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# Living with life-saving technology

Long-term follow up of recipients  
with implantable cardioverter defibrillator

Inger Flemme



**Linköping University**  
FACULTY OF HEALTH SCIENCES

Division of Nursing Science  
Department of Medical and Health Sciences  
Linköping University, Sweden

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*We have no protection against love  
No protection against life  
No protection against death  
No protection  
So without protection are we.*

*There is something magnificent in that.*

*Eeva Kilpi*

*To Thomas, Anna, Lisa and Maria  
with love*



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## ABSTRACT

The evidence that treatment of life-threatening arrhythmia (LTA) with an Implantable Cardioverter Defibrillator (ICD) can prolong life is convincing. Living with a lifelong heart disease will gradually influence the everyday life and encompasses some or all aspects of life. In order to influence health outcomes, the impact of the ICD must be considered in a broader context including not only the physical, but also the psychological and social functioning of the individual.

The general aim of this thesis was to describe everyday life in recipients living with an ICD in a long-term perspective. The aim in Paper I was to describe changes in the life situation of recipients' with an ICD over a one year period. The aim in Paper II was to describe quality of life (QOL) and uncertainty in recipients who have an ICD and to predict QOL at long-term follow up. Fifty-six recipients participated (I) and 35 of these recipients, who had survived at least five years, were further included (II). The Quality of Life Index-Cardiac version (I, II), Mishel Uncertainty in Illness Scale-Community version (I, II), Patient ICD Questionnaire (I) and multiple regression analysis (II) were used. Higher scores indicate higher QOL and uncertainty. The questionnaires were completed before implantation, three and twelve months after implantation (I) and also five years after implantation i.e. long-term follow up (II). At the long-term follow up, the average ICD recipient had lived with an ICD for six years and nine months (6.9 years). The results showed the overall QOL and QOL in the health/functioning domain were unchanged over time. QOL in the socio-economic ( $p = .002$ ) and psychological/spiritual domains ( $p = .012$ ) decreased in the first year. From baseline to long-term follow up, the QOL in the family domain ( $p = .011$ ) and overall uncertainty ( $p = .002$ ) decreased. Uncertainty related to the information decreased at year 1 in relation to baseline ( $p = .001$ ).

The aim in Paper III was to illuminate the main concern of recipients living with an ICD and how they handle this in their daily life. Sixteen recipients who had lived with an ICD between six to twenty-four months were interviewed. Data was collected and analysed in a simultaneous process according to guidelines for classical grounded theory. In the analysis, a substantive theory was generated explaining the main concern of ICD recipients and how they handle this in their daily life. The core category,

labelled “Striving to resume command”, illuminates the main concern of ICD recipients. To manage this main concern, the recipients used the following strategies: Economizing resources, Distracting oneself, Submitting to one’s fate and Re-evaluating life.

The aim in Paper IV was to explore relationships between QOL, coping strategies, anxiety, depression and perceived control in recipients living with an ICD and to compare those having received an ICD less or more than one year ago and those with a primary or secondary preventive indication. A cross-sectional, correlational, multicentre design was used, and 147 recipients who had lived with an ICD between six to twenty-four months completed Quality of Life Index-Cardiac version, Jalowiec Coping Scale, Hospital Anxiety and Depression Scale and Control Attitude Scale. The results showed that anxiety, depression and perceived control were predictors of QOL. Anxiety was also a predictor of coping with optimistic coping being the most used coping strategy. There was no relationship between QOL and coping. No differences were found in QOL, coping, anxiety, depression and perceived control between recipients implanted either on a primary or secondary preventive indication or having the device less or more than one year.

In this thesis, it was concluded that the ICD recipients strived to resume command over their life (III) and the more control the recipients perceived the more satisfied they were with their QOL (IV) and the more symptoms of anxiety, depression and uncertainty they experienced the less satisfied they were with their QOL (II, IV). Coping strategies were used more frequently by an ICD recipient perceiving more anxiety (IV). QOL was fairly good 6.9 years after implantation and ICD recipients felt less uncertain once they had passed the first year of their illness.

**Keywords:** anxiety, arrhythmia, defibrillators, depression, grounded theory, perceived control, qualitative, quality of life, uncertainty

## LIST OF PAPERS

This thesis for the doctoral degree is based on the following original papers, referred to in the text by their respective Roman numerals as:

- Paper I Flemme I, Bolse K, Ivarsson A, Jinhage B-M, Sandstedt B, Edvardsson N, Fridlund B. Life situation of patients with an implantable cardioverter defibrillator: a descriptive longitudinal study. *Journal of Clinical Nursing*. July 2001;10(4):563–572.
- Paper II Flemme I, Edvardsson N, Hinic H, Jinhage B-M, Dalman M, Fridlund B. Long-term quality of life and uncertainty in patients living with an implantable cardioverter defibrillator. *Heart & Lung*. Nov–Dec 2005;34(6):386-392.
- Paper III Flemme I, Hallberg U, Strömberg A. Striving to resume command – main concern for recipients of implantable cardioverter defibrillator. Submitted.
- Paper IV Flemme I, Johansson I, Strömberg A. Quality of life and coping strategies in recipients with an implantable cardioverter defibrillator. Submitted.

## ABBREVIATIONS

|        |   |
|--------|---|
| CAD    | - Coronary artery disease                                 |
| CAS    | - Control Attitude Scale                                  |
| CRT    | - Cardiac resynchronised therapy                          |
| EF     | - Ejection fraction                                       |
| HADS   | - Hospital Anxiety and Depression Scale                   |
| ICD    | - Implantable cardioverter defibrillator                  |
| IQR    | - Interquartile range                                     |
| JSC    | - Jalowiec Coping Scale                                   |
| LTA    | - Life-threatening arrhythmia                             |
| Md     | - Median  |
| MUIS   | - Mishel Uncertainty in Illness Scale                     |
| MUIS-C | - Mishel Uncertainty in Illness Scale – Community version |
| NYHA   | - New York Heart Association classification               |
| QLI    | - Quality of Life Index                                   |
| QLI-C  | - Quality of Life Index – Cardiac version                 |
| QOL    | - Quality of life   |
| SCD    | - Sudden cardiac death                                    |
| SD     | - Standard deviation                                      |
| VF     | - Ventricular fibrillation                                |
| VT     | - Ventricular tachycardia                                 |

## **INTRODUCTION**

The evidence that treatment of life-threatening arrhythmia (LTA) with an Implantable Cardioverter Defibrillator (ICD) can prolong life is convincing <sup>1-3</sup>. Prolongation of life is closely related to the quality of the years thus gained. Living with a lifelong heart disease, gradually affects the life situation and encompasses some or all aspects of life. In order to influence health outcomes, the impact of the ICD must be considered in a broader context including not only the physical, but also the psychological and social functioning of the individual <sup>4-5</sup>. Uncertainties may arise regarding health and function, the prognosis of the underlying condition, the welfare of the family and coping with the future <sup>6-8</sup>. In addition to their uncertainty, ICD recipients need to assimilate a large amount of new information about the medical condition, the risk of having a new or recurrent LTA, the possible benefits of ICD treatment and technical aspects of the device and details regarding the implantation procedure <sup>6-9</sup>. In the best-case scenario, the ICD recipient will consider the device as a life saver, which only operates when required, thus not interfering with normal everyday life <sup>1-3</sup>. However, an understanding of the medical necessity of the device may lead to anxiety and depression, especially as their condition, ischemia and/or heart failure, usually is progressive <sup>10,11</sup>. The device itself is a constant reminder of the risk that something dangerous or unpleasant could occur at any time <sup>11</sup>. Thus, living with the awareness of the risk for an LTA, and the discomfort the ICD shocks bring about, can influence the ICD recipient's whole life, thereby leading to changes in quality of life (QOL) <sup>12</sup>. Despite the technological advances in the prevention and treatment of LTA, the long-term effects of the ICD on QOL and how recipients cope in everyday life are less well known <sup>12-14</sup>. A more comprehensive picture of ICD recipients' everyday life can be obtained by exploring their main concern, coping strategies and QOL in a long-term perspective, as a complement to existing morbidity and mortality indicators.

## BACKGROUND

### Life-threatening arrhythmia

Cardiovascular disease is the leading cause of death in most industrialised countries. In Europe, cardiac mortality represents around 40% of all causes of death<sup>15</sup>. The major cause of cardiac mortality is sudden cardiac death (SCD) caused by a LTA such as ventricular tachycardia (VT) and ventricular fibrillation (VF). The most common etiology of SCD is coronary artery disease (CAD). One of several definitions of SCD is that it is unexpected, instantaneous death of cardiovascular origin, or death within one hour following the onset of an abrupt change in clinical status<sup>9</sup>. In Sweden, the incidence of SCD is approximately 0.1% of the population annually and about 40% of these events are not witnessed and beyond resuscitation attempts. In the few who survive as a result of immediate assistance including external defibrillation, the risk of recurrence is approximately 10% per year, reaching a recurrence rate of 50% after five years<sup>16</sup>.

LTA can start with one or more ventricular extra beats leading to shorter or longer episodes of VT before deteriorating, or may start directly as a VF. VT may be short and self-terminating, non-sustained, or sustained, i.e. lasting for >30 seconds or lead to haemodynamic collapse within 30 seconds. If the tachycardia does not stop, haemodynamic and metabolic deterioration will follow and, if not treated with an external defibrillation, death will occur within minutes<sup>16</sup>. Most ICD recipients have a history of organic heart disease such as old myocardial scars or left ventricular dysfunction that provide an electrophysiological and haemodynamical substrate for the development of LTA<sup>9,17</sup>.

The utmost goal of ICD therapy is to extend survival, made possible by the ICD's ability to rapidly detect and treat sudden LTAs<sup>1,2</sup>. Indications for implantation of an ICD refer to preventing LTAs leading to SCD in individuals who have had a serious ventricular arrhythmia (i.e. secondary preventive indication) or to be used in individuals at risk of, but not having had, a serious ventricular arrhythmia (i.e. primary preventive indication)<sup>18</sup>. Approximately 48,000 individuals in Western Europe have an ICD and about 24,000 have a cardiac resynchronised therapy (CRT) defibrillator<sup>19</sup>. Sweden has about 3,000 ICD recipients. During 2007, 679 patients were implanted of which 77% of the

ICD implantations were performed on the basis of a secondary preventive indication and 23% on a primary indication<sup>20</sup>. Due to expanded indications based on clinical trials showing improved survival the number of implantations can be presumed to increase which implies that in the future more individuals will live with an ICD<sup>21,22</sup>.

ICD treatment is palliative in the sense that it does not prevent arrhythmias, but it detects and treats them once they happen, resulting in the survival of ICD recipients who would otherwise die<sup>1, 2, 16, 17</sup>. The ICD was developed to automatically intervene and treat LTA and is usually used in combination with pharmacological anti-arrhythmic treatment in order to reduce arrhythmia recurrence. Since the early 1980s ICDs have evolved from large, non-programmable, single-chamber devices requiring a thoracotomy for insertion to smaller, sophisticated, multi-programmable devices implanted by using less invasive techniques and making a pectoral placement possible. Current ICDs include options for single-chamber, dual-chamber and biventricular cardiac resynchronization pacing for non-shock termination of VT, i.e. anti-tachycardia pacing (ATP), in addition to shock therapy for VT and VF<sup>9, 17, 23</sup>.

