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Health-related quality of life in patients with pacemakers

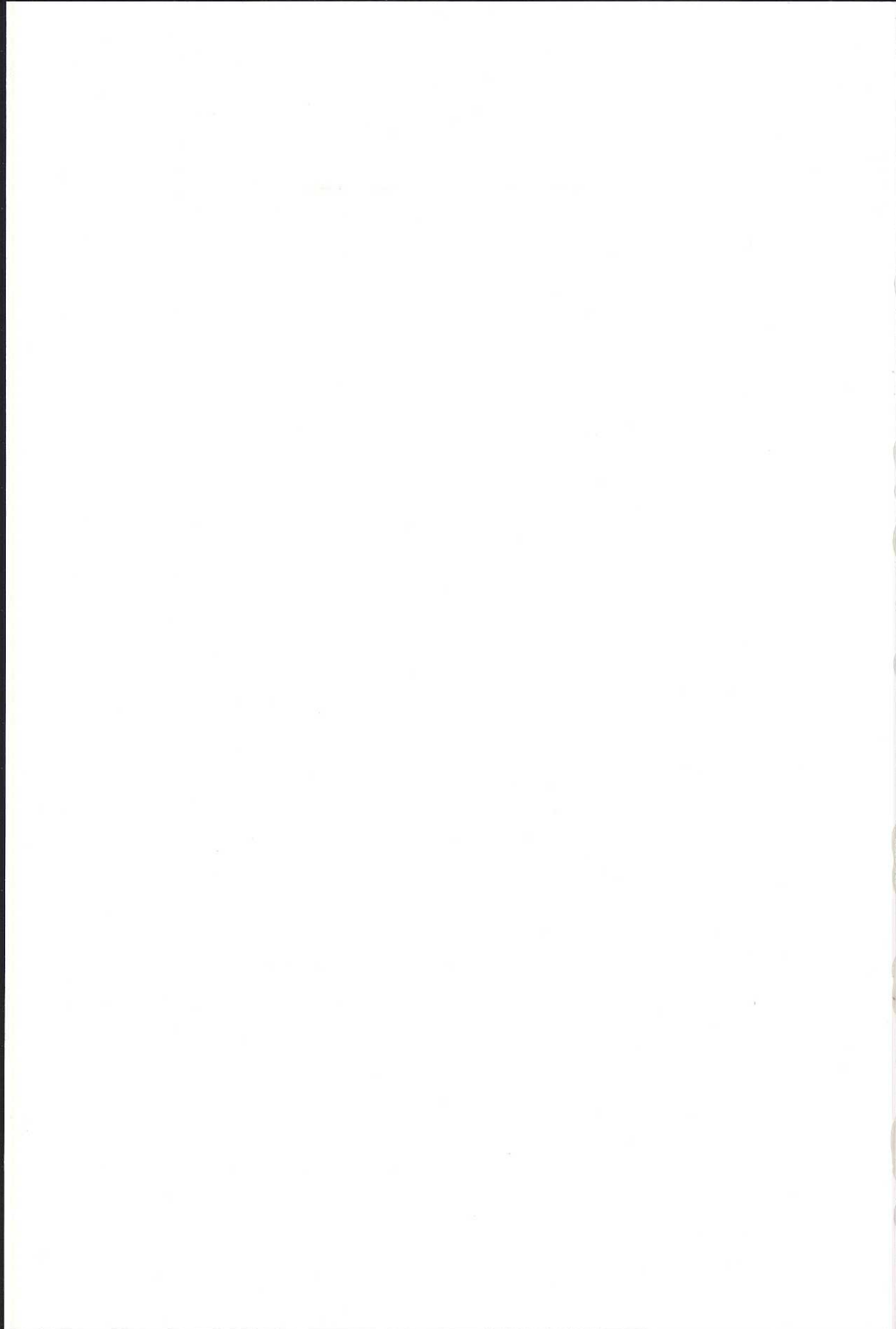


a descriptive and experimental study

DAN MALM



GÖTEBORG 2005



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Dan Malm

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- I D. Malm, J.-E. Karlsson, B. Fridlund.
Quality of life in pacemaker patients from a nursing perspective. *Coronary Health Care* 1998;(2):17-27.
- II D. Malm, E. Svensson, J.-E. Karlsson, B. Fridlund.
Health-related quality of life in pacemaker patients: a single and multidimensional self-rated health comparison study. *European Journal of Cardiovascular Nursing* 2003;(2):291-302.
- III D. Malm, L. R.-M. Hallberg.
Patients' experiences of daily living with a pacemaker. A grounded theory study. *Journal of Health Psychology* 2004; (accepted)
- IV D. Malm, J.-E. Karlsson, B. Fridlund
Patients with pacemaker: effects of a self-care program on the health related quality of life of pacemaker patients: a nursing intervention study. *Journal of Cardiovascular Nursing* 2004; (accepted)

