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Caring for Patients with an Implantable Cardioverter Defibrillator Experiences of Patients and Healthcare Professionals

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Liv är en oavbruten utveckling Att vara till är att förändras Att förändras är att mogna Att nyskapa sig själv

> Henri Bergson Fransk filosof

To Thomas, Fredrika and Aje With All My Love

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ABSTRACT

Background

An Implantable Cardioverter Defibrillator (ICD) is a technical device used in the treatment of ventricular arrhythmias. After the implantation of an ICD the entire life situation can be affected with psychological and social consequences for the patient and his/her next of kin. The healthcare professionals play a vital role in providing educational information, support, and technical follow-up of the device. During recent years more and more hospitals have introduced a more team based organisation where the physicians collaborate with specialised ICD nurses.

Aim

The overall aim of the thesis was to explore how patients with an ICD experienced their life situation and how healthcare professionals described their experiences of delivering care to ICD patients.

Methods

The design was descriptive, combining both quantitative and qualitative approaches, and the data was collected from Sweden and the USA. The Uncertainty of Illness Scale (MUIS-C) and Quality of life Index (QLI) instruments were used to determine the level of uncertainty and satisfaction with life (I), in-depth interviews with a phenomenographic approach was used to describe how Swedish and US patients living with an ICD conceived their life situation (II, III) and how healthcare professionals' experienced delivering care to patients with an ICD, (IV). Finally, to explore clinical aspects of ICD care in Sweden, the Delivery of ICD Questionnaire (DOIQ) was used to describe the healthcare professionals' experiences and a content analysis was used to describe the written educational information material provided to patients (V).

Results

There were no differences in uncertainty between pre and post ICD implantation either in Swedish or the US patients. Satisfaction with life was significantly higher among US patients compared to Swedish patients both before and after ICD implantation within the health-functioning, socio-economic and psychological-spiritual domains. The Swedish ICD patients experienced a significantly higher satisfaction with life within the socio-economic domain after 3 months. (I). The patients felt safe in having an ICD implanted, but the conceptions varied from seeing the device as a life saver to being worried about what could happen. Gratitude at having an ICD varied from happiness at being alive to something that was alien and disturbed the patient. Being more or less dependent included how patient experienced feelings from well-being to grief. Having a network varied from having sufficient support to loneliness. Having a belief in the future ranged from having confidence to look forward to resignation. Gaining awareness described patients' adaptation to living with an ICD and

limitations due to the ICD (II). The patients also underwent a transition from becoming aware of the restriction in the life situation through a process of adaption and having trust in the ICD. This phase was followed by a reorientation phase where they adapted to their life situation and the patient and his/her family regained of their lives (III). The healthcare professionals strove to provide competent and individualised care and infuse confirmation to the patients in form of information, education and support. They gave the patients tools to handle their life situation, through existential support and mediating security (IV). Half of the hospitals had nurse-based clinic and others planned to introduce them. Three hospitals performed follow-up in the form of remote home monitoring. The nurse had specific ICD education from ICD companies and/or various university courses. In the educational information material the biophysical dimensions dominated while the emotional dimension was scarcely described, and the spiritual-existential was not referred to at all (V).

Conclusions

This thesis offers a further contribution to the scholarly discussion about the relationship between technology and human existence and how to cope with this transition. Our studies revealed that the embodiment of the ICD reflects a merger of experiences about its presence and potential from both patients' and healthcare professionals' perspective. This research hopefully encourages healthcare professionals to carefully reflect on what it is like to live with an ICD and to consider practice improvement for the patients' and the next of kin.

Key words: ICD-implantation, healthcare professional, life situation, organisation of care, experiences, satisfaction, uncertainty, clinical aspects.

ORIGINAL PAPERS

This thesis is based on the following original papers, referred to in the text by the Roman numerals:

- I Bolse K, Flemme I, Ivarsson A, Jinhage B-M, Carroll D, Edvardsson N, Hamilton G, Fridlund B. Life situation related to the ICD implantation; Self-reported uncertainty and satisfaction in Swedish and US samples. *European Journal of Cardiovascular Nursing* 2002;1:243-251.
- II Fridlund B, Lindgren E-C, Ivarsson A, Jinhage B-M, Bolse K, Flemme I, Sandstedt B, Mårtensson J. Patients with implantable cardioverter-defibrillators and their conceptions of the life situation: a qualitative analysis. *Journal of Clinical Nursing* 2000;9:37-45.
- III Bolse K, Hamilton G, Flanagan J, Carroll D, Fridlund B. Ways of Experiencing the Life Situation Among United States Patients with an Implantable Cardioverter-Defibrillator: A qualitative study. *Progress in Cardiovascular Nursing* 2005;1:4-10.
- IV Bolse K, Johansson I, Strömberg A. Experiences of delivering care to patients with an Implantable Cardioverter Defibrillator from the perspective of health care professionals. (*submitted*)
- **V** Bolse K, Johansson I, Strömberg A. Organisation of care for Swedish patients with an Implantable Cardioverter Defibrillator; a national survey. (*submitted*)

ABBREVIATIONS

ATP Anti-tachycardia pacing
CVD Cardiovascular disease

DOIQ The Delivery Of ICD care Questionnaire

EF Ejection fraction

ICD Implantable Cardioverter Defibrillator

MUIS-C Mishel Uncertainty in Illness Scale-Community version

NYHA New York Heart Association Classification

QLI Quality of Life Index, Cardiac III, Parts I and II

VF Ventricular fibrillation
VT Ventricular tachycardia

INTRODUCTION

This thesis focuses on a growing patient population, who live with an implantable cardioverter defibrillator (ICD) in their body, usually with a severe underlying heart condition, and therefore also with possible multidimensional concerns about how to adapt to this situation. After an implantation of a lifesaving technology device the patient's entire life situation can be affected with psychological and psycho-social consequences for the patient and his/her next of kin ¹⁻³.

An ICD is a technical device used in the treatment of ventricular arrhythmias with automatic arrhythmia detection and possibilities to pace, convert or defibrillate ventricular fibrillation (VF) and ventricular tachycardia (VT) ⁴. The indication for receiving an ICD has been expanded from secondary indication, in patients who have already experienced serious sustained ventricular arrhythmias, to preventive indication, a prophylactic ICD implanted in patients who have not had a cardiac arrest but are at risk for ventricular arrhythmias ⁵⁻⁹. This primary preventive strategy is based on the positive results from a number of randomised trials showing improved survival when comparing ICD therapy with medical treatment ^{6, 7}. In the near future the number of implantations, especially those due to primary prevention, can be expected to further increase which justifies more research to improve ICD care.

The healthcare professionals play a vital role in assisting the patient and his/her family both before and after the ICD implantation by means of information, education, support, counselling and technical follow-up of the device. They can help patients adapt to the device and advice them on how to act in daily activities, e.g. when travelling or when having an ICD shock, teach them about common feelings and physical and mental reactions that can arise after an ICD implantation, as well as to inform and support the patient, when he/she needs to undertake necessary life style changes ¹⁰⁻¹². In order to deal with ICD patients in an adequate manner, it is important for the healthcare professional to acquire an in-dept understanding about the patients' life situation as well as their experiences of being an ICD recipient ². The objective of the ICD care is to support and educate patients in an evidence based manner, thus helping them to achieve balance in life with the transition to living with an ICD and to find a meaning with their new life situation.

After an ICD implantation the patient are only hospitalised for 1-2 days but require regular follow-up visits for the rest of their lives as well as an organisation administrating those out-patient visits. Historically, only physicians have performed and organised the follow-up care of the ICD patients, but during recent years more and more hospitals have introduced a more team based organisation when the physicians are

supplemented with specialised trained ICD nurses, who also performs technical followup of the device. It is a great challenge for all the healthcare professionals working in this context to develop and run this expanding organisation.

In order to care for the patients in an evidence based and holistic manner, it is necessary for the healthcare professionals involved to have excellent technical skills of the ICD device, but also have knowledge about psycho-social and behavioural areas in order to help patients regain charge of their lives.

However, the experiences and consequences of this more team based approach have not been properly investigated. To improve individual management it is important to describe the care of ICD patients from patients', as well as physicians' and nurses', perspectives, emphasising organisation, education and areas of improvement.

BACKGROUND

Implantable cardioverter defibrillator

Michel Mirowski developed the ICD, and the first implantation was performed in the United States in 1980. Five years later the ICD was cleared for commercial sale in the USA ¹³. In 1990 about 100 ICDs were implanted in Sweden ¹⁴ and since then there has been a seven-fold increase with approximately 84 implants/million inhabitants. The implant rate is still low, compared to the USA and other European countries ¹⁵. Today, approximately 3 700 individuals are living with an ICD in Sweden ⁵.

The early ICDs could only detect and defibrillate the heart in VF or rapid VT, but the ICDs of today can also provide bradycardia pacing support and convert VT by delivering a rapid burst of anti-tachycardia pacing (ATP). Based on the type of arrhythmia detected, and the type of therapy programmed, the ICD initiates the appropriate treatment with ATP or shock ¹⁶. After delivering the first shock a time delay is programmed to allow the ICD to re-detect whether the therapy was successful or not. If not converted, the ICD will re-charge and deliver up to six shocks for the same episode ¹⁷.

The ICD is actually a part of a defibrillation system made up of three different parts:

1) The ICD device, which is a small titanium case consisting of lots of electronic components with e.g. capacitors to deliver the high energy required for a DC shock, a memory function and a battery. 2) The second part consists of the transvenous leads that provide sensing and pacing in the right ventricle and atrium through conventional pacemaker electrodes and a high energy delivery through a right ventricular defibrillation coil. The leads are inserted through venous access at the subclavian or cephalic vein. Fixation to the myocardium is achieved either by a retractable screw or lodging small tines. 3) The third part is an external programmer, with a radiofrequency telemetry wand that is placed over the implanted device and establishes communication with the ICD. This enables the physicians and the ICD nurse to obtain stored data such as arrhythmia episodes and battery capacity, and to change parameter settings. The battery works for at least four to six years. Complications which may occur in connection with the ICD are e.g. wound infections, lead damage and inappropriate shocks ¹⁷.

Organisation and follow-up routines in the ICD care setting

In Sweden implantation of an ICD and the follow-up visits takes place at special ICD clinics. Previously this was concentrated to university hospitals, but is now changing toward also including county hospitals ⁵.

The ICD is usually checked for the first time 4-8 weeks after implantation. After that, regular visits are recommended every 3-6 months for the rest of the patient's life ¹⁸. Remote monitoring, when the patients have a monitor at home, can be a supplement to regular follow-ups. The patient sends information to an Internet based service centre where the healthcare professionals can receive information from the ICD. It has been found to decrease the time consumptions and costs of both care givers and patients and increase the safety of the device, which has made the patients satisfied with this solution ¹⁹⁻²¹

There are several goals of the ICD follow-ups; to verify that the device is functioning properly, to predict the need for possible interventions, including device replacement, check changes in the patient's condition that requires drug adjustment, and to keep track of patients, answering their questions and provide education ^{17, 19}.