The ICD can be programmed in many different ways for optimal individual treatment of VT and/or VF. The device senses the electrical activity of the heart via the electrograms recorded at the tips of the implanted leads. It analyses the heart rhythm based on selectable sensing and detection parameters. Life-threatening ventricular arrhythmias are mainly recognised by their very high rates and, if a preset rate limit is reached, the device will first detect the tachyarrhythmia and then reconfirm the diagnosis before delivering treatment. The treatment consists of a number of pre-programmed high energy shocks that may be preceded by attempts to stop the tachyarrhythmia by anti-tachycardia pacing therapy (ATP). The latter aims to control the heart rate by short trains of "overdrive stimulation" and, if successful, normal sinus rhythm will resume when pacing ceases. However, ATP may cause acceleration of the rate leading to VF, hence overdrive pacing attempts usually include a final phase of shock therapy, activated if necessary. VT can often be successfully treated with these painless trains of rapid ATPs and may terminate 60-90% of episodes, thus eliminating the need for shocks. If the arrhythmia does not terminate, the device requires five to ten seconds from diagnosis to shock delivery. The devices provide ongoing therapy, but require monitoring and adjustment throughout the recipient's lifespan<sup>9, 17, 24</sup>.

All ICDs store information that can be retrieved by telemetry. Stored information and electrograms tell the healthcare professionals whether or not

shocks were delivered, the time when they occurred and the duration of the arrhythmia. A strip of electrogram is available to show how each arrhythmia was identified and reconfirmed, when the device charged itself and how treatment was given and if successful. Moreover, since many episodes of VT are symptomless and terminated painlessly by ATP, these data may be the only source of information about such occurrences. Self-terminating episodes of a predefined rate and duration are also recorded and stored in the memory of the ICD. Information is also provided about lead impedance, battery status and remaining device longevity. Histograms of various variables over time are available <sup>9, 17</sup>.

Complications in relation to ICD treatment may concern the surgical procedure or the functioning of the device. Examples of complications related to surgery are lead dislodgment, pneumothorax, pocket and system infection. Premature battery depletion is an example of complications related to the device. The normal functional life-time of an ICD system depends e.g. on the number of options that are actively programmed, numbers of shocks and percentages in pacemaker stimulation. At least four to six years is normal, and the life-time has successively increased with each new model <sup>17, 24</sup>. Problems associated with ICD therapy include inappropriate shocks. Inappropriate treatment is the term used for shocks occurring for any other reason than LTA. For example, inappropriate treatment may occur when noise is falsely interpreted as VF or because of high heart rates during atrial fibrillation. Some ICD recipients only receive appropriate shocks, while others experience both appropriate and inappropriate shocks, only inappropriate shocks, or never have had a symptomatic arrhythmia episode or shock <sup>25</sup>.

## **Follow up routines and informational needs**

The subsequent hospital stay when receiving an ICD generally lasts one to two days. After implantation, ICD recipients must make regular visits to the outpatient ICD clinic to have their device checked, usually four to six weeks post implant and then at regular intervals depending on their condition, but at least twice a year <sup>16</sup>. Several major device companies offer a technology for remote ICD monitoring as a practical alternative for both recipients and healthcare professionals. The remote system technique involves the ICD recipient using a home monitoring base that can receive information from the ICD and then transmit the data to a central location (service centre, central server or web site) where the data can in turn be sent directly to the follow up centre and accessed by healthcare professionals <sup>26, 27</sup>. Currently however,

scheduled regular in-office follow up is still the standard and remote monitoring is regarded as a supplementary option.

One reason for retaining regular visits is that the ICD recipients usually have an underlying heart condition that requires regular follow up by a cardiologist, to assess their general condition and if needed optimize the pharmacological treatment, in addition to the remote monitoring of the device. The healthcare professionals at the clinic play a substantial role in the life of the ICD recipient, to his or her understanding of the situation and adaptation to as good a life as possible. Before and at follow up visits after implantation, many questions may be discussed concerning an appropriate level of activities and exercise as well as about driving, travelling and hobbies. Interaction with electromagnetic fields, cellular phones and the possible impact on employment are also discussed. Written patient information, the device manufacturer's guidelines, and the identification card are other issues of interest <sup>24, 28</sup>. The recipients differ in terms of their need of information about the implantation and its consequences. Some recipients may feel adequately informed and prepared for the implantation <sup>29</sup>, while others need additional information and knowledge <sup>8, 28, 30-32</sup>. Not all recipients, however, want full details about the implantation and its consequences and some recipients feel that they are given too much information <sup>8</sup>. Furthermore, some ICD recipients become emotionally unstable and their ability to assimilate and remember information may be reduced as a result of one or more LTA episodes <sup>6, 33</sup>.

## **Everyday life of ICD recipients**

After implantation the recipients handle their everyday life in different ways. Some live just like before the ICD implantation, resuming previous roles and activities in the family and at work. The ICD does not bother them and they experience the device as a life saver. They feel grateful for surviving and have a belief in the future. They try to interpret their life in a positive way and carry out necessary life style changes <sup>7, 8, 29, 34</sup>. Others experience difficulties in their everyday life. Physical concerns about body weakness, sleeping difficulties, reduced levels of energy and dizziness constitute impediments to a normal life <sup>6, 7, 10, 31</sup>. Psychosocial responses including anxiety and depression and mood disturbance are reported <sup>10, 35-39</sup>. Various sources of fear after the ICD implant have been identified such as fear of device malfunction, pain and other unpleasant experiences when having shocks, the embarrassment of becoming unconscious and having shocks in public, and thoughts about death <sup>6, 11, 13, 40</sup>. The fact that an ICD shock can occur without warning may create a feeling of lack of control both for the ICD recipients and their family members <sup>6, 36, 38-40</sup>.

Experiences of ICD shocks may be perceived in many ways and are usually described as a painful, startling experience, similar to the shock that is experienced when touching an electric fence and as a “kick from the horse”<sup>31, 41</sup>. While some ICD recipients find the shock reassuring others may become distressed<sup>6, 31, 40-42</sup>.

Life-threatening diseases are usually characterised by the unpredictability of symptom intensity, duration and recurrence. When recognition and classification of stimuli cannot occur, no cognitive structure can be built and this may result in uncertainty. When uncertainty occurs individuals may mobilize their resources to adapt to the situation. Uncertainty refers to the inability to determine the meaning of illness-related events<sup>43, 44</sup>. The experience of uncertainty in the illness situation focusing on information, symptoms, diagnosis, the function of the device and worries about the family and the future are issues that ICD recipients reported<sup>45-47</sup>. It seems this uncertainty is greater during the time following ICD implantation and those recipients experiencing great uncertainty one week after hospital discharge also showed more psychosocial problems two months after discharge<sup>48</sup>. A relationship between uncertainty and physical health has been shown where higher uncertainty relates to poorer health<sup>45-47</sup>. These experiences and an awareness of living with an underlying serious heart disease which often is progressive and being dependent on a technical device may result in a perception of loss of control<sup>6-8</sup>. Perceived control refers to an individual's beliefs about the ability to exert control over aspects of his/her life and having the resources required to cope with and change negative events in a more favorable direction. In cardiac patients, more successful coping with stress and better emotional well-being was found to be associated with a higher level of perceived control in the illness situation<sup>49, 50</sup>.

## Coping

A stressor, such as an LTA, is a condition or circumstance which an individual has to cope with, but the same stressor may not be equally stressful to different individuals<sup>51</sup>. Some ICD recipients have longstanding and entrenched heart disease and others were apparently healthy before sudden dangerous arrhythmias. Individual differences in stress responses to specific individual-environmental conditions are mainly explained by differences in cognitive appraisal. According to Lazarus and Folkman<sup>52</sup> three kinds of cognitive appraisal have been defined: primary, secondary and reappraisal. Primary appraisal involves appraisal of an encounter as irrelevant, benign-positive or stressful. Stressful appraisals can be judged as harm/loss (damage

has occurred), of threat (harm or loss is expected) or challenge (opportunity for gain). Secondary appraisal is a judgement based on the individuals' prior experiences of similar situations and on what might and can be done. Primary and secondary appraisals often occur simultaneously and interact with one another. Reappraisal refers to a changing appraisal based on new information from the environment and/or the individual <sup>52</sup>.

Coping are thoughts and behaviours an individual uses to redirect a threat or regulate emotions following stress <sup>53</sup>. The coping process includes two different functions of coping. Problem-focused strategies aim to alter or manage a stressful situation where actions may be directed at the environment or oneself including problem-solving, planning, information seeking and learning new skills. Emotion-focused strategies serve to decrease the emotional distress without changing the realities of the stressful situation and include mental and behavioural withdrawal, denial and venting emotions. Depending on the situation strategies are interchangeable and none of them is superior to the others <sup>51,53</sup>.

The most frequently used coping strategies by ICD recipients during the first year after implantation were being optimistic, self-reliant, supportive and confrontive coping <sup>54</sup>. This pattern shows a mixture of coping strategies and emotion-focused coping is described as relating positively and problem-focused negatively to emotional distress <sup>55</sup>. Denial was another strategy used when emotional stress was highlighted <sup>7,56</sup>. Recipients did not talk about their condition, questioned if they really needed the ICD and did not want too much information <sup>7</sup> while others used withdrawal from other people as a way to avoid emotional involvement <sup>57</sup>. Also, recipients who had received ICD shocks attempted to control shock therapy by reducing or avoiding activities, objects and places the recipients perceived to be associated with earlier ICD shocks <sup>36,58</sup>. However, Dunbar et al., <sup>55</sup> described avoidance as not effective in the outpatient ICD clinic because of the overwhelming information and patient education the recipients should assimilate. More active, problem-focused coping including seeking information and support from others may be more important in reducing feelings of helplessness and anxiety when confronted with heart disease and ICD implantations.

Lazarus and Folkman <sup>52</sup> have defined the concept of coping as "constantly changing cognitive and behavioural efforts to manage specific external and /or internal demands that are appraised as taxing or exceeding the resources of the person" (p. 141). Thus, coping is regarded as a process where cognitive appraisal is central in the interaction between individual and environment. This is different from the previous view of coping where a

coping pattern was determined only by individual factors and the situational context was not seen as partly determining the specific coping responses<sup>52</sup>. The definition of Lazarus and Folkman is the most commonly used definition in nursing research and has been viewed as appropriate for creating instruments to assess coping<sup>59</sup>.

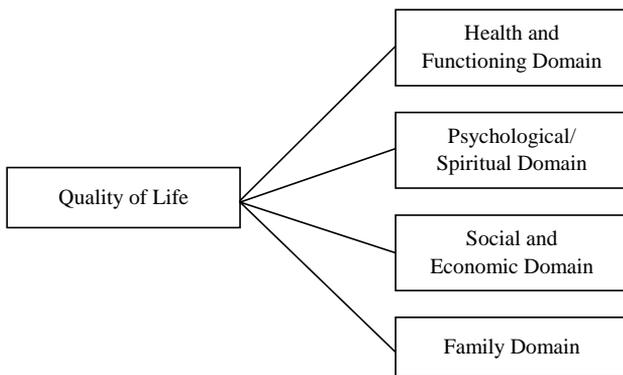
## Quality of life

The construct of QOL has attracted increasing interest over the past 30 years and has become an important outcome for research and clinical practice<sup>60, 61</sup>. This is especially true of life-long diseases for which a cure is unlikely. QOL is a multidisciplinary concept which has led to a multitude of definitions reflecting different disciplines. However, there is no general agreement regarding the definition of QOL. The consensus is that QOL is a subjective and multidimensional construct that reflects different aspects of well-being<sup>5, 62</sup>. QOL is also described as a concept that is most meaningful depending on how it is experienced by individuals. Objective definitions focus on the conditions that influence QOL rather than on the experience of life itself<sup>61</sup>.