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ABSTRACT

The general aim of this thesis was to describe and evaluate the health-related quality of life (HRQoL) of patients with pacemakers, as well as to determine the effects of a nurse-led intervention regarding health-related quality of life in the form of a self-care program for these patients. Descriptive designs were used to describe (I) quality of life (n=182) as well as (II) HRQoL (n=697) of pacemaker patients based on a nursing perspective. In order to describe the life situation of these patients from a deeper perspective (III) and examine the experiences of daily living with a pacemaker, patients (n=13) were interviewed and data were analyzed according to the grounded theory method, using constant comparative analysis. Finally (IV), 212 patients from three hospitals were allocated, using an experimental, multi-center, randomized design, to either a control (n=115) or an experimental group (n=97) to evaluate the effects of a nurse-led intervention, a 10-month self-care program, on the HRQoL of patients with pacemakers.

The total QoL for patients with pacemakers was acceptable. Through application of Orem's self-care theory, information, support and education can be provided in such a way that nursing care affects the entire QoL of patients with pacemakers. Measures should be taken on behalf women, those living alone, the elderly, blue-collar workers and retired persons, all of whom have a lower QoL (I, II). Experiences of daily living with a pacemaker generally indicate that patients with pacemakers can attain emotional stability and social participation under the condition that there is understanding, empathetic treatment and insight concerning the patient's new situation (III). There were no significant differences in HRQoL when comparisons were made between the experimental and the control group. Two main findings for patients in the self-care program (experimental group) were: a significantly better HRQoL in terms of experiencing the symptoms that were the reason for pacemaker implantation as having decreased or disappeared, and a higher level of perceived exertion in a 1 1/2-minute stair test compared with patients who had standard checkups (control group) (IV).

In order to increase the HRQoL of patients with pacemakers it is important that health care professionals support the patient in a kind and professional manner by providing clear, relevant information, and by planning a self-care program based on a nursing assessment of the patient's needs using a comprehensive approach.

Keywords: caring, elderly, gender, health-related quality of life, intervention, pacemaker population, patient education, self-care.

From the Department of Primary Health Care,
Göteborg University, Göteborg, Sweden

**Health-related quality of life
in patients with pacemakers**
a descriptive and experimental study

Dan Malm



Göteborg 2005

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Department of Primary Health Care
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ORIGINAL PAPERS

This thesis is based on the following original articles, which are referred to in the text by their Roman numerals.

- I D. Malm, J.-E. Karlsson, B. Fridlund.
Quality of life in pacemaker patients from a nursing perspective. *Coronary Health Care* 1998;(2):17-27.
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*Today, you don't think of a pacemaker
implantation as something sensational.
Well, ladies and gentlemen, then you
are all wrong. It is still a sensation
– for the patient.*

Arne Larsson, 2000

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ABBREVIATIONS

| | |
|-----------------|--|
| AAI/ R | Atrial rate adaptive pacemaker with rate response |
| AF | Atrial fibrillation |
| AV-block | Atrioventricular block |
| CVDs | Cardiovascular diseases |
| DDD/R | Atrioventricular synchronous pacemaker with rate response |
| EQ-5D | Euro-QoL questionnaire |
| HRQoL | Health-related quality of life |
| ICD | Implantable cardioverter defibrillator |
| LPQ | Living with a Pacemaker Questionnaire |
| Mode | Ventricular, atrial or atrioventricular pacing |
| PGC-MAI | Philadelphia Geriatric Center Multilevel Assessment Instrument |
| PWBG | The Psychological General Well-being Scale |
| QLI | Quality of Life Index-Cardiac III Version |
| QLPMQ | Quality of Life Pacemaker Questionnaire |
| QoL | Quality of life |
| SCOP | The subjective consequences of pacemaker therapy |
| SND | Sinus node disease |
| SRH | Self-rated health |
| VVI/R | Ventricular rate adaptive pacemaker with rate response |