Traditionally, physicians have performed the follow-up of these patients, sometimes with the assistance from a nurse or a technician. This ICD-team can also be supported by physiotherapists, social workers and other multidisciplinary professionals if necessary. Strategically balancing technology with the biophysical and psycho-social needs of the ICD recipient is a constant challenge to the physicians and nurses involved. Therefore the contribution of a specially trained ICD nurse, who does not only work as an assistant, have become more and more essential in the follow-up of the patients ⁵.

The nurse meets the patient before, during and after the implantation and it is of the utmost importance that the nurse is familiar with the set of problems involved and possesses knowledge of both psycho-social and behavioural science in order to help the patient to manage his/her life. The nurse plays a vital role in preparing the patient for life with the ICD and to ensure patients receive educational information and professional support ²². He/she can assist patients in understanding their feelings and reactions as well as inform and assist them in terms of undertaking the necessary changes to their life style and on how to act in different situations ²³⁻²⁵. Patients who are knowledgeable and feel secure need fewer contacts with the healthcare, which in the long term can lead to a reduced cost for society ²⁶. Knowledge about patients' own conceptions and experiences of living with the ICD can be a valuable contribution to the development of a team based care for these patients. Patients with an ICD are dependent

on the interaction with the healthcare professionals in order to cope with their situation. They receive educational information from both physicians and nurses and should have the opportunity to ask questions in conjunction with the preparation for the implantation. Before implantation the ICD-team provides the patients with information about the ICD, including the reason why they need the device and how their life situation can change after the implantation. The patients' are advised on e.g. what action to take when experiencing a defibrillation shock. Further they receive the timetable for planned follow-up visits and the ICD identification card, they learn about what sources of electromagnetic disturbances to avoid and receive recommendations about activities and driving restrictions ²⁷. The ICD-team also provides the patients with information on how to live with a chronic heart disease and the importance of continuing the prescribed drug therapy. Educational information and possibilities to ask questions should also be given to the patients' next of kin.

Finally, there exists hospital-based education programmes describing how to help patients begin the process of recovery after ICD implantation, but it is recommended that they must continue, and be supplemented by different protocol-driven nursing interventions, even after discharge ²⁸. Smeulders et al. ²⁹ described that a self-managed programme led by a team consisting of a patient with a cardiovascular disease and a specialist nurse may improve self-efficacy expectations, symptoms of anxiety and physical and social functioning. Further Sears et al. described that an intervention programme for ICD patients having experienced defibrillation shocks should involve ICD education and cognitive-behavioural strategies in order to reduce psychological distress and improve quality of life ³⁰.

Life situation with an ICD

The patient's life situation consists of psychological and biological dimensions which interact with the social surroundings. The humanistic view of the human being is holistic in nature and this approach constitutes the foundation of care. According to the holistic perspective, the individual should not be isolated and treated as a diagnosis or a medical case, but rather as an individual who is part of society ³¹. Holism emphasises inner well-being as the basis of health and holds that the human being consists of three parts: body, soul and spirit, which, although separate, interact with each other ³². Human actions are not predetermined, but the result of conscious choices. These conceptions are central to care as a whole, with an interrelationship of body, mind and spirit in a socio-cultural relationship and care environment.

Sarvimäki and Stenbock-Hult ³¹ described five dimensions from a holistic perspective. These dimensions are separate, but are parts of a whole and describe how the patient and their care must be based on an understanding of both the wholeness and its separate parts.

The biophysical dimension consists of different systems for maintaining life, which are either genetic or acquired. Prior to the implantation, ICD patients have been at high risk for, or have already experienced, a life-threatening arrhythmia, but after the implantation they can live quite a normal life. However, their life situation is affected by the heart disease itself as well as by the technical device within their body, and they may suffer from a changed body image after implantation ³³⁻³⁵. Furthermore, patients have shown reduced physical activity after an ICD implantation ³⁶. The sexual activity has also been found to be reduced due to fear that it can trigger a shock and that a shock can hurt their partner ³⁷. A patient's age can influence their way of experiencing their life situation. Older patients have been found to have an increased life satisfaction with advancing age ³⁸ while younger patients have reported a 50% decrease in sport activities ³⁹ and are at a risk for poor quality of life ⁴⁰.

The emotional dimension describes the individual's conception of him/herself and his/her surroundings. ICD recipients have described suffering from depression, feelings of anxiety, anger and uncertainty ^{35, 41-43}. They are subjected to emotional stress, as the situation of not knowing whether a VF will occur and a shock to be delivered without them having any control over the situation, is fraught with anxiety ^{44, 45}. Therefore, patients who have had several shocks can experience a higher level of anxiety and worry ¹ and feel uncertain because they fear that any activity may trigger a new shock from the ICD ⁴⁶. Sowell et al. ⁴⁷ found that female ICD patients reported more anxiety related to shock and death than men did.

It is known that patients with an ICD have a significant degree of psycho-social morbidity. A technical device inside the body may be considered a major life-changing event and patients can have problems with psycho-social adaption and reduced quality of life ²³. Bilge et al. found that 46% of patients with an ICD were anxious and that 41% were depressed ⁴⁸. A great deal of knowledge exists about the technical design of the ICD and the patients' physical reactions to it ^{4, 49}, while few studies deal with the patients' own conception of their life situation. Patients with ICDs experience high levels of distress before and directly after implantation, but the stress tends to reduce over time ⁵⁰. Williams et al. emphasise that it is important that health care professionals identify the patients who might experience difficulties adjusting and to identify those patients who take extended time to feel comfortable with the ICD ³⁵.

The intellectual dimension comprises the individual's interpretation of needs and the knowledge he/she employs in different situations. Cerebral hypoxia during a cardiac arrest can lead to neurological disability in form of memory impairment, impaired recall and recognition which affects intellectual capacity ⁵¹. Cognitive changes, such as a mild to moderately severe alteration in concentration and memory, were found after 21 months in 40% of patients who had suffered a sudden cardiac event ⁵². Drysdale et al. ⁵¹ also found that survivors from a cardiac arrest suffered from forgetfulness and suggested that changes in learning ability may influence the patient's ability to participate in activities.

The spiritual-existential dimension comprises the individual's norms, ideals and values. The patients have been found to be grateful for the ICD, as it made them feel more secure ⁴⁴. The ICD recipients have also expressed how they have been given a second chance, which they valued ².

The socio-cultural dimension views the individual as part of a social and cultural context. The psycho-social situation for patients struck by sudden cardiac arrest and living with an ICD is affected ²³, the patients in the shocked group reported more limitation in their leisure time activities. The patient and his/her family may experience similar problems, worries and uncertainty, which has been found to gradually diminish over time ^{53, 54}.

After implantation, the patient has a great need to talk to family members about his/her feelings ⁵⁵. Patients can experience that their family and friends are especially concerned about them, almost to the extent of being overprotective ⁵⁶. It is also found that partner to patients with an ICD reported greater anxiety than did the patients ^{47,57}.

Socio-economic status can be affected by the underlying heart disease, as it may be necessary to change one's job, and socio-economic status has been shown to be lower six months after a life-threatening arrhythmia ⁵⁸. Patients who feel safe and secure are able to adapt and better manage their life situation e.g. return to work sooner ¹.

AIMS

Overall aim

The overall aim of the thesis was to explore how patients with an ICD experience their life situation and how healthcare professionals describe their experiences of delivering care to ICD patients.

Specific aims

Specific aims of the thesis were:

To describe changes in the life situation of patients in related to the ICD implantation of Swedish and American samples with regard to uncertainty and satisfaction (I).

To describe how patients living with an ICD-device in south-western Sweden conceive their life situation (II).

To describe how a selected group of American patients with an ICD perceived their life situation from a holistic perspective (III).

To describe healthcare professional experiences of delivering care to patients with an ICD (IV).

To describe the clinical aspects of ICD care in Sweden with focus on organisation, the role and the education of nurses, patient information and education and areas in need of improvement (V).

METHODS

Design

The thesis has an explorative descriptive design combining both quantitative (**I**, **V**) and qualitative (**II**, **III**, **IV**, **V**) approaches through method triangulation in order to deepen the understanding of ICD patients' life situation and needs and healthcare professional experiences of delivering care. The studies involved patients from Sweden and USA (**I**, **II**, **III**) and Swedish healthcare professionals (**IV**, **V**) (Table 1).

Table 1. Overview of participants and research methods including study focus, sample, data collection and analysis.

Study	Focus	Focus Sample Data collection		Analysis
I	Describe changes in life situation			Descriptive
11, 111	Describe patients' experience of their life situation	15 patients from Sweden and 14 patients from the USA	Interview face to face, telephone interview	Phenomenographic
IV	Describe ICD teams' experiences of delivering care	16 ICD teams from Sweden represented by 12 nurses and 12 physicians	Interview	Phenomenographic
V	Describe clinical aspects of care	All ICD teams representing the 16 ICD clinics in Sweden	Questionnaire DOIQ Written information materials	Descriptive Deductive content analysis

A qualitative approach was used to obtain knowledge about patients' and healthcare professionals' perspectives regarding their experiences of ICD care (**II**, **III**, **IV**) and the content of ICD brochures and other written materials (**V**). A quantitative approach was used to describe changes in the life situation of patients with an ICD in relation to satisfaction and uncertainty (**I**) and to describe the clinical aspects of ICD care in Sweden with focus on organisation, the nurse role and education, patient information and education and areas in need of improvement (**V**).

Sample

Study I, II, III

A joint nursing research project between two university hospitals, one in the western part of Sweden and one in the eastern part of the USA, took place between 1993 and 2002 (**I, II, III**). The university hospitals in Sweden had a catchment area of approximately two million inhabitants and the US hospitals of six million inhabitants. The samples in papers **II, III** were selected from patients at the Swedish and the US centres involved in study **I** (Figure 1).

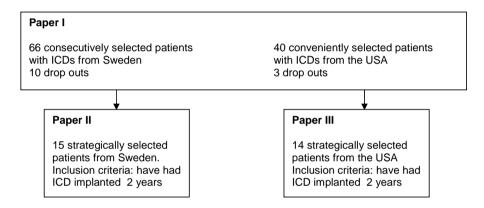


Figure 1. The distribution of participation and drop outs in the Swedish and US samples of patients in paper I-III.

The inclusion criteria were ability to speak and understand Swedish/English, being a resident in the relevant area of Sweden/the USA, surviving a life-threatening arrhythmia and being scheduled for implementation of an ICD as a secondary prevention. Exclusion criteria were psychological and/or medical disability, planned heart transplantation and language difficulties. The Swedish sample in Paper I consisted of consecutively selected patients while the US sample was a convenience sample. In Paper I, a total of 10 patients (15%) in the Swedish sample and 3 patients (7%) in the US sample dropped out. The reasons for dropping out in the Swedish sample were surgery (n=4), no reason (n=4) or death (n=2) while in the US sample no reason (n=3) was given. Consequently, Paper I included 56 consecutively selected patients from Sweden, 42 males and 14 females, with a mean age of 59, and 37 conveniently selected patients from the USA, 30 males and 7 females, with a mean age of 64 (Table 2). The

patients' conceptions of their life situation are described in Paper II, in which 15 patients from south-western Sweden participated, and in Paper III, where 14 patients from the eastern USA participated. The patients in Paper II, III were strategically selected from patients in Paper I in order to obtain as broad a variation as possible with regard to sex, age, marital status, education, working situation and ejection fraction (Table 2).

