstilstand) buiten het ziekenhuis.

In **hoofdstuk 2** wordt de relatie tussen continuïteit van zorg en kwaliteit van leven gepresenteerd. Afgelopen decennia is een toenemende interesse om kwaliteit van leven aspecten op te nemen bij de evaluatie van zorg en behandeling. Er zijn nog veel problemen met betrekking tot het meten van patiëntentevredenheid met betrekking tot kwaliteit van zorg. Dit geldt ook voor het meten van zorggebruik, gepercipieerd zorgtekort en patiëntenvoorlichting. Het conceptualiseren en meten van genoemde concepten staat nog in de kinderschoenen. De relatie tussen continuïteit van zorg, geboden zorg, gepercipieerd zorgtekort, ontvangen patiëntenvoorlichting en ervaren kwaliteit van leven bij patiënten die een hartstilstand hebben overleefd werd onderzocht. We hebben geen significante associaties gevonden tussen continuïteit van zorg, gepercipieerd zorgtekort, patientenvoorlichting en kwaliteit van leven bij zowel de ICD-groep als bij de controle groep. Wel hebben wij een associatie gevonden tussen

kwaliteit van leven en geboden zorg. In het algemeen kunnen wij concluderen dat de beide patiënten groepen tevreden zijn met de voorlichting die zij hebben ontvangen en met de continuïteit van zorg.

**Hoofdstuk 3** belicht de ervaren kwaliteit van leven het eerste jaar van patiënten die een hartstilstand hebben overleefd. Twee groepen worden met elkaar vergeleken: patiënten die een ICD hebben ontvangen als behandeling en patiënten die op een andere wijze zijn behandeld na het doormaken van een circulatiestilstand. De invloed van het hebben van een ICD over tijd is weinig bestudeerd. Evaluatie van ervaren kwaliteit van leven is noodzakelijk omdat het inzicht geeft hoe patiënten zich psychologisch aanpassen na het doormaken van een circulatiestilstand (ziekte). Tevens is het belangrijk na te gaan of de behandeling zelf van invloed is op de ervaren kwaliteit van leven. In dit prospectief longitudinaal onderzoek was het de intentie kwaliteit van leven te beoordelen van de twee groepen en ze te vergelijken. Van de 168 patiënten die een circulatiestilstand hadden overleefd hebben 133 (79%) patiënten een ICD gekregen. Een kleine groep patiënten, 35 (21%), werd op een andere wijze behandeld (medicatie, revasculatie of chirurgie). Er werden geen verschillen tussen de twee groepen gevonden met betrekking tot kwaliteit van leven en welbevinden. Een significante verbetering werd in de eerste 6 maanden geconstateerd met betrekking tot fysiek en sociaal functioneren en mentale gezondheid. Oudere patiënten ondervonden relatief minder verbetering in hun gezondheid ten opzichte van jongere patiënten. De prevalentie van angst en depressieve symptomen was hoog, ongeacht de behandelmethode. Er werd over tijd (vanaf ontslag tot 12 maanden later) geen significante verandering in de angsttoestand en depressieve symptomen gevonden. Patiënten die zeer angstig waren ervoeren minder gezondheidsverbetering, terwijl patiënten die hoge scores op de CES-D (depressieve symptomen) hadden een slechter sociaal functioneren vertoonden.

Kwaliteit van leven en welbevinden werden niet beïnvloed door het type behandeling dat patiënten hadden gekregen. Als kwaliteit van leven van beide groepen werd vergeleken met een

gezonde Nederlandse populatie, dan bleek dat patiënten die een circulatiestilstand hadden overleefd een slechtere kwaliteit van leven hadden. Daardoor concludeerden wij dat het overleven van een circulatiestilstand een grotere effect heeft op de kwaliteit van leven van patiënten dan de behandeling die zij vervolgens hebben ontvangen.

In **hoofdstuk 4** worden de factoren die de kwaliteit van leven en depressieve gevoelens 12 maanden na ontslag voorspellen beschreven. Uit literatuuronderzoek blijkt, ondanks de toenemende aandacht voor kwaliteit van leven, dat nog weinig bekend is welke factoren de kwaliteit van leven en depressie gevoelens bepalen. Psychische gezondheid, waarderingsteun, gevoelens van ongenoegen en fysiek functioneren dat gemeten is voorafgaand aan de behandeling (ICD implementatie) zijn significante predictoren van ervaren kwaliteit van leven één jaar na ontslag. Patiënten met slecht fysiek functioneren en gevoelens van ongenoegen tijdens opname hebben meer kans op een slechte ervaren kwaliteit van leven. Weinig waarderingsteun en emotionele rol-beperkingen waren voorspellers voor depressieve klachten één jaar na implementatie voor patienten die een ICD-shock hadden meegemaakt. Samenvattend concluderen wij dat deze factoren aandacht behoeven tijdens de opname van deze categorie patiënten. Daarnaast adviseren wij zorgverleners en behandelaars voorafgaand aan de behandeling kwaliteit van leven en depressieve symptomen bij patiënten in kaart te brengen, zodat patiënten met een slechte kwaliteit van leven en depressieve gevoelens kunnen worden geïdentificeerd.