INTRODUCTION

The pioneering devices of the 1960s were crude asynchronous pacemakers developed to treat life-threatening episodes of asystole in patients with complete heart block. The relatively unsophisticated, asynchronous ventricular pacing (VOO-mode) was certainly more physiologic than the alternative, which was no pacing at all. However, the expanding technology of pacemakers and the therapeutic modes available have extended modern goals of pacemaker treatment to include prevention of cardiac arrhythmias, restoration of optimal hemodynamic function and enhancement of exercise potential and quality of life (QoL)¹. The subsequent introduction of atrioventricular synchronous pacemakers (AAI and DDD-mode) and ventricular rate adaptive pacemakers (VVIR-mode) has resulted in improved hemodynamics and maximal exercise capacity compared to earlier fixed rate pacemakers (VVIC-mode)^{2,5}. In recent years the advantages of increasingly advanced pacemaker systems have been questioned in relation to expected health-related quality of life (HRQoL) for the often older patient and the costs involved in the increasingly high level of technology related to treatment. Further, several large studies comparing atrial based pacing with ventricular pacing have been completed. They show a significant decrease in the development of atrial fibrillation (AF)^{2, 6-8}, and reductions in mortality, stroke, and congestive heart failure with atrial pacing^{6,9}. QoL research is increasingly being considered as an important complement to the prevailing biomedical assessments of different treatment effects. This is because it is misleading only to use biologically defined variables to measure the effects of a treatment, since the treatment not only concerns survival, but also its conditions. There is a great deal of knowledge available today about the technical performance of pacemakers and the biophysical life of patients with pacemakers¹⁰, but more information is needed regarding the experiences of these patients themselves concerning different ways to improve their QoL¹¹.

From a nursing standpoint there are also other approaches to improve HRQoL, such as a self-care program with more in-depth patient education about the new situation as a pacemaker patient. It was found that the time in hospital (often a 24-hour period) was felt to be too short and that the information patients received was scanty or difficult to understand¹². But if nurses include the patient in a self-care program in the hospital, health care professionals can support the patient in a professional manner by providing clear, relevant information, and planning a self-care program based on the nurse's assessment of the patient's needs^{13,14}.

BACKGROUND

Core concepts

When an individual, usually elderly, faints because the conduction system of the heart is not working properly, and is then admitted to the hospital on an acute basis, the situation can be experienced as unmanageable. Treatment starts immediately with implantation of a pacemaker system, and this treatment is lifelong (Figure 1). In order for the acute as well as the future situation to be manageable, the patient should receive basic education in which pacemaker education is included. To prevent inadequate self-care, staff members caring for these patients should be familiar with how the patient experiences his or her own QoL, particularly HRQoL. In order to better understand the psychosocial situation of the patient and family, HRQoL should be measured. In that way a foundation for care is established based on the patient's perception of the nursing care that is needed, inadequate self-care is minimized, and prerequisites for good self-care are established.

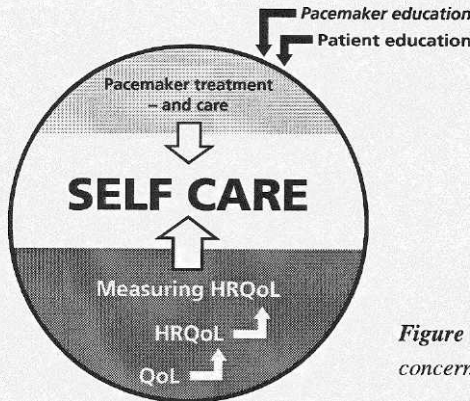


Figure 1. Conceptual line of reasoning concerning pacemaker treatment and care.

Pacemaker treatment and care

There are about 3 million people worldwide with pacemakers, and each year 500 000 pacemakers are implanted. With rare exception, implantation of a pacemaker does not change the recipient's activities or lifestyle. Although most people who receive pacemakers are aged 60 years or older, people of any age, even children, may need pacemakers¹⁵. During the last 30 years the number of pacemaker implantations in Sweden increased from approximately 100/million inhabitants to 470/million inhabitants (1999), and today (2004) there are 28 000 individuals with pacemakers¹⁶. In Western Europe, 394 pacemakers / million inhabitants are implanted as compared with 198 / million in Eastern Europe. The difference is due to the fact that the number of implantations is significantly correlated with the number of pacemaker centers per million inhabitants¹⁷.

It is estimated that 70 to 80% of all pacemakers are implanted in patients 65 years of age or older, which can be attributed to increased abnormalities in impulse generation and conduction with advancing age¹⁸. The primary goal of

pacemaker therapy other than survival is to improve how patients feel and function in their daily lives. The indication for pacemaker treatment during the 1950s and early 1960s was fainting associated with a slow heart rhythm, while today there are additional indications for implantation of pacemakers and implantable cardioverter defibrillators (ICD) ¹⁹. In 1974 an international generic code was developed to standardize the way in which pacemakers could be described. Initially there were three categories, but following the development of programmable devices this was expanded to five in 1985 ²⁰. The five categories are: chamber paced; chamber sensed, response to sensing, programmable features and antitachyarrhythmia functions. The code positions are arranged in sequence, I, II, III, IV and V across the top. Underneath, code letters describe a function or characteristic. Only one letter is possible for each position (Figure 2).

| Position | I | II | III | IV | V |
|-----------------|--|--|---|---|---|
| Category | Chambers Paced | Chambers Sensed | Response to Sensing | Programmability, Rate Modulation | Antitachyarrhythmia Functions |
| Letters | O = None A = Atrium V = Ventricle D = Dual (A + V) | O = None A = Atrium V = Ventricle D = Dual (A + V) | O = None T = Triggered I = Inhibited D = Dual (T + I) | O = None P = Simple Programmable M = Multi Programmable C = Communicating R = Rate Modulation | O = None P = Pacing (Antitachyarrhythmia) S = Shock D = Dual (P+S) |

Figure 2. The identification code of the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG) ²⁰.