Table 2. Characteristics of the consecutively selected Swedish samples and conveniently selected US samples.

	Sweden	US
Age (mean, SD)	58.8 (12.0)	63.7 (11.9)
Sex, n (%)		
Male Female	42 (75) 14 (25)	30 (81) 7 (19)
Marital status, n (%)		
Married Married	46 (82)	27 (73)
Single	5 (8)	2 (5)
Divorced	3 (5)	3 (8)
Widowed	2 (5)	5 (14)
Occupational status, n (%)		
Worker	28 (50)	13 (35)
Salaried employee	20 (36)	23 (62)
Self-employed	8 (14)	1 (3)
Ejection fraction, (%)		
Mean value (Std)	39 (15.4)	33 (16.5)
Range	15-77	9-62
Causative cardiovascular factor, n (%)		
Coronary artery disease	27 (48)	26 (70)
Cardiomyopathy	15 (27)	7 (19)
Other	14 (25)	4 (11)
NYHA, n (%)		
NYHA I	13 (23)	13 (35)
NYHA II	27 (48)	11 (30)
NYHA III	12 (22)	9 (24)
NYHA IV No classification	0	1 (3) 3 (8)
INO CIASSITICATION	4 (7)	3 (8)

Ejection fraction=objective measurement of heart failure

NYHA=New York Heart Association 59

Study IV, V

The samples in Papers IV, V were collected from all 16 Swedish hospitals that performed ICD implantation and follow-up during 2006. The annual ICD implantation rate varied between 1-115 due to catchment area and different implantation practices. There were seven university hospitals and nine county hospitals. Participants were recruited among physicians and nurses at each of the ICD clinics. Twenty four participants (12 specialist ICD nurses and 12 cardiologists), between the age of 38-57, were recruited among the ICD-teams at each hospital. The inclusion criterion was that they had experience of being involved in the clinical care of ICD patients. The participating members had worked with ICD patients between 2 to 20 years. In Paper V the ICD teams filled in a questionnaire together (n=16).

Phenomenography

The phenomenographic approach was chosen in order to describe patients' life situation and the healthcare professionals' delivery of ICD care. The foundation for the phenomenographic approach was inspired by different areas within behavioural science and pedagogy ⁶⁰. Phenomenography is related to continental philosophy ⁶⁰ and was in the 1970s also inspired by teaching psychology and gestalt psychology 61, 62. In the 1980s the phenomenographic approach was also influenced by psychoanalysis as well as phenomenology ⁶⁰. Phenomenography was first used to investigate how students learn and was introduced at the Department of Pedagogy, Göteborg University, Sweden in 1970 63 and is now also often used in nursing sciences 64. In phenomenography the focus is the variation of peoples' conceptions of a phenomenon in the surrounding world, by describing the outcome space depicting different ways to experience a phenomenon ⁶⁵. Phenomenographic studies describe experiences from second-order perspective, which means the way a person conceives something and how it appears to the context ⁶². The first-order perspective describes the phenomenon objectively. Conceptions of the life situation constitute the individual's fundamental understanding and are not delimited objects of knowledge, but part of a whole and have not been subjected to reflection ⁶⁵.

Data collection

The patients' life situation was followed over time, at baseline and after three months in the Swedish sample and after six months in the US sample (I).

The Mishel Uncertainty in Illness Scale, Community version (MUIS-C), (I)

The MUIS-C ⁶⁶ was developed by Michel to measure uncertainty related to symptoms, diagnosis, treatments, patients' relationships with healthcare professionals and the future. The community form of MUIS-C was adapted from the MUIS original for chronically ill patients ⁶⁷. MUIS-C, ⁶⁶ consists of 23 items. The instrument was chosen in order to determine the level of uncertainty among patients with an ICD before and after implantation. Patients with an ICD have to live with the device for the remainder of their lives, thus the MUIS-C was deemed a suitable instrument for measuring their life situation. Statements were rated according to a five-point scale, ranging from 'strongly agree' to 'strongly disagree'. Higher scores indicated higher perceived uncertainty. When initially testing reliability of the Swedish version of MUIS-C Cronbach's alpha amounted to 0.82 ⁶⁸. In this study, the overall MUIS-C showed a Cronbach's alpha coefficient of 0.86 for the Swedish sample and 0.80 for the US sample.

The Quality of Life Index, Cardiac version (QLI), (I)

Ferrans & Power's Quality of Life Index 69 was chosen in order to determine the level of satisfaction and importance with life before and after implantation among patients with an ICD-device. QLI was developed by Ferrans and Power to measure Quality of Life in terms of satisfaction and importance. This cardiac version is developed to specifically ⁷⁰ measure generic Quality of Life with the addition of three cardiac specific items. OLI is a widely used instrument that has been translated into many languages. The Swedish version of QLI has shown Cronbach's alpha coefficient of 0.83 to 0.87 71. It was used as it was deemed suitable for describing the life situation from a holistic perspective. This instrument measures patient satisfaction within the four domains of life situation as well as the importance of these domains to the subjects (38 statements in each domain). Satisfaction and importance were assessed by examining the healthfunctioning, socio-economic, psychological-spiritual, and family domains. The healthfunctioning domain (sixteen items) relates to physical health, ability, stress, worries and leisure activities. The socio-economic domain (eleven items) relates to emotional support, friends and economic aspects. The psychological/spiritual domain (seven items) relates to emotional, spiritual and intellectual aspects. The family domain (four

items) relates to family and next of kin. The statements were rated on a six-point scale, ranging from 'very satisfied' to 'very dissatisfied' for the satisfaction items and from 'very important' to 'very unimportant' for the importance items. The scores were recoded with a syntax, whereby each 'satisfaction' response was weighted against an 'importance' response. The highest scores were produced by a combination of high satisfaction/high importance and the lowest by high dissatisfaction/high importance. Cronbach's alpha coefficient test was performed on the domains, resulting in a score of 0.71-0.93 for the Swedish sample and 0.77-0.94 for the US sample.

The Delivery of ICD care Questionnaire DOIQ (V)

To the best of our knowledge there is no instrument for evaluating ICD care. Therefore this tool was developed as there was no validated tool in Swedish that we could use or in other languages that we could translate. The construction of the questionnaire was based on a systematic literature review and then guided by an expert group consisting of a nurse and a physician with clinical expertise in the ICD field and two nursing researchers with experience in the field of ICD care and follow-up. The format was inspired by existing questionnaires on the subject of heart failure care ^{72, 73}. The questionnaire comprised twenty-three questions, including both multiple choice questions (with response alternatives) and open questions. The questionnaire had four sections (1) Organisation, (2) The role and education of nurses, (3) Patient information and education and (4) Areas in need of improvement. It was tested for content validity by an expert group made up of one cardiologist and two experienced ICD nurses who were not involved in the study. Minor adjustments were made regarding reformulating of the questions and the sequence of the questions.

Phenomenographic interviews (II, III, IV)

In Paper II, III, IV a preliminary interview guide was constructed intending to introduce biophysical, emotional, intellectual, socio-cultural and spiritual-existential fields. The following questions were used in Paper II: "How do you conceive what has happened to you concerning your ICD implantation? How do you conceive your bodily functions related to your ICD implantation? How has the ICD implantation affected your inner self? How do you conceive the information you have received from healthcare professionals about your ICD device? How do you conceive the healthcare environment which you as a patient have encountered? How do you conceive that your family and closest friends have been affected by your ICD device? What is your outlook on the future? How can your family and closest friends influence your future? How can healthcare influence your future?"

The following questions were used in Paper III: "What is it like for you to have an ICD?" Follow-up questions varied from patient to patient in order to explore their responses.

In Paper IV an interview guide was designed comprising preliminary questions aimed at identifying variations in clinical aspects of delivering care. Each participant was asked the following introductory question; "Can you please tell me about your experiences of providing clinical care to patients with an ICD?" The interviewer posed probing questions in order to deepen, develop, clarify and explore their responses. In all qualitative studies informal conversation took place before the start of the audio-taped interview, The interviews lasted between 20 and 70 minutes and took place in the patient's home (II) or at the hospital (III, IV).

In Paper III some of the patients were contacted by telephone and an appointment for a telephone interview was arranged. An informal conversation took place prior to the tape-recorded interviews in order to establish a good researcher-patient relationship. In Paper IV the 24 healthcare professionals were interviewed by the researcher (KB) at the hospital where they worked.

Written patient information materials (V)

All educational brochures and information material, given to patients as part of standard care, were collected from each participating hospital. The materials analysed were brochures from companies and produced material from respective ICD clinic. The researcher (KB) collected the written information materials in connection with the interviews and completion of the questionnaire at each hospital.

Analysis

Quantitative analysis

In Paper I all data were treated as non-parametric due to the fact that none of the data were normally distributed and the sample sizes were small ⁷⁴. Wilcoxon's non-parametric signed rank test was used to analyse data over time for the Swedish and US samples. Differences between the groups were analysed using the Mann-Whitney U-test and descriptive analysis. Statistical significance was set at 5%. The analysis was supported by use of SPSS TM version 11.0. In Paper V descriptive statistics were used to describe the sample and summarise the study variables. The results from the multiple choice questions were tabulated to illustrate frequency distribution. Open questions were classified.

Qualitative analysis

Phenomenographic analysis

In order to improve the quality, and structure of the findings, data were analysed in accordance with the analysis scheme recommended by the phenomenographic tradition 75

Analysis means clearly distinguishing between the constituent parts of a context. All the interviews were transcribed verbatim, after which the data analysis began.

The analysis in Paper II started with the researcher reading each interview a number of times in order to gain an overall impression. Interviews were then processed by looking for statements which described plausible conceptions of the life situation. There were 454 statements and the analysis went on to compare different statements, which revealed similarities and differences, in relation to the study aim. They were grouped in order to obtain an overall picture of how differences and similarities could be connected. These patterns were scrutinised critically in order to detect dimensions. By interaction between the whole and its parts a final pattern emerged which resulted in six categories. In this study the categories comprised conceptions the so called positive and negative poles.

The analysis in Paper III, IV was carried out in accordance with the following principles, suggested by Dahlgren and Fallsberg 75 .

Familiarisation; each interview was listened to and read several times in order to obtain an overall understanding of the material. The focus was on the aim of the study.

Condensation; each interview was searched for statements that corresponded to the aim. The statements with a similar content were grouped together and condensed for preliminary classification. Data were condensed by selecting appropriate statements that describe the content of the interviews. A total of 243 statements (III) and 498 statements (IV) emerged.

Comparison; the identified statements were analysed in order to find similarities and differences in the life situation of patients with an ICD implant. Those with similar content were grouped together which resulted in preliminary conceptions.

Grouping; the statements were grouped according to their characteristics in order to obtain more understanding on how they were connected with each other and formed conceptions. The preliminary conceptions resulted in seven conceptions in each Paper (III, IV).

Articulating; the seven statements were compared and grouped on the basis of similarities and differences. The analysis moved back and forth between grouping and articulation until three (III, IV) different descriptive categories emerged.

Labelling; the conceptions that formed the descriptive categories were labelled to reflect their meaning.

Contrasting; the descriptive categories that emerged were compared in terms of similarities and differences in order to ensure that they had a unique character and were on the same level of description.