In **hoofdstuk 5** worden kwaliteit van leven, depressieve symptomen en angst beoordeeld van patiënten die wel of niet een ICD-schok hebben ervaren. Een kleine groep ICD patiënten (26%) heeft een ICD schok ontvangen. Indien de ICD een schok afgaf omdat het een levensbedreigende hartritmestoornis waarnam, dan vond dit voornamelijk in de eerste 6 maanden plaats. Significante verschillen werden gevonden tussen de groepen over tijd bij fysieke rol-beperkingen ( $p < 0.051$ ). Patiënten die tijdens het eerste jaar meerdere schokken

hadden ervaren voelden zich meer beperkt in hun dagelijkse activiteiten wegens fysieke en mentale gezondheidsproblemen. Alle patiënten uit de verschillende groepen rapporteerden een verbetering in hun gezondheid ( $p < 0.001$ ). Algemene kwaliteit van leven veranderde niet significant in de laatste 6 maanden. Er werden geen significante veranderingen gevonden met betrekking tot angst en depressieve symptomen over de tijd. Van de hele groep werden bij 11% - 66% van de ICD-patiënten depressieve symptomen gevonden. Bij diezelfde groep was 31% - 83% angstig. Een jaar na ontslag waren patiënten die een ICD-schok hadden ervaren angstiger dan patiënten die geen ICD-schok hadden ervaren.

Wij concluderen dat de algehele kwaliteit van leven en psychische welbevinden niet verandert bij patiënten die een ICD hebben. Dit is onafhankelijk van het al dan niet ontvangen hebben van een ICD-schok. De hoge prevalentie van depressieve klachten en angst kan beschouwd worden als een respons op de fysieke en mentale rol-beperkingen die patiënten met een ICD ervaren bij hun dagelijkse activiteiten. De uitkomst van ons onderzoek laat zien dat ICD patiënten die een ICD-schok hebben ervaren zich niet goed aanpassen: zij zijn angstiger dan patiënten die geen schok hebben ervaren. Niettemin is het afwachten van een volgende schok minder stressvol dan de periode voorafgaand aan een eerste schok-episode. Bovendien concluderen wij dat angst en depressieve gevoelens niet zomaar verdwijnen. Psychosociale interventies zijn hoogstwaarschijnlijk nodig om te zorgen dat ervaren kwaliteit van leven verbetert en dat angst en depressieve gevoelens verminderen.

De uitkomst van het kwalitatieve onderzoek wordt in **hoofdstuk 6** beschreven. Wereldomvattend zijn er tot het moment van schrijven maar 7 kwalitatieve onderzoeken uitgevoerd waarbij de persoonlijke ervaring met het leven van een ICD wordt beschreven. Vijf onderzoeken zijn uitgevoerd in de Verenigde Staten van Amerika. In al de verwezen studies werden patiënten met een ICD maar één keer geïnterviewed. Ons onderzoek richt zich op de veranderingen over tijd waardoor drie semi-gestructureerde interviews werden afgenomen. De interviews werden opgenomen en vervolgens woord voor woord uitgewerkt. Om de data te

verwerken en te analyseren is er gebruik gemaakt van de methode van 'inhoudsanalyse'. Zeven categoriën werden geïdentificeerd: fysieke achteruitgang, cognitieve veranderingen, waargenomen sociale steun, afhankelijkheid, contact met de specialist, confrontatie met de dood, en onzekerheid rondom de mogelijkheid om een schok te krijgen.

Angst, onzekerheid, teleurstelling, frustratie, onverwachte hindernissen, aanvaarding van het hebben van een ICD en er van afhankelijk zijn spelen een belangrijke rol in de levens van patiënten met een ICD. In zijn geheel verbeterde het welzijn tijdens het eerste jaar. Gedurende de eerste maanden na ontslag was men voornamelijk gericht op de lichamelijke gezondheid. Reflectie op het effect en de gevolgen van het overleven van een hartstilstand, het verwerken van wat er was gebeurd, vond voornamelijk plaats in de tweede helft van het eerste jaar.

Tijdens de analyse van de interviews is het vermoeden ontstaan dat er een verschil bestaat tussen de belevingswereld van mannen en vrouwen. Het lijkt of vrouwen meer problemen ondervinden tijdens het herstel en de verwerking dan mannen. Wellicht komt het verschil voort uit het al dan niet deelnemen aan het arbeidsproces buitenshuis. Veel van de vrouwen die geïnterviewd zijn namen niet deel aan het arbeidsproces buitenshuis en hebben daardoor geen officieel ziekteverlof. Zij vervullen de rol van huisvrouw en nemen zodra zij weer thuis zijn deze rol snel weer op zich, terwijl het grootste deel van de mannelijke respondenten wel deelneemt aan het arbeidsproces en dus een officiële ziekteperiode heeft. Zij blijven in deze periode thuis en kunnen rustig herstellen en keren pas terug in het arbeidsproces wanneer ze weer goed functioneren.