The multidimensional construct of QOL includes at least the physical, psychological and social dimensions in the context of disease<sup>5, 61, 62</sup>. Scales and questionnaires intended to measure these dimensions were developed but generally only captured the physical dimension<sup>5</sup>. Conceptual distinctions between QOL and related concepts such as health, health status, health-related quality of life, physical functioning, functional status, symptoms, psychosocial adjustment, well-being, life satisfaction and happiness have been vague and aggravate comparisons and conclusions from data<sup>60</sup>. Commonly used definitions in healthcare can be classified in two groups, where one focuses on the level of functioning and the other on patient satisfaction<sup>4</sup>. Both classifications are important healthcare outcome measures, as the first provides information about the actual level of functioning and the second about self-rated QOL. Individuals' assessments of functional ability can differ from their assessment of their life, especially in lifelong disease, as they tend to make adjustments to compensate for functional disability, which can help to maintain satisfaction with life<sup>63</sup>. When the term health-related QOL is used the focus is on the effects of illness and treatment on QOL<sup>5, 62</sup>.

According to Ferrans and co-workers<sup>61</sup>, their definition of QOL focuses primarily on satisfaction and QOL was defined as "a person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her" (p. 296). Satisfaction was chosen as a construct of QOL because it suggests a cognitive experience, which better fits conceptually

with the idea that QOL is determined by evaluation of life's condition. The definition of QOL also takes into account the fact that different individuals have different values, which means that the impact of various aspects of life on QOL varies between individuals. It also takes into consideration that individuals who are greatly satisfied with the domains of their life enjoy a better QOL than those who are dissatisfied. Ferrans<sup>61</sup> stated that definition of QOL should reflect the domains that are of particular interest for research (Figure 1).



**Figure 1.** Conceptual model for Quality of life according to Ferrans<sup>61</sup>. Copyright by Springer Publishing Company. Used with permission.

QOL is not only influenced by both disease and device but also by the adaptation to a changed life situation as a result of the implantation<sup>64</sup>. All recipients have to make changes in their everyday life and living with an ICD can positively influence QOL by increased security provided by the device<sup>12, 38, 65-69</sup>. However, QOL and its physical, psychological and social dimensions may be temporarily changed for some time, but most of the recipients return to their normal life after a period of time<sup>10, 13, 41, 46, 47</sup>. However, it has also been shown that after living a lengthier time with an ICD, QOL has decreased<sup>70</sup>. A more comprehensive picture of ICD recipients' everyday life can be obtained by exploring their main concern, coping strategies and QOL in a long-term perspective.

## **AIMS OF THE THESIS**

The general aim of this thesis was to describe everyday life in recipients living with an implantable cardioverter defibrillator in a long-term perspective.

The specific aims were to:

- describe changes in the life situation of recipients with an implantable cardioverter defibrillator over a one year period (I).
- describe quality of life and uncertainty in recipients who have an implantable cardioverter defibrillator and predict quality of life at long-term follow up (II).
- illuminate the main concern of individuals living with an implantable cardioverter defibrillator and how they handle this in their daily life (III).
- explore relationships between quality of life, coping strategies, anxiety, depression and perceived control in recipients living with an ICD and compare those having received an ICD less or more than one year ago and those with a primary or secondary preventive indication.

## **METHODS**

### **Design**

This thesis has a multimethod research design including both quantitative and qualitative studies intended to complement each other<sup>71</sup> describing the multidimensional and complicated aspects of ICD recipients everyday life. A descriptive design was used to gain understanding about everyday life in ICD recipients (I, II, III, IV). Papers I and II had a longitudinal design where differences in the same recipients were described over an extended period of time as at baseline, three and twelve months after implantation (I) and at baseline, twelve months and five years after implantation (II) (Table 1). At five years after implantation the recipients on average had lived with an ICD for six years nine months (range four years eleven months to eight years seven months) i.e. long-term follow up. In this thesis, six years nine months is further expressed as long-term follow up and described as 6.9 years. Cross-sectional and correlational design was used to explore relationships in ICD recipients in various stages after ICD implantation i.e. between six to twenty-four months (IV). The predictive design was used to describe relationships by predicting the amount of variance in the dependent variables QOL and coping strategies explained by a set of independent variables – physical, psychological, socio-demographic and coping variables (II, IV). The qualitative perspective (III) was used to obtain a deeper understanding of the ICD recipients' everyday life.

**Table 1.** Overview of methods included in the thesis

|                      | <b>Design</b>   | <b>Partici-<br/>pants, N</b> | <b>Time<br/>frame</b>                                  | <b>Instruments</b>                              | <b>Data analysis</b>  | <b>Validity<br/>Reliability</b>                               |
|----------------------|---|------------------------------|--|---|---|---|
| <b>Paper<br/>I</b>   | Descriptive, longitudinal<br>- 1 year<br>follow up                                | 56                           | Baseline, 3<br>mths, 12<br>mths<br>postimplant         | QLI-C, MUIS-<br>C, Patient ICD<br>questionnaire | Sum, range,<br>Wilcoxon's,<br>Friedman's,   | Cronbach's alpha,<br>factor analysis                          |
| <b>Paper<br/>II</b>  | Descriptive, longitudinal<br>- 6.9 years<br>follow up,<br>predictive              | 35                           | Baseline,<br>12 mths,<br>6.9 years<br>post-<br>implant | QLI-C,<br>MUIS-C                                | Mean, SD, range,<br>ANOVA, Bonferroni<br>correction, multiple<br>regression analysis          | Cronbach's alpha  |
| <b>Paper<br/>III</b> | Qualitative   | 16                           | 6-24 mths<br>postimplant                               | Grounded<br>theory                              | Constant<br>comparative methods<br>according to Glaser  | Trustworthiness,<br>fit, work,<br>relevance,<br>modifiability |
| <b>Paper<br/>IV</b>  | Descriptive, multicentre,<br>cross-<br>sectional,<br>correlational,<br>predictive | 147                          | 6-24 mths<br>postimplant                               | QLI-C, CAS<br>JCS, HADS                         | Md, IQR, Spearman<br>R correlation, Mann<br>Whitney U-test<br>multiple regression<br>analysis | Cronbach's alpha  |

mths = months, baseline = before implantation, QLI-C = Quality of Life Index- cardiac version, MUIS-C = Mishel Uncertainty in Illness Scale – community version, CAS = Control Attitude Scale, JCS = Jaloviec Coping Scale, HADS = Hospital Anxiety and Depression Scale, SD = standard deviation, Md = median, IQR = interquartile range.

## Setting

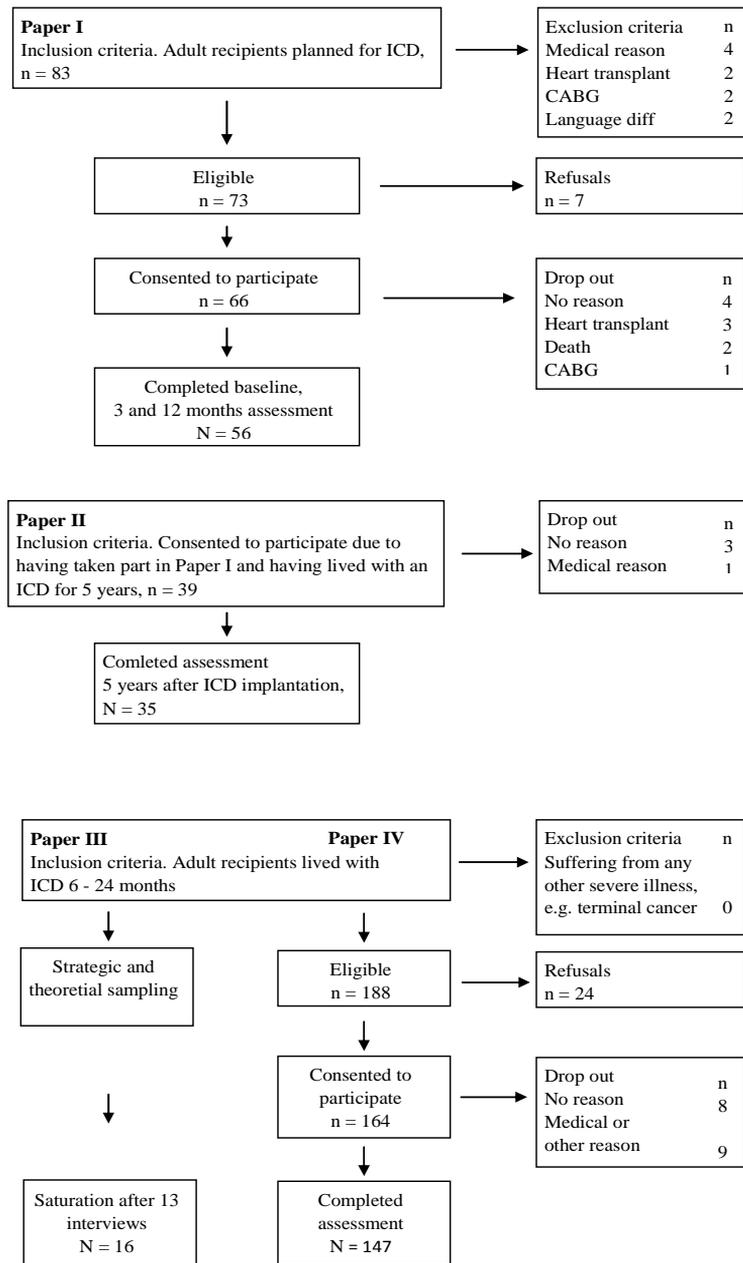
The recipients were enrolled at departments of cardiology from one university hospital (I, II), from two university hospitals and one county hospital (III) and from three university hospitals and one county hospital (IV) covering a large part of the ICD population in southern Sweden. Multicentre settings were used to be able to enrol a sufficient number of recipients to perform statistical analysis and compare subgroups (IV) and to form a heterogeneous group (III) by using ICD recipients belonging to hospitals of different sizes, geographic locations and routines for follow up.

## Participants and time for study inclusion

Eighty-three consecutive patients (Figure 2) with LTAs were recruited over a period of three years and eight months (December 1993 to August 1997) (I). Inclusion criteria were adult patients with planned implantation of an ICD as a

form of secondary prevention. After checking for exclusion criteria and drop-out a total of 56 patients completed the questionnaires. As the study was extended to a long-term follow up (II), the recipients who had participated in Paper I, and who had lived with the ICD for at least five years, were approached and invited to participate in the extended study. Seventeen ICD recipients were not included because they did not fulfil the two inclusion criteria. Although they had participated in Paper I, they had not lived with an ICD for five years. One recipient underwent a heart transplant, two had their device explanted and fourteen were dead at the time of the start of the follow up study. Thus, 39 ICD recipients were eligible for further participation, four of whom dropped out, leaving a total of 35. Data were collected from April 2002 to September 2002.