Deductive content analysis (V)

Deductive content analysis was used to describe how information was presented in the brochures and information material for ICD patients ^{76, 77}. Deductive content analysis is a method that starts with a theory that serves as guidance for themes. In the study by Sarvimäki and Stenbock-Hult ³¹ holistic dimensions were used. The data analysis of the text began by reading the brochures and informational material to gain an understanding of the whole text and capture the essential meaning. The text was then read and re-read several times and meaning units describing the different dimensions were sorted and summarised into themes under each suitable dimension. All meaning units in each dimension were summarised, after which percentage calculations were performed in order to describe the distribution of meaning units between the dimensions.

The text was sorted into Sarvimäki and Stenbock-Hult's ³¹ dimensions; biophysical, emotional, intellectual, spiritual and socio-cultural. The biophysical dimension consists of different systems for maintaining one's life situation which are either genetic or acquired. The emotional dimension describes the individual's conception of him/herself

or his/her surroundings in the living world. The intellectual dimension comprises the individual's interpretation of knowledge needs. The spiritual-existential dimension consists of the individual's norms, ideas and values, while the socio-cultural dimension views the individual as part of a social and cultural context.

ETHICAL ISSUES

The studies presented in this thesis were performed in accordance with the Helsinki declaration ⁷⁸ and approved by the Committee for Ethics in Medical Investigations, Göteborg University, Sweden, and The Human Research Committee of the University Hospital in Massachusetts, USA. In Paper **IV**, **V** ethical permission was not needed as the informants were healthcare professionals. Permission to study the implementation was obtained from the hospital manager. Informed consent was given by all informants.

All studies (I-V) in this thesis were based on clinical data collected from medical records at the hospital, questionnaires and from interviews. The participants were given both verbal and written information. It was made clear that participation was voluntary, that they were free to withdraw from the study at any time and confidentiality was guaranteed. Withdrawal from the study did not affect patient care. Informed consent was obtained from the participants prior to the studies. There was no dependent relationship between the informants and researchers, which could have influenced the informants' right to decide not to participate in the study. The completion of the questionnaires and the interviews took place in a private setting at the hospital (I, III, IV, V) or in the patient's home (II). All data were treated confidentially. The tape-recorded interviews and the completed questionnaires were locked in a safe place. The findings were presented in such a way as to make it impossible to identify any of the patients or healthcare professionals.

RESULTS

Review of the papers

Life situation related to the ICD implantation; self-reported uncertainty and satisfaction in Swedish and US samples (I)

This study explored self-reported uncertainty and satisfaction in a Swedish and a US sample. The US patients were older than those from Sweden (p<0.05). A statistically significant difference (p<0.05) was also found regarding cardiovascular factor, indicating that the US sample had a greater incidence of coronary artery disease.

There was no significant difference in uncertainty over time between pre and post ICD implantation either in the Swedish or the US patients. In comparison regarding uncertainty, the US patients had a higher a level of uncertainty before the ICD implantation (p<0.01) while, the Swedish patients had a higher level of uncertainty after the ICD implantation (p<0.001). The Swedish samples showed a statistically significant difference over time in self reported satisfaction with life within the socio-economic domain, indicating an improvement following implantation (p<0.05). Satisfaction with life before implantation showed statistically significant differences between the Swedish and the US sample, indicating a higher satisfaction level within the health and functioning, socio-economic and psychological-spiritual domains for the US sample. After implantation there were statistically significant differences, revealing that the US sample had higher levels within the health and functioning, socio-economic, and psychological-spiritual domains (Table 3).

Table 3. Comparison between Swedish (n=56, 3 months) and US samples (n=37, 6 months) regarding self-reported satisfaction with life before and after ICD implantation.

	Sweden Mean ranl	US k		Sweden Mean ra	US nk	
	Before		p-value	After		p-value
Health-functioning	40.7	52.0	0.046	40.0	53.0	0.026
Socio-economic	37.5	59.1	0.001	36.5	55.9	0.001
Psychol/ spiritual	40.0	52.0	0.031	41.1	56.0	0.009
Family	39.3	49.4	0.071	46.2	41.9	0.438

Mann-Whitney U-test

Patients with implantable cardioverter-defibrillator and their conceptions of the life situation: a qualitative analysis (II)

The aim of this study was to describe how Swedish patients living with an ICD conceive their life situation. The categorisation of the 454 statements resulted in six descriptive categories (Table 4).

Table 4. Descriptive categories and conceptions of the Swedish patients (II)

Descriptive categories

Conceptions

Safety in having an ICD implant	ICD saves one's life Courage to make an effort
Gratitude at having an ICD implant	Happiness at being alive Grief that result from needing a device
Being more or less dependent	Well being that their health condition is good Grief that the device causes discomfort
Having a network	Helpful and understanding network of family, friends and healthcare professionals Indifferent network resulting in a feeling of loneliness
Having a belief in the future	Hope and confidence that life must go on Anxiety and resignation that the best part of their life is behind them
Gaining awareness	Ability to adapt one's life, having accept the ICD, limitations because of the heart disease

Safety in having an ICD implant involved the conceptions describing how patients had a feeling of safety after the ICD implantation. The conceptions ranged between the device being seen as a life saver and the worries about what would happen if or when the ICD went off. They described how their life and emotional reactions had changed, for instance they would become angry more easily.

Gratitude at having an ICD implant concerned the conceptions of happiness at being alive but also that the ICD is alien and disturbed the patients from time to time.

Being more or less dependent described how the ICD patients experienced wellbeing when their health was good despite the heart disease. They felt independent compared to when they felt unwell and more dependent and feared that the ICD would cause memory disturbances. The patients described being extremely afraid, that they still experienced fear and that they did not want to be alone when the ICD went off.

Having a network ranged between patients' descriptions of good support from their social network after the ICD implantation e.g. understanding and helpful friends, next of kin and healthcare professionals compared to an indifferent network resulting in loneliness and a need of both formal and informal support.

Having a belief in the future described how the patients tried to see existing possibilities and feeling confident that life must go on but also resignation about the fact that the best part of life had gone. They had acquired an inner sense of security and could look ahead to the future with confidence. They experienced less anxiety after some time as they realised that the device functioned.

Gaining awareness described how patients' adaptation to living with an ICD device comprised physical, mental and social aspects and involved limitations imposed by specific life circumstances.

Ways of Experiencing the Life Situation Among United States Patients with an Implantable Cardioverter Defibrillator: A qualitative Study (III)

The aim of this qualitative study was to describe how patients living with an ICD in the USA conceived their life situation. The interview analysis resulted in 243 statements, seven conceptions and resulted in three descriptive categories (Table 5).

Table 5. Descriptive categories and conceptions of the American patients (III)

Descriptive categories	Conceptions
Trust	Being comfortable Having confidence in the future
Adaptability	Handling restlessness Tackling restrictions Managing daily life
Empowerment	Receiving emotional and tangible layman support Informational and tangible professional support

Trust described patients being confident that the ICD would function properly in the event of a life-threatening cardiac episode. They had acquired an inner sense of security, were less anxious and felt increasingly comfortable over time and were able to plan for the future

Adaptability involved patients receiving assistance with driving and the tasks of daily life and carrying out everyday activities such as returning to work, driving again and resuming their normal household duties. In many cases they no longer thought much about the ICD. They described the restrictions they were obliged to accept to handle a change in certain habits.

Empowerment involved experiences of an extremely supportive network to a weak one. Patients described having received support from family and friends as well as healthcare professionals who supported and assisted them in undertaking the necessary changes to their life situation.

However, the experiences also involved weak, unappreciative and indifferent networks. A poor network resulted in feelings of loneliness and a need for professional psychological support. Experiences of the information provided a range from giving the ICD patients a sense of security due to the increased medical and technical knowledge and they also described empathy from the healthcare professionals involved to patients being less satisfied with the information. Patients wanted to know more about what was happening to them and what they could do once they were discharged from hospital. They were satisfied with the information received in connection with surgery, but would have liked more individually tailored information as well as information provided in groups consisting of people of the same age and with similar experiences to themselves.

Experiences of delivering care to patients with an Implantable Cardioverter Defibrillator from the perspective of healthcare professionals (IV)

The focus of this qualitative study was to describe healthcare professionals' experiences of delivering care. The categorisation of the 498 statements from the interviews resulted in two descriptive categories (Table 6).

Table 6. Descriptive categories and conceptions of the Swedish healthcare professionals delivering ICD care (IV)

Descriptive categories

Conceptions

Striving to provide competent care	Providing access to care Improving one's qualifications Individualising care
Striving to infuse confirmation	Promoting independence Providing existential support Mediating security Comprising needs of next of kin

Striving to provide competent care involved how the healthcare professionals provided access to care and described the importance of being available for each patient: from the importance of prioritising time to having the courage and a strategy to discuss problems, and allowing patients access to the healthcare professional in order to reflect on and ask questions about the device. The importance of increased knowledge and skills in the technical as well as the psychosocial area was pointed out. They emphasised that individualisation should be based on a dialogue with the patient, in which he/she states his/her preferences, but also on assessment of, e.g., cognitive functions and self-care abilities. Checking the ICD by remote monitoring provided new possibilities for follow-ups.

Striving to infuse confirmation described how the healthcare professionals tried to help the patient to mediate security and independence. They promoted independence by giving the patients tools to handle their life situation and provided existential support through sensitive communication and the opportunity to meet other ICD-team members, such as a psychologist or a social worker. They mediated security by being there for the patient, and responding to the needs of next of kin.

They tried to provide existential support which included the importance of the ICDteam being able to identify and meet the patient's needs and enhancing the team members' experience and knowledge, e.g., by holding regular support group meetings that allowed patients to meet other ICD patients and next of kin's.

Organisation of care for Swedish patients with an Implantable Cardioverter Defibrillator; a national survey (V)

This study described clinical aspects of the ICD care in Sweden with focus on organisation, the role and education of the nurses, patient information and areas in need of improvement.

In Sweden ICD implantations are usually performed in university hospitals but they are also carried out in county hospitals. The organisation of care always involves physicians, usually accompanied by nurses. However, in 4 of the 16 hospitals there were only nurses from the ward assisting the physicians. A multi-disciplinary team was available at all hospitals, but used in a different ways. Physiotherapists were members of the ICDteam in seven hospitals, psychologists in five and social workers in nine. ICD company representatives were present during ICD implantation at all hospitals.

The first follow-up following ICD implantation occurred between 3 to 8 weeks after the surgery. After the first visit, all hospitals performed follow-ups every 6 months if no complications occurred. Five hospitals carried out telephone follow-up with patients 14 days after implantation. This was performed by an ICD nurse. All patients had easy access to telephone consultation with an ICD physician or nurses. Three hospitals performed distance follow-up by means of remote monitoring.

Nurses performed ICD follow-up independently in the outpatient clinic and were responsible for the technical control of the device, patient education, documentation and planning of follow-up visits in seven of the hospitals. In the other hospitals the physicians performed the ICD controls with nurses providing the patient with educational information pre- and post-implantation and planning of follow-up visits. All the ICD nurses had received specific ICD education from ICD companies, the Heart Rhythm Society and/or through various university courses. In three out of the seven hospitals the ICD nurses had a written delegation including technical control of the device, although none of them were permitted to make changes in the functioning of the device without consulting a physician.