Wij concluderen dat patiënten met een ICD een complex eerste jaar hebben gehad. Met name de eerste zes maanden zijn moeilijk. Het blijkt dat de ICD veel verandert in het leven van de patiënt; zowel op psychisch, sociaal als fysiek gebied. Cognitieve achteruitgang en confrontatie met de dood moet meer aandacht krijgen van toekomstige onderzoekers.

In de **algemene discussie** worden de uitkomsten van de onderzoeksvragen en de beperkingen van het onderzoek bediscussieerd. Ook worden in dit hoofdstuk de gevolgen voor de

patiëntenzorg en aanbevelingen voor toekomstig onderzoek besproken.

De voornaamste problemen waar patiënten met een ICD mee worden geconfronteerd zijn: slechte kwaliteit van leven en fysiek functioneren, depressieve gevoelens, angst (met name voor de eerste schok), aanvaarding van het hebben van een ICD en accepteren dat men er van afhankelijk is, teleurstelling, frustratie, verslechterd sociaal functioneren ten gevolge van depressieve gevoelens en hoge leeftijd. Onze resultaten laten zien dat wanneer men adequate zorgverlening wil bieden om te zorgen dat patiënten met een ICD zo spoedig mogelijk herstellen en hun "normale" leven weer kunnen oppakken, er aandacht moet uitgaan naar hun psychosociale gezondheidstoestand.

Toekomstige onderzoekers zouden meer aandacht moeten geven aan lichamelijke klachten, type hartziekte, linkse ventriculaire ejectie fractie, medicatie, sociale steun, depressie, cognitie en geheugenproblemen. Wij vinden dat in toekomstig onderzoek meer aandacht moet worden gegeven aan persoonskenmerken van een patiënt met een ICD. Tot slot adviseren wij toekomstige onderzoekers meer meetmomenten te incorporeren tijdens de opname en een langere onderzoeksperiode na ontslag te hanteren. De uitkomst van dit onderzoek doet ons geloven dat het overleven van een hartstilstand een grotere invloed heeft op de kwaliteit van leven dan de behandeling zelf. Gedurende de eerste maanden is alle aandacht er op gericht om weer in een gewoon ritme te komen.



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*I shall be telling this with a sigh  
Somewhere ages and ages hence:  
Two roads diverged in a wood, and I -  
I took the one less traveled by,  
And that has made all the difference.*

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## **Curriculum Vitae**



Helen Kamphuis werd op 22 april 1964 geboren in Groningen. In december 1982 behaalde zij haar Higher School Certificate aan Gynea High School te Sydney, Australia. Begin 1983 verhuisde zij terug naar Nederland. In augustus van dat jaar begon zij met de Hogere Beroepsopleiding tot Verpleegkundige (HBO-V) aan de Rijkshogeschool Groningen. Na het behalen van haar diploma in 1987 werkte zij als verpleegkundige op de afdeling cardiologie van het Academisch Ziekenhuis Utrecht (AZU). In 1988 startte zij in Maastricht met de studie Gezondheidswetenschappen, afstudeerrichting Verplegingswetenschap. Deze opleiding volgde zij parttime. Aan het begin van haar studie heeft zij een korte periode gewerkt als verpleegkundige op de polikliniek KNO van het AZU. In 1989 ging zij werken bij Patientenservice van het AZU. In 1994 behaalde zij haar doctoraal diploma.

In 1997 heeft zij een onderzoeksvoorstel geschreven dat in het zelfde jaar gehonoreerd werd met een subsidie van de Nederlandse Hartstichting. In 1998 begon zij met het in dit proefschrift beschreven onderzoek bij de werkgroep Psychologie van Gezondheid en Ziekte van het Universitair Medisch Centrum (UMC) te Utrecht. In het eerste jaar van dit promotietraject werkte zij voor 2 dagen per week aan het onderzoek en 3 dagen bij Patientenservice. Vanaf januari 1999 tot juni 2001 had zij een 80% dienstaanstelling als onderzoeker bij het UMC. Gedurende haar promotietraject volgde zij de onderzoeksopleiding Klinische Epidemiologie van het Academisch Medisch Centrum te Amsterdam en de opleiding voor promovendi aan de Research Institute for Psychology & Health te Utrecht.

Vanaf juli 2001 heeft zij het onderzoek in eigen tijd uitgevoerd. Daarnaast is zij fulltime werkzaam als site- en projectmanager bij Pinkroccade.