In Papers III and IV, inclusion criteria were that adult recipients had lived with an ICD between six to twenty-four months. In Paper III, the sample consisted of sixteen ICD recipients, interviewed between August 2007 and December 2007. In Paper IV, all recipients who met the inclusion criteria on a certain date at the four hospitals were selected and data collection was carried out between November 2007 and April 2008. In total 188 participants were eligible for the study. After checking for exclusion criteria and drop-out a total of 147 patients completed the questionnaire (IV). In the drop-out analysis (IV) comparing study participants and those that either refused participation from the beginning or dropped out, it was found that those who participated had lower ejection fraction-values ( $p < .05$ ). Of those who participated, two thirds had moderate to severe impaired left ventricular function compared to half of those who did not agree to participate.



**Figure 2.** Flowchart of the sample size, inclusion criteria and drop-out in recipients with an ICD in Paper I-IV.

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## Instruments

### **Mishel Uncertainty in Illness Scale - community version**

The Mishel Uncertainty in Illness Scale (MUIS) was developed by Mishel to measure uncertainty related to symptom, diagnosis, treatment, relationship with caregivers, and planning for the future <sup>72</sup>. The community form of the MUIS (MUIS-C) was modified from the original MUIS for use with chronically ill patients <sup>43</sup>. It is a self-reported questionnaire composed of 23 items rated on a 5-point scale from “strongly agree” to “strongly disagree” with a theoretical range between 23 and 115. Higher scores indicate greater perceived uncertainty. The Swedish version of the MUIS-C reveals a Cronbach’s alpha coefficient of .82 <sup>73</sup>. Internal consistency reliability reveals a Cronbach’s alpha coefficient of .90 (I) and .79 (II).

### **Hospital Anxiety and Depression Scale**

The Hospital Anxiety and Depression Scale (HADS) was developed by Zigmond and Snaith to measure the level of symptoms of anxiety and depression individuals experience in life <sup>74</sup>. The HADS aims to identify clinical cases (possible and probable) of anxiety disorders and depression among somatically ill, non-psychiatric patients. It is a self-reported questionnaire composed of fourteen items in two parts where seven items measure symptoms of anxiety (HADS-A) and the remaining seven items symptoms of depression (HADS-D). Items are rated on a 4-point scale with different alternative answers for each item and with a theoretical range between 0 and 21 in each part. Mild to moderate symptoms of anxiety and depression are apparent with the score 8 to 10, and more than 10 points speak for a clinically significant condition, which gives grounds for more intense diagnostics and possibly treatment. HADS is composed for use in somatic, mental, and primary healthcare. In a review of studies using HADS Cronbach’s alpha varied from .68 to .93 in the anxiety scale and .67 to .90 in the depression scale <sup>75</sup>. Internal consistency reliability reveals a Cronbach’s alpha coefficient of .86 for the anxiety scale and for the depression scale .69 (IV).

### **Patient Implantable Cardioverter Defibrillator Questionnaire**

The Patient ICD Questionnaire was developed by Brodsky to measure fear and concerns regarding ICD. It is a self-reported questionnaire composed of seven subscales with four to eleven items in each subscale. Items are rated on a 3-point scale from “not at all”, “some” and “a lot” with a theoretical range between 42 and 126. Higher scores indicate greater fear/concerns. The items deal with the fear caused by the ICD triggering an ICD shock in connection

with physical activities (five items), embarrassment caused by the ICD triggering an ICD shock in connection with certain activities (five items), suffering described in terms of fear of pain and of death (five items), worry caused by the fear that the ICD will stop functioning (four items), wishes regarding the appearance of the ICD and its location in the body (four items), recipients' worry of being a burden to the family (eleven items) and life changes after implantation in terms of changes in physical, emotional and social activities (eight items). Internal consistency reliability reveals a Cronbach's alpha coefficient of .76 –.85 (I).

### **Control Attitude Scale**

The Control Attitude Scale (CAS) was developed by Moser and Dracup to measure the level of control the participants perceived related to their heart disease<sup>49, 50</sup>. It is a self-reported questionnaire composed of four items rated on a 7-point scale from “no control at all” to “very much control” with a theoretical range between 4 and 28. Higher scores indicate greater perceived control. Instrument reliability was assessed by internal consistency with a Cronbach's alpha of .89<sup>49</sup>. Internal consistency reliability reveals a Cronbach's alpha coefficient of .75 (IV).

### **Jalowiec Coping Scale**

The Jalowiec Coping Scale (JCS) was developed by Jalowiec to measure use of coping strategies and how helpful these strategies are perceived to be by the individual<sup>76, 77</sup>. It is a self-reported questionnaire composed of two parts, each with 60 items. Part A measures how much each coping strategy is used and part B measures how helpful or effective it is perceived. Items are rated on a 4-point scale from “never used/not helpful” to “often used/very helpful” with a theoretical range between 0 and 180 for the total scale and 0 and 3 for the subscales. Higher scores indicate greater use of coping strategies in part A. Effective ratings are performed only for those strategies the recipient reports using in part A and therefore the response rates are lower in part B. Because few recipients responded to part B only part A was included (IV). The 60 items are classified into eight coping strategies: confrontive (ten items) such as constructive problem-solving, evasive (thirteen items) such as doing things to avoid confronting problems, optimistic (nine items) such as positive thinking or positive attitudes about the problem or the situation, fatalistic (four items) such as pessimistic thinking or pessimistic attitudes towards the problem or situation, emotive (five items) such as expressing/ releasing emotions, palliative (seven items) such as doing things to make yourself feel better, supportive (five items) such as using support systems and self-reliant (seven

items) such as depending on yourself to deal with the situation, rather than on others. The confrontive and supportive coping strategies are classified as problem-focused coping and the other six as emotion-focused coping. The Swedish version of JCS has shown a Cronbach's alpha coefficient for total scale .96 to .75 and for the subscales .55 to .65<sup>78</sup>. Internal consistency reliability reveals a Cronbach's alpha coefficient .96 for the overall scale and for subscales varied between .63 to .89 (IV).

### **Quality of Life Index – Cardiac version**

The Quality of Life Index (QLI) was developed by Ferrans and Powers to measure QOL in terms of satisfaction with life in healthy populations as well as those with diseases<sup>79</sup>. The QLI measures both satisfaction and the importance of various aspects of life. Importance ratings are used to weight satisfaction responses, so that the scores reflect the respondents' satisfaction with the aspects of life they value. Items that are rated as more important have a greater impact on the scores than those of lesser importance. A common set of items forms the basis of all versions, and items relevant to a particular disease are added to create illness-specific versions. In this thesis, the Quality of Life Index - Cardiac version (QLI-C) was used. It is a comprehensive instrument specifically designed to measure generic QOL with an added disease component. It is a self-reported questionnaire composed of two parts, each with 38 items. Part I measures satisfaction within four different domains of life while part II measures the importance of the same four domains to the individual. Items are rated on a 6-point scale from "very satisfied/very important" to "very dissatisfied/very unimportant" with a theoretical range between 0 and 30. Higher scores indicate greater satisfaction with life. Overall QLI-C is the total satisfaction score. The four QLI-C subscales represent four major life domains: health/functioning, socio-economic, psychological/-spiritual, and family.

The health/functioning domain (sixteen items) relates to physical health, functional ability, stress/worries and leisure activities. Specific items related to cardiac disease are added to this domain. The socio-economic domain (eleven items) refers to economic aspects such as financial independence and standard of living, friends and emotional support. The psychological/ spiritual domain (seven items) refers to cognitive, emotional and spiritual aspects of life. The family domain (four items) refers to family, spouse and children. Furthermore, fifteen illness-specific versions of the QLI have been developed for use with various conditions and the cardiac version is translated into eleven languages<sup>80</sup>. The Swedish version of the four QLI subscales has shown a Cronbach's alpha coefficient of .83 to .87<sup>81</sup>. Internal consistency reliability reveals a

Cronbach's alpha coefficient of .70 to .89 for the four subscales and .81 for the total scale (I), subscales .65 to .87 and total scale .78 (II) and subscales .66 to .87 and total scale .90 (IV).

Permission was obtained from all constructors of the instruments used in the thesis and recoding of items in the questionnaires was performed following the constructor's instructions.

### **Grounded theory**

Originally, grounded theory was developed by the two sociologists Glaser and Strauss in order to develop a new perspective on phenomena that could not be surveyed with quantitative methods<sup>82</sup>. According to Glaser and Strauss "all is data" and what is important in the studied field will present itself, i.e. emerge<sup>82</sup>. Glaser's version of grounded theory is now referred to as classical grounded theory. In this thesis, the classical grounded theory approach was chosen, since such an inductive method is especially suitable when the research question concerns theory generation and social processes in sparsely studied areas<sup>83</sup>. The method offers researchers a set of guidelines for building conceptual frameworks that specify the relationships among categories i.e. theory generation. While the qualitative study in this thesis relies on the guidelines of the classical version of grounded theory there are also other modes of the method on a Glaser-to-Charmaz continuum<sup>84</sup>. Hallberg<sup>84</sup> argues that grounded theory has developed in a historical context and has been modified by the era in which it exists. The overall aim of a grounded theory study is to generate a theoretical model which can increase understanding and explain the area under study. Grounded theory is thus a theory-generating method<sup>85</sup>.

Criteria for judging the validity of a grounded theory study include fit, work, relevance and modifiability<sup>83, 85</sup>. Fit is what Glaser calls validity. The emerged categories, grounded in data, should express that pattern in data which needs to be explained. The theory should be relevant for the studied area and deal with the individual's main concern. A grounded theory should capture the individuals concerned and the reader who will recognize the core category as an important concept in the studied area. The theory should work i.e. identify and explain the main concern and the variety in how individuals solve their concerns. Modifiability means that the theory is flexible and can be modified when new data emerge. Grounded theory should adapt to data and not the reverse.

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## The quantitative studies (I, II, IV)

### Data collection

During their hospital stay and before ICD implantation the patients were asked to participate in the study by healthcare professionals and those who agreed to participate completed the questionnaires (QLI-C, MUIS-C) on three occasions: before implantation, three and twelve months after implantation and the Patient ICD Questionnaire three and twelve months after implantation (I). Before implantation, patients completed the questionnaires at the hospital and at three and twelve months after they filled them in either at hospital or at home. In Paper II, the ICD recipients were contacted by telephone around five years after implantation and asked if they agreed to further participation. Those agreeing to participate were contacted personally (n = 30) or by telephone (n = 5) and completed the long-term follow up questionnaires at the hospital or at home. In Paper IV the questionnaires were distributed to the recipients by post and three follow up reminders were sent. Demographic data, clinical data and number of ICD shocks were collected from the medical records, self-reported questionnaires (I, II, IV) and ICD memory (IV).