ICD patients received verbal and written information before and after implantation in all hospitals. The written information material consisted of brochures from ICD companies. In addition, four hospitals had produced their own material in order to include more in-depth and detailed information. A deductive content analysis was conducted of all the available educational material in line with the dimensions of Sarvimäki and Stenbock-Hult ³¹. The biophysical dimension was present in 59% of all information in the educational material. The emotional dimension covered 2% and the intellectual dimension covered 20% of the educational content. The spiritual-existential dimension was not referred to in any of the materials. The socio-cultural dimension constituted 19% of the information contained in the brochures and information materials.

In all hospitals the family was offered information together with the patient. One hospital offered the patients an opportunity to meet an ICD recipient in a similar life situation pre- and post implant, in order to discuss the experiences of living with an ICD. Three hospitals provided regular group information meetings, usually once a year, for patients and their families with members of the ICD-team.

The majority of the ICD-teams were in favour of the development of quality assurance by means of increased staff education, check lists, guidelines and the ICD registry.

The majority of the teams that did not already involved nurses in independent ICD follow-up wished to implement this strategy in the near future. Several of the teams mentioned the need for greater financial support in order to increase the ICD implantation rate, conduct more research, expand follow-up and patient support. Furthermore, several ICD-teams were interested in organising follow-up by remote monitoring.

DISCUSSION

Methodological considerations

The research design of this thesis consisted of both quantitative (**I**, **V**) and qualitative (**II**, **III**, **IV**, **V**) approaches, which can be considered complementary and enhance validity of the findings ⁷⁹. The first three studies (**I-III**) described the patients' perspective of their life situation and data were collected using both phenomenographic interviews (**II**, **III**) and questionnaires (**I**) thus measuring satisfaction with life and uncertainty. The last two studies (**IV**, **V**) described the healthcare professionals' experiences of delivering care and the clinical aspect of ICD care in Sweden with focus on organisation, the nurse's role, patient information and areas in need of improvement. Data were collected using both interviews and a questionnaire. This triangulation of methods for data collection aimed to determine the congruence of the phenomenon and has made it possible to view the findings from different perspectives ^{79,80}.

The patients' life situation was followed over time, at baseline and after three months (Swedish sample) and six months (US sample). The fact that the US patients were investigated at a later stage after the implantation than their Swedish counterparts may have influenced the results. Studies have revealed that the time factor is important, as patient security has been shown to increase over time following implantation ³. The samples consisted of well-defined groups of men and women scheduled for an ICD implantation and living in a specific area in the south of Sweden and the north-east of the USA. The dropout rate is acceptable and mostly understandable. In Paper I 15% of the Swedish patients dropped out due to surgery or death while 7% of the US patients dropped out without giving a reason.

The MUIS-C was chosen in order to determine the level of uncertainty at baseline and three months after the implantation for the Swedish ICD patients and six months for the US patients. The community version of MUIS-C has been used in a wide variety of subjects with chronic illness ⁶⁷. However, a better adaptation of the MUIS-C to the ICD would be desirable. The overall MUIS-C showed acceptable internal consistency with reliability scores of 0.86 and 0.80 for the Swedish and US sample, respectively ⁷⁴. The Swedish version of the MUIS-C was translated and tested for reliability by Hallberg and Erlandsson ⁶⁸. However, this Swedish version has not been tested for validity.

The QLI Cardiac version examines the quality of life in cardiac patients ⁸¹. It has been used for a wide variety of individuals living with cardiovascular disease (CVD). It has been used in many studies with satisfactory reliability and validity. Satisfaction and importance were assessed by investigating the health-functioning, socio-economic, psychological-spiritual and family life domains. The QLI Cardiac version was deemed

to describe the life situation from a holistic perspective. Cronbach's alpha coefficient showed acceptable internal consistency with reliability scores of 0.71-0.93 for the Swedish sample and 0.77-0.94 for the US sample ⁷⁴. The Swedish generic version of the QLI has been translated and validated ⁷¹, but not the Cardiac version. However, there are only three additional questions added in the Cardiac version compared to the generic.

The Delivery of ICD care Questionnaire (DOIQ) (V) seems to have covered the field of interest well, since the healthcare professional did not have any problems to complete the questionnaire. Further, even though they had the chance to add additional areas they did not see a need for that. This could be explained by the fact that the group which designed the questionnaire consisted of two nursing researchers with experiences in the field of ICD care and follow-up as well as a physician and a nurse with clinical expertise in this field.

The phenomenographic approach was considered appropriate for identifying and exploring patients' conceptions of their life situation (**II**, **III**), and the healthcare professional conceptions of delivering clinical care to patients (**IV**), due to the fact that the starting point is empirical knowledge rather than a ready-made model or theory ⁶³. According to Marton ^{60, 63}, the phenomenographic approach is a holistic interpretation of data. The holistic perspective should permeate the entire research process and motivate the choice of method.

The methodological objective was to remain close to the empirical data in order to gain a better understanding of the life situation of patients living with an ICD. It was considered logical and appropriate to use the phenomenographic approach in this thesis, as the aim was to explore how patients with an ICD perceive their life situation and healthcare professionals' experiences of delivering care to ICD patients. Phenomenographic data collection and data processing are explorative by nature ⁶³. Phenomenography does not prescribe a particular data collection procedure or analysis, a fact that has often led to criticism ⁶⁵, although the most common method is interviews ⁶⁰. The phenomenographic interviews are characterised by an open issue approach and the interview starts with a predetermined question ⁶⁰. The interview allows informants to speak freely and to give concrete example to discover all the variations of understanding the phenomenon. The semi-structured interview has open issues, which both provides an opportunity for respondents to express themselves freely within the limits that the issues permit. It also allows the respondent to ask the interviewer additional questions if anything is unclear and needs to be developed. A sample size of about 20 informants is considered sufficient to describe existing variations of the phenomenon in phenomenographic studies ⁸². In Paper II the interview guide contained nine questions. In Paper III, IV open questions were used. There is a risk that the many questions in Paper II could have influenced the patients' answers and the analysis. However, the results are clearly separated from the interview guide mirroring are a higher abstract level and clearly detached from the raw data. There were 15 and 14 informants in Paper II, III respectively, whereas there were 24 informants in Paper IV which can be viewed as a development of the phenomenographic approach towards including more informants.

The phenomenographic approach has been developed over the years, which can also be seen in our studies ^{62, 64}. In Paper II the analysis was expressed in other terms and the conceptions comprised so-called positive and negative poles. In Paper III, IV the analysis was carried out in accordance with recommendations by Dahlgren and Fallsberg ⁷⁵. The congruence between the categories (II, III, IV) can also be considered as validating the results. In phenomenographic studies the last step in the analysis can be to investigate the relation between the descriptive categories and to constitute the outcome space ⁶⁵. In Paper III the outcome space varied from the patients' trust to adaptability and empowerment and in Paper IV the outcome space varied from striving to provide competent care to striving to infuse confirmation.

In this thesis the studies were scrutinised in terms of four criteria's of trustworthiness: credibility, dependability, conformability and transferability of the findings and the methods employed ⁷⁹.

Credibility In order to overcome the effect of bias, the analysis was performed jointly by several researchers with content and methodological knowledge (investigator triangulation). The patients were carefully chosen, a well defined group of men and women living in specific areas in Sweden and the USA. Strategic sampling was used for the data in line with the phenomenographic tradition ^{63,75} (**II, III, IV**).

Dependability In order to avoid any biased results the researcher was not involved in the patients' care and was not previously known by the informants. The phenomenon was well defined, and the semi-structured interviews were based on guidelines developed from a holistic perspective, which was deemed suitable for capturing the phenomenon of the study. The follow-up questions allowed the patient to reflect over his/her life situation (**II**, **III**) and the healthcare professional to reflect over delivering care (**IV**).

Ensuring **conformability** refers to objectivity and can be understood in terms of several researchers with different perspectives and knowledge, who carefully analysed and discussed the conceptions in a systematic manner in accordance with the

phenomenographic tradition ^{63, 75}. The supervisors had specialist knowledge about patients with CVD and were thus able to interpret the findings and place them in an appropriate context. The phenomenon was delimited by the use of semi-structured interview questions, but it cannot be excluded that the interviewer's expectations and background, the way the questions were framed and their content as well as the patient's expectations and background may have influenced the responses. Such effects are unavoidable due to individuals influencing each other in an interview situation. During the analysis of Paper III, two English speaking researchers (JF and GH) ensured that the analysis would not be influenced by misunderstandings due to language.

Transferability refers to the extent to which the findings can be transferred to other groups. In order to obtain variation among patients from Sweden and the USA, strategic sampling was used for the data collection in line with the phenomenographic tradition. There was a great variation with regards to age, sex, education, working situation and medical history (**II**, **III**). This makes the findings transferable to a larger group of Swedish and American ICD patients. However, some years have passed since the data collection in Paper **I-III** and the indication for an ICD implantation has expanded. Some of the results might therefore not be transferable to patients receiving their ICD due to primary prevention.

In Paper IV, V all ICD clinics were represented and healthcare professionals varied in age, profession, gender and number of years caring for ICD patents. These conceptions can probably be generalised to include most Swedish healthcare professionals in the ICD field.

Discussion of results

This thesis offers several insights from different groups of ICDs patients (I-III) and healthcare professionals (IV, V) in order to guide nurses, physicians and others to understand the experiences of living with an ICD as well as providing care to this population.

Data describing the patients' perspective were collected in two centres in different parts of the world (Sweden and the USA). All patients interviewed had received their ICD due to secondary prevention. This means that they have been seriously ill and was more or less dependent of the ICD for their survival. This homogeneity in ICD indication might explain why there were more similarities than differences in the patients' experiences of their life situation (II, III) despite dissimilarity in the social culture and the healthcare system between countries. The social culture includes for example the individual's life style, food habits, level of physical activity, social network, and religion as well as a different system in the society such as the educational system and the healthcare system.

The Swedish and the US patients both completed the questionnaire before the implantation, but after implantation the questionnaire was completed after three months in Sweden and after six month in the USA (I). This may have affected the outcome, as the US patients had more time to adapt to their new life situation. However, when the Swedish patients and the US patients had had their devices for two years, they experienced that the life situation had stabilised (II, III).

They had changed from being afraid, angry and feeling insecure about their life situation to feeling confident and hopeful and trusting the device. The patients also described how their life situation had been altered by the device e.g. they had reduced their level of physical activity and had made other necessary changes in their life. Similar results were shown by Hamilton et al. ³⁶. Hence, overall it seemed that the patients in our studies (**II**, **III**) had adapted to their new life situation and experienced that the device mostly gave them a sense of security, which also other studies found ^{3,56}. This can reveal that they were in, or had finalised, a process of transition. Transition is a process of movement from one state to a new situation, e.g. living with an ICD ⁸³. The time it takes from ending a process to beginning a new one can vary from days to years due to different social environments, cultures and individual contexts. During the transition changes like disorientation and anxiety can occur ⁸³. Those experiences appeared in patients both from Sweden and in the USA in our studies (**II**, **III**).

Factors that may influence the transition are meanings, expectations, level of emotional and physical wellbeing, level of knowledge, skill and environment.

Transition can be seen as a movement in the life situation, from adapting to living with an ICD to finding a new meaning of life involves the whole patient in its environment and context. A lack of holistic approach might cause problems later on in transition, which is why it is of utmost importance that the healthcare professionals are aware of this transition process and try to help the patient by providing multidisciplinary care guided by a holistic team perspective.

The patients described how they wanted more individual information; they wanted to know more about the device itself, how it works and what happens when they receive a shock (II, III). This was in congruence with the healthcare professionals' ambitions to improve the educational information by e.g. developing a website where the patients could find information when issues arose (IV). Eads et al. ¹¹ found that patients felt increasingly secure when information is repeated over time.

One way to reach the patient could be to develop structured management programmes, which have already been implemented in rehabilitation after acute coronary syndrome and in heart failure care. These types of programmes have been found to have beneficial effects on several factors; i.e. mortality, exercise capacity, lipid levels, blood pressure, weight loss, stress and psycho-social functioning ⁸⁴.

Both patients (III) and healthcare professionals (IV, V) require a comprehensive individual education programme that continues over a longer period. This need is well recognised in patients experiencing various cardiac problems, including ICD implantation ^{12, 16}. The amount and complexity of the information required support the need for this type of programmes. In addition, the time available for clinicians to offer education to patients and next of kin has significantly reduced as a result of technological and practice changes, with for example an increasing population living with an ICD, in the last decade. The patient's average length of hospital stay for ICD implantation has also reduced from one week in the early 1990s, to today's approximately 2-3 days, which gives the healthcare professionals less time to educate the patient ⁵. These conditions increase the necessity for a coordinated, continuous follow-up programme. This programme also has to address the patient's and next of kin's needs for social support, as social support has been shown to positively enhance the patient's emotional and physical recovery after a cardiac event, including the receipt of an ICD ^{25, 85, 86}.

However, the development and delivery of an education programme and different support interventions for patients and their next of kin need to be looked into. We found that the educational information material given to ICD patients seemed to be sufficient in terms of physical and technical aspects, but the information regarding socio-cultural

and intellectual areas was poor and the spiritual-existential and emotional areas were lacking. This was found in the content analysis of the educational material in Paper V and it was also highlighted in the interviews with the healthcare professionals and the patients (III, IV). To provide holistic and patient-centred education and information in dialogue is complex. The education is often provided in circumstances of emotional and physical stress and the patient can then have a great difficult to absorb and retain the information ⁸⁷. It is therefore essential to evaluate patients' understanding of the education given and their own perception of whether they need further education to manage their life situation with for example the insecurity and uncertainty they might experience 88. It is also important to remember that some patients who have undergone a cardiac arrest suffer from reduced cognitive abilities 51. The patients in our studies wished for more individually based information and knowledge in relation to their age, needs and interests. They wanted to participate in support groups where the participants were of similar age, background, and had similar device indication and experiences of the ICD implantation. This would give the patients an opportunity to discuss issues and experiences and to learn from their support group members. This was also strengthened by the healthcare professionals' experiences, who also thought it would be useful to have tailored support groups since the life situation may look very different for the individual patient (III, IV). These different kinds of educational programmes would begin at the time of the patient's pre-ICD information, and continue through the first year of their recovery, as our studies as well as others' 89-91 have found that the patients are in the greatest need for advice, support and education during this time span.

Several studies ⁹²⁻⁹⁴ described how psychological support can reduce anxiety and depression, and that psychosocial support reduces psychological distress and facilitates quality of life. Harrowing experiences, such as life threatening arrhythmias, can lead to a crisis and patients might need professional and supportive care to handle them ²³.

Therefore it seems both logical and important to screen for quality of life, uncertainty, depression and anxiety in ICD patients during the regular follow-up visits in order to detect psychological distress at an early stage ⁹⁵. The patient could be asked to complete these questionnaires that then act as a basis of discussion about the patients' life situation and thereby provide a more individualised care.

Mauro ⁹⁶ found that ICD patients with greater uncertainty had less overall psychosocial adjustment; less adjustments in the domestic environment, sexual and social relationships and suffered from greater psychosocial distress after 1-8 weeks following hospital discharge. Three ICD clinics in Sweden (**IV**) offered the patients home-monitoring of the ICD and several wanted to develop this form of follow-up

which apart from the psychological effect, would make everyday life easier for patients living at a distance from the hospital. Ricci et al. ²¹ confirms that home-monitoring in the shape of an Internet-based remote control of the ICD is feasible and reliable and suggested that an organisation based on a specialist nurse and a physician in collaboration required little time and seemed to be cost-effective.

Not only the patient but also his/her next of kin can become anxious after an ICD implantation and might therefore be in need of psycho-social support to cope with the illness and the device and its effect on the family. Several studies have reported that spouses can experience even more anxiety than the patient ^{47, 97} which emphasises the need for information and education for both patients and spouses. The anxiety of the spouses can lead to being overprotective towards the partner and hinder the patient in his/her daily life. Thus, there is a need for support groups for both the patient and next of kin providing education about the device itself and how to support their partner to go on living with an ICD ^{23, 57}.

The organisation of ICD clinics in Sweden needs to be developed and complemented to also include nurse-based follow-up visits, where the nursing role could include a supportive and educational function, guided by a holistic approach, but also to perform independent technical controls, in consultation with a physician when necessary. This patient group of ICD recipients is no longer homogenous as it to some extent was at the beginning of ICD implantations, and it is therefore even more important to individualise the care of each patient. Today more Swedish hospitals have begun to implant ICDs and for that reason it is important that nurse-based visits are a part of the changing organisation.

All of the implanting centres in Sweden are included in the thesis (**IV**, **V**), but at some hospitals either the physician or the nurse was interviewed while in others both shared their experiences. It is important to point out that the purpose was not to compare the different professionals' experiences, but to describe how the ICD-team jointly experienced the ICD care. As the thesis aims to describe multi-disciplinary care aspects it can be seen as a limitation that no other healthcare professionals but physicians and nurses were interviewed (**IV**, **V**). However, the reason for this choice is that in every hospital physicians are involved in the direct care of ICD patients, and most often nurses too, but rarely other healthcare professionals which support the fact that physicians and nurses must be considered to have the largest amount of experience regarding the organisation of ICD care.

In our study (V) the healthcare professionals pointed out additional resources needed for providing an ICD-related staff education programme, more qualitative research and

extended services for the patients. However, if these suggested recommendations are to be implemented it assumes organisational approval and the provision of adequate personnel, as well as, administrative and budgetary resources.

Further, the healthcare professionals wanted to provide a community based education programme aiming to increase the community awareness of the ICD (V). Rapid expansions in the use of ICDs increase the likelihood of healthcare professionals caring for patients in a range of emergency care situations in hospitals settings as well as in nursing homes. The experience from the healthcare professionals in this thesis is that few clinical staff is sufficiently informed to be able to appropriately care for these patients. Hence, education regarding patients with ICD should be included also in nursing- and medical schools as well as in the training to become a paramedic. Information should for example include emergency care of the ICD patient, what to do at shock delivery and ethical considerations at the end of life.

This thesis offers a further contribution to the scholarly discussion about the relationship between technology and human existence and how to cope with this transition. Our studies revealed that the embodiment of the ICD reflects a merger of experiences about its presence and potential from both patients' and healthcare professionals' perspective. Additionally, this research hopefully encourages healthcare professionals to carefully reflect on what it is like to live with an ICD and to consider practice improvement to positively enhance the patients' and next of kin's experiences of ICD care.

Conclusions

There was no difference in uncertainty between pre and post ICD implantation either in the Swedish or the US patients. Satisfaction with life was significantly higher among American patients compared to Swedish patients both before and after ICD implantation within the health-functioning, socio-economic and psychological-spiritual domains. The Swedish ICD patients experienced significantly higher satisfaction with life within the socio-economic domain after 3 months. There was no other difference in the domains of satisfaction with life in the Swedish or the American patients before and after ICD implantation (I).

ICD patients experienced safety and gratitude, but also dependency when having the ICD implanted. They also reported the importance of having a belief in the future, a supporting network and the ability to adapt and make the best out of their life situation (II).

Living with an ICD can be understood as a transition comprising three interdependent conceptions, firstly the patients' trust in the device, followed by an adaptation to the new life situation which included empowerment from family and healthcare professionals (III).

The healthcare professionals strove to provide competent and individualised care based on a holistic perspective and high accessibility to the ICD-team. The ICD-team suggested more structured educational information according to guidelines and strove to increase their own competence by improving their skills and continuous education (IV).

The organisation of ICD care and follow-up in Sweden is developing towards more team-based clinics. ICD-teams consisting of a variety of healthcare professionals are important for the provision of care with a holistic perspective including the biophysical, emotional, intellectual, spiritual-existential and socio-cultural dimensions. The written information materials need to be developed to include all holistic dimensions (V).

IMPLICATIONS

Clinical implications

In order to support the patients' transition after an ICD implantation and to help them have trust, adaptability and empowerment there is a need for team-based clinics with a structured follow-up programme. The healthcare professionals could provide time to verbalise and allow discussions of holistic care face to face or in support groups. Educational information material consisting of brochures, videos, websites and other computer-based tools including a holistic perspective needs to be further developed.

As the number of hospitals implementing ICDs increases, there is a need for an organised forum for the healthcare professionals aiming to discuss best clinical practise, educational strategies and support programmes to ensure that the patients receive equal care regardless of where they live and have their ICD follow-up. Finally, different multidisciplinary interventions should be highlighted in the clinical guidelines of ICD. Scientific societies, such as the European Society of Cardiology, can play a key role in this field by promoting a more team-based ICD care.

Research implications

There is a need for evaluation of intervention programmes that include a holistic perspective of educational information. Computer-based educational information about the device and patients' life situation could also be developed and evaluated. As the indications for receiving an ICD has been expanded it is important to also describe the primary preventive patients' experiences of living with an ICD. Additionally, it would also be of interest to describe American healthcare professionals' experiences of their organisation and compare it with the Swedish studies.

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SUMMARY IN SWEDISH

Hjärt- och kärlsjukdomar är den vanligaste dödsorsaken för både män och kvinnor över 50 år. Många avlider i hjärtstopp orsakat av rytmrubbningar. Behandling av livshotande arytmier har utvecklats under senare år och en teknologi som har påverkat överlevnaden är den implanterbara defibrillatorn (ICD). En ökning av antalet implantationer förväntas i framtiden på grund av nya indikationer, vilket innebär att även vården och andelen uppföljningar av dessa patienter kommer att öka. Patientens hela livssituation kan påverkas med psykologiska och psykosociala konsekvenser för både patienten själv och de anhöriga. Att vårda patienten och hans/hennes familj både före och efter ICD implantation ställer krav på vårdpersonalens förmåga att ge information, utbildning, stöd, rådgivning och teknisk uppföljning utifrån ett holistiskt perspektiv.

Det övergripande syftet med avhandlingen var att beskriva hur patienter med en ICD uppfattade sin livssituation och hur vårdpersonal beskrev sina erfarenheter av att vårda patienter med en ICD.

Forskningsdesignen var beskrivande med både kvantitativa och kvalitativa metoder, och data har samlats in från Sverige och USA.