### Data analysis

The computer software SPSS, version 11.0 to 16.0 was used for data analysis (SPSS inc., Chicago, IL, USA) (I, II, IV). In Papers I, II and IV descriptive statistics such as mean, standard deviation (SD), median (Md), interquartile range (IQR) (25<sup>th</sup>–75<sup>th</sup> percentile) and range have been used. The non-parametric Wilcoxon Signed Rank test and Friedman's Two Way Anova test were used to analyse differences in QOL, uncertainty and fear variables over time (I). The parametric repeated-measures analysis of variance statistics was used to test for differences in QOL and uncertainty over time (II). Mann Whitney U-test was used to compare QOL, anxiety, depression and perceived control between groups of primary or secondary preventive indication and time since implantation less or more than one year. The Spearman R correlation test was performed to test for bivariate correlations (IV). Multiple regression analyses with backward elimination were used to identify predictors of QOL (II and IV) and of coping strategies (IV). The choice of independent variables was based on the aim and related to clinical status, nursing care, known and unknown predictors. Independent variables comprising gender, age, marital status, uncertainty, New York Heart Association classification (NYHA) <sup>86</sup> and number of perceived ICD shocks were used (II) and anxiety, depression, perceived control and either coping

strategies or QOL depending on the dependent variable (IV). The level of significance was set at a p-value of  $< .05$ <sup>71, 87</sup>.

## **The qualitative study (III)**

### **Data collection and analysis**

An open sampling of recipients was done to form a heterogeneous group and thereby maximize variations in ICD recipients' experiences and descriptions. The exclusion criterion for participation in the study was suffering from any other severe illness, e.g. terminal cancer.

The recipients were contacted by telephone by the nurse at the outpatient ICD clinic, who informed them about the study and requested their participation. Recipients willing to participate in the study were contacted by telephone by the main author (IF) in order to schedule time and place for the interview. Data were collected by the main author by means of tape-recorded, open interviews and took place in the recipient's home (thirteen recipients) and in a university office (three recipients). The interviews lasted up to 90 minutes and concerned themes such as problems in everyday life, strategies to handle their problems and thoughts about the future. During the interview the recipients had the opportunity to raise questions relevant to them and the interviewer asked follow up and probing questions. At the end of the data collection, theoretical sampling, directed by the emerging results, was used in order to saturate each category. Theoretical sampling was done either by interviewing new recipients or by reanalysing earlier assessed data. After thirteen interviews saturation was reached, i.e. no new information was received despite new data. However, in all, sixteen interviews were carried out to secure saturation<sup>83</sup>. The study sample consisted of ICD recipients who have had their ICDs for between six and twenty-four months. Nine of the recipients were men (51-78 years) and seven women (31-72 years) (Table 2).

In line with guidelines for grounded theory, data collection and data analysis were performed simultaneously. The analysis comprised a systematic process of coding and comparisons of raw data (interview transcripts), as well as a parallel use of memos. Interviews were coded as they were collected step-by-step and memos were continuously written on ideas and preliminary hypotheses which emerged from the data. In the first open coding step, raw data were transformed into theoretical constructs. This means the transcribed interviews were read line-by-line, and codes illuminating the meaning of data were identified and constantly compared to one another in order to identify differences and similarities. Codes with similar meaning were grouped into

preliminary categories. Each category was further developed and related to its subcategories or properties. A core category was then identified and described a social process which illuminated the recipients' main concern in everyday life. In the last coding step all the emerging categories were integrated and refined in this study to form a theoretical model or a saturated substantive theory. The core category was central in the data and was consistently related to all other emerging categories.

## **Ethical considerations**

Throughout the thesis the principles outlined in the Declaration of Helsinki were followed <sup>88</sup>. Ethical approval was obtained from the Regional Ethical Review Board at Göteborg University, Sweden for Papers I and II (Ad 349-93, T 090-02) and for Papers III and IV from the Regional Ethical Review Board in Linköping (Dnr M121-07). All ICD recipients were invited to participate and were informed verbally and written about the study and their rights. The information disclosed that participation was voluntary, that they could withdraw from the study at any time without giving a reason and that participation in or withdrawal from the study would have no consequences for their treatment or care. Recipients were also assured of the confidential nature of the study and no individual answers could be identified, as data were treated at group level. For Paper III, recipients were informed that the interview would be tape-recorded and transcribed verbatim. When recipients agreed to participate, they signed a written informed consent form. Completion of questionnaires or participation in interviews can possibly be perceived as a violation of integrity but the risk of causing temporary discomfort nevertheless was estimated as minimal. For recipients who may have felt uncertain about the future, participation could have increased or decreased their worry. Recipients had access to the main author's phone number in case they wanted to make contact before or after participation.

## RESULTS

### **Characteristics of the recipients**

In this thesis, comprehending 254 ICD recipients, 77% were men (Table 2). The average age for all recipients was 62 years. Men were around 10 years older than women, 64 years old compared to 55 years. Seventy-nine per cent were cohabiting. Of the recipients 59% were retired due to age or disability. Coronary artery disease was the main cause for ICD implantation (50%) and 52 % had not received ICD shocks. There were no differences in recipients receiving the ICD either on a primary or secondary preventive indication or having lived with the ICD more or less than one year concerning QOL, anxiety, depression, perceived control and use of coping strategies.

### **Uncertainty, anxiety, depression, fear and perceived control**

Uncertainty related to information had decreased at year one in relation to baseline ( $p = .001$ ) and lower scores showed an improvement regarding experienced uncertainty (I). In Paper II, uncertainty decreased from baseline and year one to the long-term follow up ( $p = .002$ ). In Paper IV, 65% of the recipients had no symptoms of anxiety but 18% had mild to moderate symptoms of anxiety and 17% suffered from severe symptoms. The majority of recipients had no symptoms of depression (88%), 11% had mild to moderate symptoms of depression and 1 % suffered from severe symptoms. A statistically significant difference in the subscale life changes was found ( $p = .028$ ) showing that the ICD recipients' fear and concerns decreased one year after implantation (I). The recipients perceived moderate control (Md 17, IQR 15 to 22) over their heart condition.

**Table 2.** Characteristics of ICD recipients

|   | Paper I, N=56 | Paper II, N=35 | Paper III, N=16 | Paper IV, N=147 |
|---|---------------|----------------|-----------------|-----------------|
| <b>Age, mean, SD</b>                              |               |                |                 |                 |
| All   | 58.8 ±12.0    | 65.5 ±11.9     | 57.6 ±13.6      | 63.0 ±13.0      |
| Men   | 60.9 ±10.0    | 68.8 ±8.6      | 60.6 ±12.0      | 65.0 ±11.6      |
| Women   | 52.8 ±15.5    | 59.2 ±15.0     | 53.7±15.6       | 54.0 ±14.0      |
| <b>Gender, n</b>                                  |               |                |                 |                 |
| Men   | 42            | 23             | 9               | 121             |
| Women   | 14            | 12             | 7               | 26              |
| <b>Marital status, n</b>                          |               |                |                 |                 |
| Cohabiting  | 46            | 25             | 13              | 116             |
| Single  | 10            | 10             | 3               | 31              |
| <b>Working status, n</b>                          |               |                |                 |                 |
| Retired due to age or disability                  | 27            | 26             | 8               | 89              |
| Working   | 20            | 9              | 8               | 56              |
| Missing   | 9             | 0              | 0               | 2               |
| <b>Causative cardiovascular ICD indication, n</b> |               |                |                 |                 |
| CAD   | 27            | 18             | 6               | 76              |
| Heart failure                                     | -             | -              | -               | 8               |
| Cardiomyopathy                                    | 15            | 7              | 7               | 49              |
| Other   | 14            | 10             | 3               | 14              |
| <b>Ejection fraction, %</b>                       |               |                |                 |                 |
| EF >40, n   | 19            | 8              | 5               | 37              |
| EF 30–40, n                                       | 20            | 3              | 3               | 46              |
| EF <30, n   | 14            | 4              | 4               | 52              |
| Missing, n  | 3             | 20             | 4               | 12              |
| <b>Self-reported ICD shocks, n</b>                |               |                |                 |                 |
| No shock  | 31            | 10             | 8               | 84              |
| Shock   | 25            | 25             | 8               | 51              |
| Missing   | 0             | 0              | 0               | 12              |

N = number, SD = standard deviation, CAD = coronary artery disease, ICD = implantable cardioverter defibrillator, Other: as alternative answer in the variable causative cardiovascular ICD indication comprising long QT-syndrome, Brugada syndrome, idiopathic, EF = ejection fraction.

## Self-reported implantable cardioverter defibrillator shocks

Number of ICD shocks experienced by ICD recipients was self-reported (Table 4). The majority of recipients reported the number of ICD shocks to be between one and ten (I, II, III, IV). It was shown that the longer the recipients had lived with the ICD, the greater the risk of receiving ICD shocks (I, II). Secondary preventive recipients were more likely to report having received a shock from their devices (34% versus 21.5%) compared to primary preventive recipients (IV).

**Table 4.** Distribution of ICD recipients self-reported number of received ICD shocks

| Time period                | Number of ICD shocks |              |           |                |
|----------------------------|----------------------|--------------|-----------|----------------|
|                            | 1–10 shocks          | 11–20 shocks | >21shocks | 0 shock at all |
| <b>T<sup>1</sup> N=56</b>  | 13                   | 2            | 1         |                |
| <b>T<sup>2</sup> N=56</b>  | 21                   | 2            | 2         | 31             |
| <b>T<sup>3</sup> N=35</b>  | 11                   | 1            | 1         |                |
| <b>T<sup>4</sup> N=35</b>  | 21                   | 2            | 2         | 10             |
| <b>T<sup>6</sup> N=16</b>  | 8                    | 0            | 0         | 8              |
| <b>T<sup>7</sup> N=135</b> | 45                   | 4            | 2         | 84             |

N= number

T1 = time period from baseline to three months after implantation (I)

T2 = time period from baseline to twelve months after implantation (I)

T3 = time period from baseline to one year after implantation (II)

T4 = time period from baseline to six years nine months after implantation (II)

T6 = time period from six to twenty-four months after implantation (III)

T7 = time period from six to twenty-four months after implantation (IV)

## Use of coping strategies

Out of the eight coping strategies optimistic coping was the most frequently used followed by confrontive, self-reliant and fatalistic coping (Table 5). Emotive and supportive coping were almost never used. The total item score for all coping strategies used showed a median rating of 1.1 (range 0.7 to 1.4). This reflects that the total use of all coping strategies was quite low with 1 being defined as seldom used<sup>76,77</sup>. Use of coping strategies showed only a few weak correlations with QOL (range,  $r = .02$  to  $.32$ ).

**Table 5.** Total and subscale scores for use of coping strategies (N = 147)

|                              | N   | Md  | IQR     |
|------------------------------|-----|-----|---------|
| <b>Total score</b>           | 147 | 73  | 46/91   |
| <b>Total item score</b>      | 147 | 1.1 | 0.7/1.4 |
| <b>Subscale item scores:</b> |     |     |         |
| confrontive                  | 138 | 1.3 | 0.6/1.8 |
| evasive                      | 135 | 0.9 | 0.4/1.3 |
| optimistic                   | 141 | 1.9 | 1.4/2.2 |
| fatalistic                   | 143 | 1.3 | 0.8/1.8 |
| emotive                      | 137 | 0.4 | 0.2/1.0 |
| palliative                   | 139 | 0.9 | 0.4/1.3 |
| supportive                   | 142 | 0.8 | 0.4/1.4 |
| self-reliant                 | 138 | 1.3 | 0.5/1.9 |

N = number, Md = median, IQR = interquartile range

Total scores can range from 0 to 180. Subscale scores can range from 0 to 3.

However, coping strategies had no correlation with QOL, but did show strong correlation with anxiety, depression and perceived control (IV). Evasive and fatalistic coping correlated with anxiety ( $r = .49$ ,  $r = .56$ ), depression ( $r = .44$ ,  $r = .35$ ) and negatively with perceived control ( $r = .40$ ,  $r = .40$ ), respectively. Emotive coping correlated with anxiety ( $r = .62$ ) and depression ( $r = .42$ ). Confrontive, palliative and self-reliant coping correlated with anxiety ( $r = .38$ ,  $r = .48$ ,  $r = .38$ ), respectively. Overall use of coping strategies correlated with anxiety ( $r = .50$ ) and depression ( $r = .37$ ). In the regression analysis (IV) the independent variable anxiety was positively correlated ( $\beta = 3.27$ ,  $p = .001$ ) with the dependent variable overall use of coping strategies and accounted for 21% of the variance, suggesting that greater symptoms of anxiety were related to

greater use of coping strategies. No relation was found between use of coping strategies and QOL, depression or perceived control.

## **Quality of life**

In Papers I, II, and IV QOL in ICD recipients was studied using the questionnaire QLI-C which indicates greater QOL when higher scores are reported (Table 3). In the 1-year follow up (I), no statistically significant differences in QOL between the time periods were shown. In the long-term follow up (II), QOL in the family domain decreased from baseline to the long-term follow up ( $p = .001$ ) but QOL in the health/functioning, socio-economic and psychological/spiritual domains and overall QOL were unchanged. However, there were significant differences between different time periods within the domains. Follow up post hoc measures indicated that the socioeconomic ( $p = .002$ ) and psychological /spiritual domains ( $p = .025$ ) decreased from baseline to year 1. In Paper IV, QOL scores showed similar values to those reported in Papers I and II (Table 3). In the three studies measuring QOL the rating of the family domain was the highest and of health/functioning the lowest. There was a weak relationship between overall QOL and its four domains and the use of coping strategies. However, overall QOL and its four domains strongly correlated positively with perceived control and negatively with depression and anxiety.

In the regression analysis (II) the independent variable uncertainty was negatively correlated ( $\beta = .44$ ,  $p = .011$ ) with the dependent variable QOL in the health/functioning domain accounting for 19% of the variance, suggesting that higher uncertainty was related to lower QOL in this domain. There were no other significant predictors of the variables gender, age, marital status, NYHA classification and perceived ICD shocks at the long-term follow up. In the regression analysis (IV) the independent variables anxiety and depression were negatively correlated ( $\beta = .16$ ,  $p = .025$ ,  $\beta = .30$ ,  $p = .012$ ) respectively and perceived control was positively correlated ( $\beta = .26$ ,  $p = .001$ ) with the dependent variable overall QOL. Collectively, these variables accounted for 42% of the variance, suggesting that higher perceived control and fewer symptoms of anxiety and depression were related to higher QOL. No relationship was found between overall QOL and the use of coping strategies.

**Table 3.** Quality of Life Index-Cardiac version (QLI-C) scores

|                         | Paper I         |                 |                 | Paper II        |                     |                     | Paper IV                  |
|-------------------------|-----------------|-----------------|-----------------|-----------------|---------------------|---------------------|---------------------------|
|                         | Before implant  | 3 mths after    | 12 mths after   | Before implant  | Year 1 after        | 6. 9 years after    | Cross-sectional 6–24 mths |
|                         | Mean<br>± SD        | Mean<br>± SD        | Mean<br>± SD              |
| <b>N</b>                | 56              | 56              | 56              | 35              | 35                  | 35                  | 147                       |
| <b>Paper</b>            | I               | I               | I               | II              | II                  | II                  | IV                        |
| <b>Overall QLI-C</b>    | 22.61<br>± 2.80 | 21.91<br>± 3.68 | 21.51<br>± 3.12 | 22.91<br>± 2.96 | 21.73<br>± 3.01     | 22.42<br>± 2.88     | 21.91<br>± 3.50           |
| <b>Health/function</b>  | 19.44<br>± 4.62 | 18.70<br>± 5.53 | 19.02<br>± 4.75 | 19.53<br>± 4.67 | 19.62<br>± 4.18     | 20.50<br>± 4.42     | 20.51<br>± 5.28           |
| <b>Socio-economic</b>   | 21.41<br>± 3.48 | 21.27<br>± 3.88 | 19.88<br>± 3.60 | 21.67<br>± 3.76 | 19.72 **<br>± 3.60  | 21.04<br>± 3.48     | 22.32<br>± 3.58           |
| <b>Psycho/spiritual</b> | 22.02<br>± 3.35 | 20.48<br>± 4.43 | 20.33<br>± 3.42 | 22.38<br>± 3.32 | 20.74 *<br>± 3.06   | 22.22<br>± 2.92     | 21.63<br>± 3.87           |
| <b>Family</b>           | 27.60<br>± 2.97 | 27.20<br>± 3.56 | 26.83<br>± 4.00 | 28.04<br>± 2.52 | 26.84 ***<br>± 4.33 | 25.92 ***<br>± 3.70 | 27.02<br>± 3.44           |

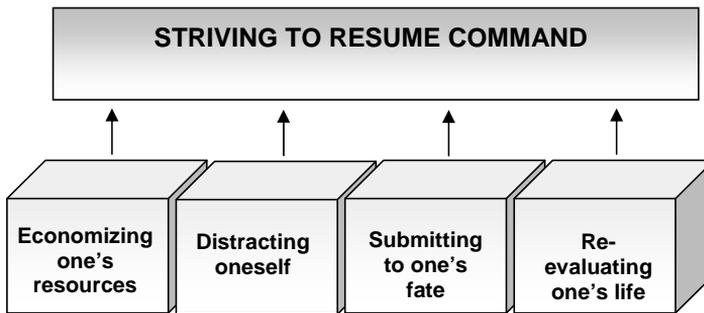
SD = standard deviation, mths = months, N = number, psycho = psychological, \* =  $p < .05$ , \*\* =  $p < .01$ , \*\*\* =  $p < .001$ . Scale 0–30. The higher the score on the QLI-C the higher the perceived quality of life.

## Striving to resume command

In Paper III, results showed that ICD recipients handle their life by “striving to resume command” which was the identified core category. Striving to resume command is a continuously ongoing process implying the wish to have more control over one’s life. Recipients referred not only to the ICD device but to their whole life situation. The recipients wanted to live their lives as they did before the ICD implantation and if a recipient can control what will be expected, the uncertainty associated with this event can be reduced or alleviated. However, the difficulty to resume command was considerable when the lifelong disease and the device were constant reminders of their vulnerability. In managing to resume command the recipients used four strategies, one at a time or in combinations: economizing resources, distracting oneself, submitting to one’s fate and re-evaluating life (Figure 3).

When recipients economized with resources they balanced the level of activity towards their available resources so they felt they were able to partly control their lives. They described how they were able to influence everyday

life by imposing personal restrictions and careful planning of daily life. However, initially in their life as recipients they are uncertain about how much and what type of physical activity they could undertake without triggering a tachyarrhythmia episode. With careful daily and weekly planning they could optimize the quality of everyday life and live as good a life as possible. This was through strategies to minimize stress and based on their understanding of what was possible and appropriate for them.



**Figure 3.** A substantive theory on “Striving to resume command” based on data from recipients with ICD, N = 16 (III).

Another strategy contributing to resuming command over one’s life was to distract oneself which implies to divert attention from the health problems at hand and physically and/or mentally engage in something else. This strategy decreased the stress level raised by awareness of the vulnerability of one’s physical condition. Recipients avoided loneliness and strived for involvement with other people and pets. They tried not to ponder too much about their heart events and they often suppressed thoughts about their diseases.

A third strategy contributing to recipients being able to resume command over their lives was to realize that they could do nothing to change what had happened to their health but accept the situation and submit to their fate. Recipients who accepted their poor health and submitted to their fates perceived that they felt more in control and their emotional stress decreased. Recipients felt more or less dependent on others and they submitted and accepted such service because nothing else was possible. The recipients received support mainly from family members. Initially, when they needed most support, they felt frustrated by being overprotected and controlled by

family members but also had concerns about being too much of a burden on the family. However, not all recipients had access to family members but some sought information from healthcare professionals and others avoided contacting them, being afraid of disturbing them. These recipients submitted to their fate and retained the uncertainty of not knowing.

Re-evaluating one's former life and adjusting it to current conditions was a way for recipients to resume command. Re-evaluating life includes altering emotions by reformulating the meaning of one's life goals. They changed their attitudes and way of thinking in a positive manner and thereby felt more in control over their life situation. In general, recipients became more reflective over life and expressed an existential awareness. Recipients felt gratitude for surviving a cardiac arrest or a life-threatening arrhythmia and expressed a feeling of security with having an ICD. At the same time as they were grateful to the ICD, recipients felt disappointed by suffering from a heart disease, requiring a device as well as pharmacological treatment with associated side-effects. In addition, they were forced to live the rest of their lives with the uncertainty of not knowing.

## DISCUSSION

### **Methodological aspects**

This thesis has a multimethod approach where both quantitative and qualitative methods have been used with the intention that the data will complement each other. Thus, a more comprehensive picture of the studied phenomenon is given when data are supposed to be somehow “more valid” if generated by more than one type of method <sup>71</sup>.

### **The quantitative studies (I, II, IV)**

#### ***Design***

The longitudinal, prospective design (I, II) may be seen as strength with data since it gave possibilities to determine changes that have occurred over time and changes pre-post ICD implant. The cross-sectional study design (IV) was appropriate for describing relationships among variables at a fixed point in time, but has a limitation in that it does not permit causal conclusions <sup>71</sup>. Self-reporting of the number of perceived shocks may be regarded as a weakness due to its memory effect (I, II, IV) <sup>71</sup>. No attention was paid to objectively measuring the number of ICD shocks from the ICD memory in Paper I, II. However, in Paper IV the self-reported number of ICD shocks was compared with the number of ICD shocks measured from the ICD memory with a strong correlation ( $r = .94$ ,  $p = .001$ ).

#### ***Participants***

In selecting a sample there is always a risk of selection bias. Issues concerning the representativeness of the sample and the generalizability to the population therefore need to be addressed. In this thesis the sampling was consecutive in Paper I, II and in Paper IV it can be defined as a total population consisting of all ICD recipients of the four included centres that had had their ICD between six to twenty-four months. The small sample size at follow up and also sampling from one hospital must be taken into account when interpreting the data (I, II). However, Paper IV consisted of a rather large sample for an ICD group (N=147) with a multicentre design which can be regarded as a strength in finding a representative sample of participants. There was an imbalance in

the gender distribution with an over-representation of men (I, II, IV). However, the study population reflects the distribution among ICD recipients in Sweden <sup>20</sup>.