I studie I var syftet att beskriva förändringar i livssituationen hos 56 svenska och 37 amerikanska patienter, före samt 3 respektive 6 månader efter ICD implantationen. Ferrans and Power Quality of Life Index (QLI) användes för att mäta patienternas tillfredsställelse med sin livssituation och Michel's Uncertainty in Illness Scale (MUISC) användes för att utvärdera otrygghet.

Studie I visade att de svenska patienterna hade en högre tillfredsställelse i sin livssituation inom den socio/ekonomiska dimensionen efter ICD implantationen, däremot påvisades inga förändringar över tid för de amerikanska patienterna. Studien visade att de amerikanska patienterna skattade sin tillfredställelse i livssituationen högre inom hälsa/funktion, socio/ekonomisk samt psykologisk/andlig dimension jämfört med de svenska patienterna både före och efter ICD implantationen. De amerikanska patienterna upplevde en större otrygghet i livssituationen efter implantationen medan de svenska patienterna upplevde en större otrygghet före.

I studie **II** var syftet att beskriva patienternas uppfattning av sin livssituation. Data insamlades från femton svenska patienter som hade haft sin ICD implanterad i två år. Sex deskriptiva kategorier framkom; *säkerhet, tacksamhet, att vara, att ha ett nätverk, att ha en tro på framtiden* samt *att ha en medvetenhet*. Patienterna upplevde säkerhet och kände tacksamhet men även ett beroende av sin ICD. De beskrev vikten av att ha en framtidstro, att ha ett stödjande nätverk och att ha en förmåga att anpassa sig och göra det bästa av sin livssituation.

I studie **III** var syftet att beskriva patienternas uppfattning av sin livssituation utifrån ett holistiskt perspektiv. Data insamlades genom att fjorton amerikanska patienter, som hade haft sin ICD implanterad i två år, intervjuades. Tre beskrivningskategorier framkom; *tillit, anpassningsförmåga* samt *bekräftelse*. Att leva med en ICD beskrevs som att känna förtroende och vara beroende av den, samt att anpassa sig till den nya livssituationen där delaktighet från närstående och vårdpersonal ingår.

I studie **IV** var syftet att beskriva läkares och sjuksköterskors uppfattning av att vårda och följa upp patienter med ICD. Data insamlades från tjugofyra läkare och sjuksköterskor från de sexton kliniker i Sverige som implanterade ICDer och följde upp dessa patienter. Två beskrivningskategorier med sju sub-kategorier framträdde: *Att sträva efter att erbjuda kompetent vård; erbjuda tillgänglig vård, utveckla sin kompetens, individualisera vården. Att sträva efter att ingjuta mod; främja oberoende, ge existentiellt stöd, förmedla trygghet samt involvera anhöriga. ICD-teamet strävade efter att ge kompetent och individanpassad vård utifrån ett helhetsperspektiv. De strävade efter att förbättra sin egen kompetens samt att utveckla vården.*

I studie V var syftet att beskriva den kliniska vården med fokus på organisation, sjuksköterskors utbildning och roll, patient information samt behov av utveckling och insamlades ett frågeformulär förbättring. Data genom (DOIO) informationsmaterial insamlades från respektive klinik. Resultatet visade att hälften av sjukhusen hade sjuksköterskebaserade ICD mottagningar och att ytterligare ett flertal planerade att införa liknande modeller. I informationsmaterialet dominerade den biofysiska dimensionen med information om tekniska och medicinska aspekter av ICDn. Den sociokulturella och intellektuella dimensionen var tillfredställande beskriven i materialet, den emotionella var dock sparsamt beskriven medan den andligt existentiella dimensionen saknades helt.

Denna avhandling kan ge en ökad förståelse för patientens livssituation samt läkares och sjuksköterskors erfarenheter av att vårda denna patientgrupp. Avhandlingen kan användas för att överväga rutiner och förbättra framtida vård i syfte att stärka patienternas förutsättningar för ett optimalt välbefinnande.

REFERENCES

- 1. Sears SF, Jr., Conti JB. Quality of life and psychological functioning of ICD patients. **Heart.** May 2002;87(5):488-493.
- Tagney J, James JE, Albarran JW. Exploring the patient's experiences of learning to live with an implantable cardioverter defibrillator (ICD) from one UK centre: a qualitative study. Eur J Cardiovasc Nurs. Sep 2003;2(3):195-203.
- Kamphuis HC, Verhoeven NW, Leeuw R, Derksen R, Hauer RN, Winnubst JA. ICD: a qualitative study of patient experience the first year after implantation. J Clin Nurs. Nov 2004;13(8):1008-1016.
- **4.** Sandstedt B, Kennergren C, Edvardsson N. Bidirectional defibrillation using implantable defibrillators: a prospective randomized comparison between pectoral and abdominal active generators. **Pacing Clin Electrophysiol.** Sep 2001;24(9 Pt 1):1343-1353.
- 5. Svenska ICD- och pacemakerregistret. Årsrapport 2008 Stockholm: Karolinska sjukhuset; 2008.
- **6.** Connolly SJ, Hallstrom AP, Cappato R, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg. Canadian Implantable Defibrillator Study. **Eur Heart J.** Dec 2000;21(24):2071-2078.
- 7. Nanthakumar K, Epstein AE, Kay GN, Plumb VJ, Lee DS. Prophylactic implantable cardioverter-defibrillator therapy in patients with left ventricular systolic dysfunction: a pooled analysis of 10 primary prevention trials. **J Am Coll Cardiol.** Dec 7 2004;44(11):2166-2172.
- 8. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Circulation. May 27 2008;117(21):e350-408.
- 9. Nationella riktlinjer för hjärtsjukvård. (In Swedish) (The National Board of Health and Welfare) In: Socialstyrelsen, ed. Stockholm; 2008.
- 10. Reid SS, McKinley S, Nagy S. Outcomes, problems and quality of life with the implantable cardioverter defibrillator. **Aust J Adv Nurs.** Jun-Aug 1999;16(4):14-19.
- Eads AS, Sears SF, Jr., Sotile WM, Conti JB. Supportive communication with implantable cardioverter defibrillator patients: seven principles to facilitate psychosocial adjustment. J Cardiopulm Rehabil. Mar-Apr 2000;20(2):109-114.
- **12.** Dougherty CM. Family-focused interventions for survivors of sudden cardiac arrest. **J Cardiovasc Nurs.** Oct 1997;12(1):45-58.
- Mirowski M, Reid PR, Mower MM, et al. Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings. N Engl J Med. Aug 7 1980;303(6):322-324.

- **14.** Blomstrom-Lundqvist C, Blomstrom P, Rosenqvist M. Implantable defibrillator-an advance in the treatment of ventricular arrhythmias. **Läkartidningen.** Aug 22 1990;87(34):2573-2578.
- **15.** Israel CW. Do some implant too many defibrillators or others too few? **Europace.** Aug 2009;11(8):982-984.
- Ocampo CM. Living with an implantable cardioverter defibrillator: impact on the patient, family, and society. Nurs Clin North Am. Dec 2000;35(4):1019-1030.
- 17. Kenny T. The Nuts and Bolts of Cardiac Pacing: Blackwell Publishing; 2006.
- **18.** Senges-Becker JC, Klostermann M, Becker R, et al. What is the "optimal" follow-up schedule for ICD patients? **Europace.** Jul 2005;7(4):319-326.
- **19.** Brugada P. What evidence do we have to replace in-hospital implantable cardioverter defibrillator follow-up? **Clin Res Cardiol.** 2006;95 Suppl 3:III3-9.
- **20.** Lazarus A. Remote, wireless, ambulatory monitoring of implantable pacemakers, cardioverter defibrillators, and cardiac resynchronization therapy systems: analysis of a worldwide database. **Pacing Clin Electrophysiol.** Jan 2007;30 Suppl 1:S2-S12.
- 21. Ricci RP, Morichelli L, Santini M. Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization. **Europace.** Feb 2008;10(2):164-170.
- **22.** Tagney J. Can nurses in cardiology areas prepare patients for implantable cardioverter defibrillator implant and life at home? **Nurs Crit Care.** May-Jun 2004;9(3):104-114.
- **23.** Duru F, Buchi S, Klaghofer R, et al. How different from pacemaker patients are recipients of implantable cardioverter-defibrillators with respect to psychosocial adaptation, affective disorders, and quality of life? **Heart.** Apr 2001;85(4):375-379.
- **24.** Moon M. Implantation of implantable cardioverter defibrillators: implications for nursing practice. **Nursing in Critical Care.** 2001;6(3):133-138.
- 25. Carlsson E, Olsson SB, Hertervig E. The role of the nurse in enhancing quality of life in patients with an implantable cardioverter-defibrillator: the Swedish experience. **Prog Cardiovasc Nurs.** Winter 2002;17(1):18-25.
- **26.** Naik AM, Peter CT. Are implantable cardioverter- defibrillators cost-effective? **Curr Cardiol Rep.** Jul 2000;2(4):341-345.
- **27.** Fetzer SJ. The patient with an implantable cardioverter defibrillator. **J Perianesth Nurs.** Dec 2003;18(6):398-413.
- **28.** Dougherty CM, Pyper GP, Frasz HA. Description of a nursing intervention program after an implantable cardioverter defibrillator. **Heart Lung.** May-Jun 2004;33(3):183-190.
- Smeulders ES, van Haastregt JC, Dijkman-Domanska BK, van Hoef EF, van Eijk JT, Kempen GI. Nurse- and peer-led self-management programme for patients with an implantable cardioverter defibrillator; a feasibility study. BMC Nurs. 2007;6:6.
- **30.** Sears SF, Sowell LD, Kuhl EA, et al. The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients. **Pacing Clin Electrophysiol.** Jul 2007;30(7):858-864.

- 31. Sarvimäki A, Stenbock-Hult B. Vård. Ett uttryck för omsorg. Falköping: Liber: 1996.
- Keegan L, Keegan GT. A concept of holistic ethics for the health professional. J Holist Nurs. Sep 1992;10(3):205-217.
- Ahmad M, Bloomstein L, Roelke M, Bernstein AD, Parsonnet V. Patients' attitudes toward implanted defibrillator shocks. Pacing Clin Electrophysiol. Jun 2000;23(6):934-938.
- **34.** Sowell LV, Kuhl EA, Sears SF, Klodell CT, Conti JB. Device implant technique and consideration of body image: specific procedures for implantable cardioverter defibrillators in female patients. **J Womens Health (Larchmt).** Sep 2006;15(7):830-835.
- **35.** Williams AM, Young J, Nikoletti S, McRae S. Getting on with life: accepting the permanency of an implantable cardioverter defibrillator. **Int J Nurs Pract.** Jun 2007;13(3):166-172.
- **36.** Carroll DL, Hamilton GA. Long-term effects of implanted cardioverter-defibrillators on health status, quality of life, and psychological state. **Am J Crit Care.** May 2008;17(3):222-230; quiz 231.
- 37. Steinke EE, Gill-Hopple K, Valdez D, Wooster M. Sexual concerns and educational needs after an implantable cardioverter defibrillator. **Heart Lung.** Sep-Oct 2005;34(5):299-308.
- **38.** Hamilton GA, Carroll DL. The effects of age on quality of life in implantable cardioverter defibrillator recipients. **J Clin Nurs.** Feb 2004;13(2):194-200.
- **39.** Wojcicka M, Lewandowski M, Smolis-Bak E, Szwed H. Psychological and clinical problems in young adults with implantable cardioverter-defibrillators. **Kardiol Pol.** Oct 2008;66(10):1050-1058; discussion 1059-1060.
- **40.** Friedmann E, Thomas SA, Inguito P, et al. Quality of life and psychological status of patients with implantable cardioverter defibrillators. **J Interv Card Electrophysiol.** Oct 2006;17(1):65-72.
- **41.** Carroll DL, Hamilton GA. Quality of life in implanted cardioverter defibrillator recipients: the impact of a device shock. **Heart Lung.** May-Jun 2005;34(3):169-178
- 42. Schaffer R. ICD therapy: The patient' perspective. AJN. 2002;102(2):46-49.
- **43.** Thomas SA, Friedmann E, Kelley FJ. Living with an implantable cardioverter-defibrillator: a review of the current literature related to psychosocial factors. **AACN Clin Issues.** Feb 2001;12(1):156-163.
- **44.** May CD, Smith PR, Murdock CJ, Davis MJ. The impact of the implantable cardioverter defibrillator on quality-of-life. **Pacing Clin Electrophysiol.** Jul 1995;18(7):1411-1418.
- **45.** Bainger EM, Fernsler JI. Perceived quality of life before and after implantation of an internal cardioverter defibrillator. **Am J Crit Care.** Jan 1995;4(1):36-43.
- **46.** Sears SF, Todaro JF, Urizar G, et al. Assessing the psychosocial impact of the ICD: a national survey of implantable cardioverter defibrillator health care providers. **Pacing Clin Electrophysiol.** Jun 2000;23(6):939-945.
- **47.** Sowell LV, Sears SF, Jr., Walker RL, Kuhl EA, Conti JB. Anxiety and marital adjustment in patients with implantable cardioverter defibrillator and their spouses. **J Cardiopulm Rehabil Prev.** Jan-Feb 2007;27(1):46-49.

- **48.** Bilge AK, Ozben B, Demircan S, Cinar M, Yilmaz E, Adalet K. Depression and anxiety status of patients with implantable cardioverter defibrillator and precipitating factors. **Pacing Clin Electrophysiol.** Jun 2006;29(6):619-626.
- **49.** Rosenqvist M, Beyer T, Block M, den Dulk K, Minten J, Lindemans F. Adverse events with transvenous implantable cardioverter-defibrillators: a prospective multicenter study. European 7219 Jewel ICD investigators. **Circulation.** Aug 18 1998;98(7):663-670.
- **50.** Glikson M, Friedman PA. The implantable cardioverter defibrillator. **Lancet.** Apr 7 2001;357(9262):1107-1117.
- 51. Drysdale EE, Grubb NR, Fox KA, O'Carroll RE. Chronicity of memory impairment in long-term out-of-hospital cardiac arrest survivors. **Resuscitation.** Sep 2000;47(1):27-32.
- **52.** Suave M. Long-term physical functioning and psychological adjustment in survivors of sudden cardiac death. **Heart Lung.** 1995;24:133-144.
- 53. James J. Caring for patients with an automatic internal cardioverter defibrillator. Coronary Health Care. 1999;3:25-31.
- **54.** Albarran JW, Tagney J, James J. Partners of ICD patients an exploratory study of their experiences. **Eur J Cardiovasc Nurs.** Sep 2004;3(3):201-210.
- **55.** White MM. Psychosocial impact of the implantable cardioverter defibrillator: nursing implications. **J Cardiovasc Nurs.** Apr 2002;16(3):53-61.
- 56. Eckert M, Jones T. How does an implantable cardioverter defibrillator (ICD) affect the lives of patients and their families? Int J Nurs Pract. Jun 2002;8(3):152-157.
- 57. Pedersen S, Erdman R, Jordaens L, Son Jv, Berg Mvd, Theuns D. Increased anxiety in partners with a Cardioverter-Defibrillator: The role of indication for ICD therapy, shocks and personality. **Pace**. 2009;32:184-192.
- **58.** Carroll DL, Hamilton GA, McGovern BA. Changes in health status and quality of life and the impact of uncertainty in patients who survive life-threatening arrhythmias. **Heart Lung.** Jul-Aug 1999;28(4):251-260.
- **59.** Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. In: Association TCCotNYH, ed. 7th ed. Boston: Little Brown; 1994.
- **60.** Kroksmark T. Fenomenografisk didaktik- en didaktisk möjlighet. **Didaktisk tidskrift.** 2007;17(No 2-3):31.
- 61. Svensson L. Theoretical foundations of phenomenography. **Higher Education Research & Development.** 1997;16(2):159-171.
- **62.** Wenestam C-G. The phenomenographic method in health research. In: Hildingh BFC, ed. **Qualitative Research Methods in the Service of Health**. Stockholm: Studentlitteratur; 2000:97-111.
- **63.** Marton F. Phenomenography describing conceptions of the world around us. **Instructional Science.** 1981:10:177-200.
- **64.** Sjostrom B, Dahlgren LO. Applying phenomenography in nursing research. **J Adv Nurs.** Nov 2002;40(3):339-345.
- **65.** Marton F, Booth S. **Om lärande**. Lund: Studentlitteratur; 2000.
- **66.** Mishel MH. The Measurement of Uncertainty in Illness. **Nursing Research.** 1981;30(5):258-263.
- Mishel M. Uncertainty in chronic illness Annual Rev Nursing Research. 1999;17:269-294.

- **68.** Hallberg LR-M, Erlandsson SI-E. Validation of a Swedish Version of the Michel Uncertainty in Illness scale. **Scholarly Inquiry for Nursing Practice: An International Journal.** 1991;5(1):57-71.
- **69.** Ferrans CE, Powers MJ. Psychometric assessment of the Quality of Life Index. **Res Nurs Health.** Feb 1992;15(1):29-38.
- **70.** Ferrans CE. Ferrans and Powers Quality of Life Index (QLI). Available at: www.uic.edu/orgs/qli. Accessed 0909, 2009.
- 71. Gustafsson G. *Quality of Life and Functional Capacity among Elderly with Locomotor Disability*. Linköping: Faculty of Health Sciences, Linköping University; 1996.
- **72.** Stromberg A, Martensson J, Fridlund B, Dahlstrom U. Nurse-led heart failure clinics in Sweden. **Eur J Heart Fail.** Jan 2001;3(1):139-144.
- **73.** Jaarsma T, Stromberg A, De Geest S, et al. Heart failure management programmes in Europe. **Eur J Cardiovasc Nurs.** Sep 2006;5(3):197-205.
- 74. Burns N, Grove S. The practice of nursing research: conduct, critique and utilisation. Philadelphia: WB Saunders; 2002.
- **75.** Dahlgren LO, Fallsberg M. Phenomenography as a Qualitative Approach in Social Pharmacy Research. **J Soc Admin Pharm.** 1991;8(4):150-156.
- **76.** Berg B. **Qualitative research methods for the social sciences.** Vol 3. Boston: Allyn and Bacon; 2004.
- 77. Hsieh H-F, Shannon S. Three approaches to qualitative content analysis. Oualitative Health Research. 2005:15:1277-1288.
- **78.** Association TWM. Declaration of Helsinki. *The World Medical Association* (*WMA*). Available at: http://www.wma.net/e/policy/b3.htm. Accessed 2009-08-30, 2009
- Patton M. Qualitative Research & Evaluation Methods. London: Sage Publications Ltd; 2002.
- **80.** Nilstun T. Paradigms and critical communication. **Scand J Caring Sci.** 1995;9(4):193-194.
- **81.** Ferrans CE, Powers MJ. Quality of life index: development and psychometric properties. **ANS Adv Nurs Sci.** Oct 1985;8(1):15-24.
- **82.** Larsson J, Holmström I. Phenomenographic or phenomenological analysis: does it matter? Examples from a study on anaesthesiologists' work. **International Journal of Qualitative Studies on Health and Well-being.** 2007;2:55-64.
- 83. Schumacher KL, Meleis AI. Transitions: a central concept in nursing. Image J Nurs Sch. Summer 1994;26(2):119-127.
- **84.** Grace SL, Abbey SE, Shnek ZM, Irvine J, Franche RL, Stewart DE. Cardiac rehabilitation I: review of psychosocial factors. **Gen Hosp Psychiatry.** May-Jun 2002;24(3):121-126.
- 85. Burke LJ. Securing life through technology acceptance: the first six months after transvenous internal cardioverter defibrillator implantation. **Heart Lung.** Sep-Oct 1996;25(5):352-366.
- **86.** Hildingh C, Fridlund B, Segesten K. Social support in self-help groups, as experienced by persons having coronary heart disease and their next of kin. **Int J Nurs Stud.** Jun 1995;32(3):224-232.
- **87.** Luderitz B, Wolpert C. The patient's informed consent for pacemakers and ICD implantation: how to write and how to explain it. **Z Kardiol.** May 2003;92(5):377-383.

- **88.** Sossong A. Living with an implantable cardioverter defibrillator: patient outcomes and the nurse's role. **J Cardiovasc Nurs.** Mar-Apr 2007;22(2):99-104.
- **89.** Dougherty CM, Lewis FM, Thompson EA, Baer JD, Kim W. Short-term efficacy of a telephone intervention by expert nurses after an implantable cardioverter defibrillator. **Pacing Clin Electrophysiol.** Dec 2004;27(12):1594-1602.
- **90.** Lewin RJ, Coulton S, Frizelle DJ, Kaye G, Cox H. A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions. **Heart.** Jan 2009;95(1):63-69.
- **91.** Crossmann A, Pauli P, Dengler W, Kuhlkamp V, Wiedemann G. Stability and cause of anxiety in patients with an implantable cardioverter-defibrillator: a longitudinal two-year follow-up. **Heart Lung.** Mar-Apr 2007;36(2):87-95.
- **92.** Kohn CS, Petrucci RJ, Baessler C, Soto DM, Movsowitz C. The effect of psychological intervention on patients' long-term adjustment to the ICD: a prospective study. **Pacing Clin Electrophysiol.** Apr 2000;23(4 Pt 1):450-456.
- 93. Sears SE, Jr., Conti JB. Understanding implantable cardioverter defibrillator shocks and storms: medical and psychosocial considerations for research and clinical care. Clin Cardiol. Mar 2003;26(3):107-111.
- 94. Myers GM, James GD. Social support, anxiety, and support group participation in patients with an implantable cardioverter defibrillator. **Prog Cardiovasc Nurs.** Fall 2008;23(4):160-167.
- 95. Flemme I. Living with life-saving technology. Long-term follow up of recipients with implantable cardioverter defibrillator. Linköping: Division of Nursing Science, Department of Medical and Health Sciences, Linköping University; 2009.
- **96.** Mauro AM. Uncertainty as a predictor of adjustment to an implantable cardioverter defibrillator. **Prog Cardiovasc Nurs.** Fall 2008;23(4):151-159.
- **97.** Dougherty CM. Psychological reactions and family adjustment in shock versus no shock groups after implantation of internal cardioverter defibrillator. **Heart Lung.** Jul-Aug 1995;24(4):281-291.