Drop-out rate ranges from 15% (I), 10% (II) and 21% (IV) which is at an acceptable level. In Paper IV, drop-out analysis including the 41 non-participants (21%) showed that recipients agreeing to participate had a poorer cardiac function than those who declined. One explanation is perhaps that those who felt more ill had a higher motivation to answer the questionnaire and perhaps later experience benefit from partaking. In all other demographic and clinical variables there were no significant differences.

### **Questionnaires**

When using self-reported questionnaires it might have been difficult for the ICD recipients to disassociate between experiences in everyday life caused by the underlying heart disease and by the ICD implantation since both influence the recipient's everyday life. Self-reported use of coping strategies was quite low. This might be explained by that the majority of the ICD recipients had adapted to the heart disease and/or to the device and needed less coping strategies or by limitations in the JCS in measuring coping strategies. The questionnaire was rather comprehensive to fill in with 60 items in both part A and part B. Ratings for part B should only be performed for those strategies reported in part A <sup>76</sup>. This can be confusing when filling in the questionnaire. Coping strategies may be used with other valid, but less comprehensive instruments such as a checklist <sup>89</sup>.

### **Statistics**

The questionnaires used in the thesis have data on an ordinal scale level which implicate the use of non-parametric tests. However, in Paper II the journal demanded the use of parametric tests which we then followed. The alpha level was adjusted for the multiple statistical tests (II). To avoid type I errors, the Bonferroni correction was used. However, this can increase the risk for type II errors, failing to detect differences when they really exist <sup>90</sup>. A clinically significant difference can be defined as the smallest change in an instrument's score that is experienced by the recipient as a real decrease or increase in their condition. This has been suggested to be 0.50 SD <sup>91</sup>. When following this rule of thumb, the results of QLI-C scores should be interpreted with some caution (I, II).

Factor analyses were performed to ensure construct validity of MUIS-C, QLI-C and the Patient ICD questionnaire (I). However, the number of observations was too low in relation to the number of variables as it is

recommended ten observations for each variable <sup>92</sup>. Henceforth, the original version of the questionnaires was used (II, IV).

When using non-parametric tests, the value of the sum instead of the value of the median is described in the tables due to some misunderstanding on how to summarize the instrument (I). This value of QLI-C (I) has been corrected and described as mean values in Paper I and IV in order to make it possible to compare the studies using QLI-C in this thesis (I, II, IV) (Table 3). All questionnaires used in the thesis have been tested and found to have satisfactory reliability and validity. The value of .70 is stated as a fairly minimal requirement for a useful instrument <sup>92</sup>. The family subscale in QLI-C and the emotive and supportive subscales in JCS had a Cronbach's alpha below .70. These subscales stand for four and five items each which may be a reason for the somewhat low reliability. These results should be interpreted with some caution.

### **The qualitative study (III)**

Transferability of results from the grounded theory study in this thesis depend on the study design, including research question, sampling procedures and saturation of data, indicating what an adequate transferability would be <sup>82</sup>. The interviews gave access to the recipients' own perspective of their everyday life without beforehand given answer alternatives. All recipients contributed with their views and experiences, which gave depth and rich qualitative data. The interaction in the interviews was friendly and an extensive variation on the phenomenon was revealed. The results are grounded in empirical data from recipients who have had an ICD device for between six to twenty-four months. The results of study III illuminate and confirm a number of aspects of the everyday life of ICD recipients described in earlier research, but also present a more complex picture with the core category and categories. Transferability of results might be limited by the fact that the majority of recipients had received their ICD due to a secondary preventive indication. Therefore, the results of this grounded theory study should be tested in other groups of ICD recipients. Thus the theory can be validated or supplemented by additional strategies used by recipients in their striving to resume command over their lives.

When using the open and theoretical sampling the selection of recipients cannot be planned in advance and it continues throughout the study until saturation is reached <sup>83</sup>. No recipient refused participation. For practical and legal reasons the selection of recipients had to be carried out by ICD nurses at the outpatient ICD clinic. A weakness in the study may be difficulties in the theoretical sampling to recruit the most appropriate recipient. However, recipients were selected from three different hospitals and outpatient ICD

clinics which can be seen as strength. All interviews were carried out and analysed by the main author. The main author's preconception was dealt with by undertaking a conscious and critical approach to the emerging results. Data analysis of all interviews was also carried out by the supervisor and during the analyse process constant discussions were ongoing between the authors. The main author's theoretical sensitivity reflects personal and professional experiences as well as methodological knowledge and thereby data can be seen in new and abstract ways concerning the process of developing theory<sup>82</sup>. Trustworthiness in the study design was maintained by the systematic process of collecting and analysing data, the emergence of categories that were grounded in data and the generation of a core category that can explain the main concern for ICD recipients and their strategies to manage everyday life<sup>83</sup>.

## Results aspects

In this thesis, comprehending three quantitative studies and one qualitative study, results describing everyday life with an ICD were generated. ICD recipients strived to resume command over their life (III) and the more control the recipients perceived the more satisfied they were with their QOL (IV) and the more symptoms of anxiety, depression and uncertainty they experienced the less satisfied they were with their QOL (II, IV). Coping strategies were used more frequently by an ICD recipient perceiving more anxiety (IV). The core category striving to resume command may be "validated" by the predictor perceived control which was the most influential predictor of QOL (III, IV). No difference in the overall QOL over the long-term follow up was found. QOL was fairly good 6.9 years after implantation and ICD recipients felt less uncertain once they had passed the first year of their illness. QOL in the health/functioning domain remained stable over time. A downward fluctuation during the first year after implantation was seen in QOL in the socio-economic and in the psychological/spiritual domain as well as QOL in the family domain had decreased over the long-term follow up.

## Perceived control

We found that the more control the recipients perceived in their everyday life the more satisfied they were with their QOL. This is in accordance with results from other studies where a high level of perceived control is associated with high QOL and low levels of emotional distress<sup>49,50</sup>. Perceived control has been shown to predict psychosocial adjustment positively with possibilities to influence the individual, thus it is an important construct for use in theoretical and clinical implications by healthcare professionals<sup>49,50</sup>. However, living with

a life-threatening arrhythmia and an ICD device is usually characterised by the unpredictability of symptom intensity, duration, and recurrence<sup>43</sup>. Predictability means knowing something about an event, whether or not being able to do anything about it. Having control makes events less uncertain, controllable events may hurt less and waiting for a controllable event is less uncertain<sup>44</sup>. This is in accordance with ICD recipients' experience of their first life-threatening arrhythmia and ICD shock and the discomfort of not perceiving control may lead to stress (III). However, when the stressor as an ICD shock was identified and recognized, the stress decreased<sup>6</sup>. Maintenance of control in everyday life has been used as an intervention in studies of ICD recipients. According to Sears et al.,<sup>93, 94</sup> one way to improve control is to increase security and acceptance of the device and Pedersen et al.,<sup>95</sup> suggests improving exercise capacity. These authors suggested that an optimal intervention should consist of a behavioural intervention in combination with physical exercise training. Conversely, van Ittersum et al.,<sup>96</sup> described fear of exercise as a negative predictor of health and the experience of fear may also hinder lifestyle changes. Studies of patients with heart failure<sup>97</sup>, their spouses<sup>98</sup> and heart transplant recipients<sup>99</sup> showed mutual positive interactions between physical activity, perceived control, and QOL.

### **Anxiety and depression**

Conflicting evidence remains regarding the psychological impact of an ICD implantation on QOL, but a recent review stated that recipients run the risk of several adverse psychological effects for at least six to twelve months after implantation<sup>100</sup>. Anxiety and depression are described as common psychological symptoms in ICD recipients, especially soon after implantation, with those recipients with multiple shocks being at particularly high risk<sup>38</sup>. That QOL is influenced by ICD shocks only if it is measured within one to two months after the shock is described<sup>25</sup>. Crossman et al.,<sup>101</sup> found no correlation between anxiety and ICD shocks. Bilge et al.,<sup>102</sup> showed that the highest depression scores were found in recipients during the first three to six months after implantation and after five years. When setting the cut off >7 for anxiety and depression measured by HADs<sup>74, 75</sup>, our data showed nine out of ten recipients had no symptoms of depression and only 1% had severe symptoms of depression. This was the same prevalence as reported in a larger Swedish sample from the general population that was of a somewhat younger age and consisting of a higher percentage women<sup>103</sup>. Anxiety was more prevalent in our study compared to a general Swedish sample<sup>103</sup> with one third of the recipients experiencing symptoms of anxiety, half of them being severe. This finding underlines that one out of three recipients is in need of supportive

interventions to reduce anxiety as long as two years after implant and that cognitive behavioural therapy may be one way to treat these symptoms <sup>104</sup>.

### **Uses of coping strategies and resuming command**

ICD recipients did not use coping strategies to a great extent, most strategies were reported as seldom used (IV). The most frequently used coping strategy was the optimistic strategy followed by confrontive, self-reliant and fatalistic coping which is congruent with other studies in individuals living with a ICD <sup>54</sup> or another lifelong disease <sup>105, 106</sup>. However, use of coping strategies was lower in paper IV compared to other studies <sup>106, 107</sup>. Optimistic coping is described as having a positive outlook and thinking positively and Sears et al., <sup>108</sup> found optimism and positive health expectations related to benefits in the postoperative recovery period. By using confrontive coping recipients make attempts to cope with problems directly and try to maintain the situation under control rather than withdrawing from it.

However, in attempting to gain some control recipients distracted themselves by ignoring their illness and symptoms by doing something which was fun, trying to keep busy or doing some physical activity (III). This behaviour is in line with the palliative coping strategy described by Jalowiec <sup>76, 77</sup> and is also described as “concealment of symptoms” <sup>8</sup>. However, palliative coping was seldom used, however in combination with an optimistic view of life this may be seen as a consolation and an adequate manner for ICD recipients to live <sup>109</sup>. Self-reliant coping means depending on yourself rather than on others in dealing with the situation and fatalistic coping is described as pessimism, hopelessness and a feeling of little control over the situation <sup>77</sup>. The use of both problem-focused and emotion-focused coping strategies indicates that the recipients’ coping efforts are directed towards changing both the situation and the individuals’ feelings about it <sup>52</sup>. A flexible use of a variety of coping strategies has previously been proposed by Persson and Rydén <sup>89</sup> as most effective in individuals with disabilities such as arrhythmias and cardiac disease.

### **Quality of life**

The overall impression was that the ICD recipients in this thesis experienced a fairly good QOL. The overall QOL was observed to be relatively stable during the follow up (I, II) and differences in QOL appeared within the different domains during different time periods. When the first two studies in this thesis were carried out (1993-2004) no longitudinal study had been published focused on QOL in ICD recipients. Today, the situation is different and a great number of studies having a longitudinal design exist <sup>12, 13, 68, 110</sup> yet still not

measuring QOL over such a long period of time as 6.9 years as we have done. Further, when the data collection in the first two studies was carried out ICD implantation in Sweden was only made on a secondary preventive indication. When data collection for the two last studies was carried out implantation on a primary preventive indication was established and in studies of ICD recipients it was natural that the study sample comprised both of the groups. However, when comparing these two groups no differences in QOL were shown which is in accordance with Groeneveld et al.,<sup>65</sup> who found remarkably few differences in QOL between primary and secondary preventive ICD recipients. The mean score in the overall QLI was however moderate (I, II, IV) and comparable to a general Swedish population in the same age group as well as individuals living with familial hypercholesterolemia, a mixed group consisting of those having a cardiovascular disease and others that are at high risk<sup>111</sup>. Patients with a manifest cardiac disease undergoing cardiac rehabilitation had also similar or somewhat higher scores on QLI<sup>112</sup>.

### **Quality of life in the health/functioning domain, uncertainty and resuming command**

QOL in the health/functioning domain was rated as lowest but constituted the most stable domain compared to the other domains during all measured time periods (I, II, IV) which is in agreement with other ICD studies<sup>40, 47, 113, 114</sup>. This level of QOL may be related to the underlying heart disease which is understandable in relation to the unpredictability regarding the progression of the disease<sup>14</sup>. Uncertainty decreased during the long-term follow up (II). Initially, the recipients showed a high level of uncertainty, which persisted during the first year, after which an improvement could be observed. This first year may be the most stressful and uncertain period for recipients before acceptance of and adaptations to a changed situation have been achieved. Uncertainty was negatively related to overall QOL (IV) and to QOL in the health/functioning domain (II) and it seems to be a stable negative relationship independent of when in time during the first year the measuring is carried out<sup>40, 46, 114, 115</sup>. Decreasing the level of uncertainty as well as symptoms of anxiety and depression may have consequences as it has been suggested that mental stress can increase the ICD recipient's risk of LTA<sup>116</sup>.

By balancing the level of activity ICD recipients were able to partly resume command in their everyday life (III). Other studies have shown that the level of imposed restrictions during the first year varied but during the first six months the focus was on regaining physical health and most recipients have adapted to the changed situation six to twelve months after implantation<sup>6-8</sup>. However, restrictions in physical activity can be perceived as a loss of

control and individuals might experience stress if they perceive themselves as losing personal, social and material resources or implementing lifestyle changes <sup>117</sup>. This implies that support from healthcare professionals regarding lifestyle changes is an important component in the follow up.

### **Quality of life in the domains socio-economic, psychological/spiritual, family and resuming command**

QOL in the socio-economic and psychological/spiritual domain decreased during the first year and in the family domain during the long-term follow up (II). Similar results were reported in other studies <sup>40, 111, 113-115</sup>. This pattern could be expected when ICD recipients may be preoccupied with the imminent operation, the incidence of ICD shocks, uncertainty about the disease and their future. Lifelong disease can both strengthen family relationships <sup>118</sup> and lead to familial conflict and discord <sup>119</sup>. To be obliged to cut down on working hours or to quit altogether is experienced as stressful and financial security and social identity can suffer (III). Decreased QOL in these domains has previously been reported and depression has been found to be common among ICD recipients forced into retirement because of the device <sup>39</sup>.

Recipients submitted to their fate and accepted being dependent and seeking support mainly from family members (III). The individual's beliefs about family members' control in the illness situation is described as of importance for the individuals' own perceived control <sup>49</sup>. Family members of heart patients who were trained to perform cardiopulmonary resuscitation reported one month afterwards increased perceived control and less anxiety and depression <sup>49</sup>. It is vital that family members are supported in their own psychological adjustment to increase their perceived control.

Further, the recipients' need for professional support was commonly related to medical concerns, but also holiday and driving restrictions. By assistance from healthcare professionals to bring about clarity the recipient gains an increased predictability, which may reduce the uncertainty and precipitate the recovery process (I). However, hardly any attention was paid to existential concerns such as experience of cardiac arrest (III) and it is suggested that surviving cardiac arrest may have greater impact on recipients than the ICD treatment itself <sup>6</sup>. One reason may be that contact with healthcare professionals is limited by the time factor and thereby there is less time for conversations besides the traditional follow up of technical aspects <sup>6, 8</sup>. Other results show that SCD survivors feel empowered and stronger as a result of having lived through their worst experience <sup>6, 46, 113</sup>. Recipients reformulate the meaning of their life goals and became more reflective and expressed an existential awareness. They changed their attitudes and way of thinking in a

positive direction and thereby felt more in control over their life (III). At the same time recipients felt disappointed by suffering from a heart disease requiring a device and those not having experienced LTA questioned the need for the device, as also shown in another study <sup>55</sup>. However, re-evaluating life was more about changing oneself and one's expectations than changing the situation.

## CONCLUSIONS

- ICD recipients strive to resume command in their lives. Being in command, or having control over one's life, is important for physical and psychological well-being. Strategies used by ICD recipients were: Economizing resources, Distracting oneself, Submitting to one's fate and Re-evaluating life.
- The more control the ICD recipients perceived over their heart condition, the more satisfied they were with their QOL and the more symptoms of anxiety, depression and uncertainty they experienced the less satisfied they were with their QOL. However, ICD recipients felt less uncertain once they had passed the first year of their illness.
- Optimism was found to be the most frequently used coping strategy, but the ICD recipients did not use a multitude of coping strategies. Coping strategies were used more frequently by an ICD recipient perceiving more anxiety.
- QOL was fairly good 6.9 years after implantation. Overall QOL and QOL in the health/functioning domain remained stable over time. A downward fluctuation during the first year after implantation was seen in QOL in the socio-economic and in the psychological/spiritual domain as well as QOL in the family domain had decreased over the long-term follow up.

## Implications

### Clinical implications

Despite being a cost-effective, reliable and efficient implanted device for reducing the incident of sudden cardiac death, the ICD can be associated with notable consequences in the recipient's everyday life.

- We suggest that follow up with educational and psychosocial support should be provided more intensively during the first six months after implantation and thereafter be tailored toward those recipients experiencing symptoms of anxiety and depression, a lower perceived control in life and a diminished QOL.

- By using HADS <sup>74</sup> and the expanded version of the CAS used in this study, namely the validated 8-items Control Attitude Scale–Revised (CAS-R) <sup>120</sup> as screening tools at follow up after implantation in the outpatient ICD clinic, recipients perceiving low control and mental strain in their everyday life can be identified and supportive interventions considered in order to increase their QOL.
- The ICD team should support the ICD recipients in their striving to be in command and thereby contribute to optimizing their sense of control in everyday life.
- The ICD team should educate the ICD recipients about the function of the device and counsel them about daily living and thereby optimize security and acceptance of their everyday life by providing recipients with increased understanding.
- Because family members/close friends are viewed as an important part of the ICD recipients' lives, it is suggested that these individuals should become more involved in their care.

### **Research implications**

- Coping strategies in a long-term perspective with start-up during the first six months after implantation should be further explored in research in order to support ICD recipients in using appropriate coping strategies.
- In the future more individuals possibly will live with an ICD and as participants in this thesis were mostly of male gender it would therefore be valuable to study similar issues from a female gender perspective.
- The family member's role is of importance for the recovery of the ICD recipients and should be further investigated.

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## SAMMANFATTNING

Hjärt-kärlsjukdomar är den främsta orsaken till dödfall i västvärlden. En hjärt-kärlsjukdom kan leda till livshotande rytmrubbningar (arytmier) som i sin tur kan leda till plötslig hjärtdöd. Implanterad hjärtdefibrillator (implantable cardioverter defibrillator, ICD) har utvecklats för att upptäcka och behandla livshotande arytmier. En ICD känner av hjärtats elektriska aktivitet och rytm. När hjärtrytmen är för snabb skickas först impulser ut med syfte att avbryta den pågående arytmien. Om impulserna inte lyckas, levererar ICD en elektronisk chock. Forskning visar att behandling med ICD förlänger livet, och en sådan förlängning är nära relaterad till livskvaliteten under de extra åren.

Livskvalitet är ett mångfacetterat begrepp som inkluderar fysiska, psykiska och sociala dimensioner i livet samt kan beskrivas som en känsla av välbefinnande som härrör från tillfredsställelse eller otillfredsställelse med områden i livet som är betydelsefulla för individen. Livskvalitet påverkas inte bara av sjukdomen utan också av den förändrade livssituation som det innebär att leva med en ICD. Coping är ett begrepp som används för att beskriva hur individer hanterar stress genom att använda olika typer av strategier. Omfattande kunskap finns om den tekniska utformningen av ICD och dess funktion på individens fysiska hälsa, men mer kunskap behövs om ICD-bärares livskvalitet och hur de hanterar sitt dagliga liv.

Studiernas syfte var att beskriva ICD-bärares dagliga liv i ett längre tidsperspektiv genom att utifrån frågeformulär beskriva livskvalitet och otrygghet under det första året (studie I) samt i ett långtidsperspektiv, här sex år och nio månader (studie II). Vidare beskriver ICD-bärare sex till tjugofyra månader efter implantationen i intervjuer vad som är problemet i det dagliga livet och hur det hanteras (studie III) samt via frågeformulär upplevelser av ångest, depression och den kontroll de uppfattar sig ha samt vilka copingstrategier som används för att hantera det dagliga livet (studie IV).

Studierna visar att ICD-bärarna strävar efter att återta kontrollen över sitt liv, något som var viktigt för deras fysiska och psykiska välbefinnande. Genom att begränsa och planera sitt dagliga liv hushållade de med sina resurser. De distraherade sig genom att undvika ensamhet och förtränga tankar. I stället försökte de sysselsätta sig och underkastade sig sitt öde genom att acceptera att vara beroende och söka stöd. De omvärderade livet och upplevde tacksamhet för att vara i livet och för möjligheten att ha fått en ICD

implanterad, vilket upplevdes som en trygghet. Samtidigt fanns en känsla av besvikelse över att ha drabbats av en hjärtsjukdom och ha blivit beroende av en teknisk apparat resten av sitt liv. Ju mer kontroll ICD-bärarna uppfattade att de hade, desto mer tillfredsställda var de med sin livskvalitet. De ICD-bärare som upplevde ångest, depression och osäkerhet var mindre tillfredsställda med sin livskvalitet. ICD-bärare som upplevde mer ångest använde fler copingstrategier och optimistic coping var den mest frekvent använda copingstrategin. Livskvaliteten var ganska god 6 år och 9 månader efter implantationen. Den totala livskvaliteten och livskvaliteten specifikt inom hälsa och funktionsdomänen var oförändrad över tid. Däremot sjönk socioekonomisk och psykologisk/andlig livskvalitet under det första året liksom livskvaliteten inom familjedimensionen sjönk över långtidsuppföljningen.

Slutsatsen av studierna är att ICD-bärare strävar efter att återta kontrollen över sitt liv. Ju mer kontroll de uppfattar sig ha över sin hjärtsjukdom, desto mer tillfredsställda är de med sin livskvalitet. Ju mer symtom av ångest, depression och otrygghet de upplever, desto mindre tillfredsställda är de med sin livskvalitet. Optimistisk coping var den mest använda strategin, men ICD-bärare använde överhuvudtaget inte så många copingstrategier. Emellertid användes fler sådana av dem som upplevde mer ångest. Livskvaliteten var ganska god sex år och nio månader efter implantationen, och ICD-bärare kände sig mindre otrygga när det första året efter implantationen hade passerat.

Vi föreslår att uppföljning med utbildning och psykosocialt stöd bör erbjudas mer intensivt under de första sex månaderna efter implantationen för att därefter "skräddarsys" till de ICD-bärare som har ångest och depression samt uppfattar sig ha mindre kontroll och sänkt livskvalitet.

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