The survival rates of patients with bradyarrhythmias were radically altered by the arrival of pacemaker technology. The first pacemakers were single-chamber, fixed-rate devices, which could not sense the intrinsic electrical activity of the heart. Pacemaker implantation was a major operation requiring left anterior thoracotomy to expose the myocardium ²¹. The past 40 years have seen dramatic strides in the treatment of patients needing pacemaker implantation. Demand devices, batteries which allow the pulse generator to be sealed, and a decrease in the size of the batteries have all changed patient outcomes for the better. The decreased size of the pulse generator made pectoral implants possible, and the devices are inserted almost exclusively under local anaesthetic. Today the weight of the pulse generator varies depending on the manufacturer, but it is usually between 25 and 35 g and is 0.5 cm thick. The battery lasts 8-12 years depending on use ¹.

As pacemaker technology has become increasingly sophisticated in an attempt to mimic normal cardiac physiology, more physiologic pacing is being developed to enable application of pacemaker technology to problems other than symptomatic bradycardia. Included here are pacing to prevent atrial arrhythmias,

to improve haemodynamic function and symptoms in patients with hypertrophic or dilated cardiomyopathy, and to prevent neurocardiogenic syncope. Thus, much of the interest in modern pacemakers concerns indications other than primary bradycardia. Atrial arrhythmias and in particular atrial fibrillation (AF) are common in patients with SND and constitute one of the most common indications for permanent pacing. Early retrospective studies showed a major reduction in the incidence of AF with atrial based pacing (AAI or DDD modes) as compared with VVI pacing alone^{5, 6, 22}. Traditionally, atrial leads were positioned in the right appendage for stability. Today, with the development of active fixation, leads can be positioned virtually anywhere in the atrium. Misier and colleagues²³ studied the role of multisite pacing and showed that overdrive pacing with simultaneous stimulation reduced the frequency of arrhythmia compared with single site pacing²³.

In contrast to the generally disappointing results of right ventricular pacing in congestive heart failure, biventricular based pacing has emerged as an exciting new approach. Mortensen et al²⁴ were unable to demonstrate significant clinical improvement based on NYHA functional class over a 3-month follow-up period in a group of 189 patients with NYHA functional class III or IV heart failure²⁴. Interest in permanent pacing for the treatment of hypertrophic cardiomyopathy began in the 1970s following several case reports and small series demonstrating symptomatic improvement in those patients with outflow tract obstruction. More recently, several double blind randomized trials of pacing in hypertrophic cardiomyopathy have been completed. Unfortunately, the results of these trials have been largely disappointing, as there were no significant differences in the functional parameters measured or in QoL^{25, 26}. One explanation for the difficulty in measuring QoL in this very ill patient group can be the patient's expectations concerning improvement in connection with the interventions. This is in accord with a study on patients who underwent DDD pacemaker implantation, but with programming to a non-pacing mode; despite the lack of pacing, most QoL parameters improved. Similarly, a potent placebo effect has been reported in this population following implantation of a device²⁷.

Vasovagal or neurocardiogenic syncope is a common benign condition. Various medications have been studied with the aim of reducing event-rates and improving QoL. Results have been mixed, with few drugs demonstrating any benefit. Bradycardia usually accompanies vasovagal syncope during positive tilt table tests, and is recorded in up to 50% of clinical syncopal spells documented on electrocardiographic loop recorders. Pacing has been considered in these patients as a result of logical, observational studies. A randomized and double-blinded study, VPS II²⁸, was recently published, and the results undermine the findings of these preceding studies: the cumulative risk of syncope at 6 months was 40% for the control group and 31% for the actively paced group, and despite a 30% trend towards reduced syncope in patients with active pacing the results were not statistically significant²⁸. This left clinicians with a dilemma: whether

or not to pace in patients with disabling syncope despite conservative therapy. Future clinical trials of therapies for vasovagal syncope should be randomized and placebo-controlled²⁹. Due to continuously more advanced pacemaker technology, training and continued education for staff involved in pacemaker care is required to enable them to provide continuing education and information to these patients.

Patient education

Patient education can be defined as the process of influencing behaviour by producing changes in knowledge, attitudes, and skills required to maintain and improve HRQoL. The process may begin with the imparting of information, but it also includes interpretation and integration of information in order to bring about attitudinal or behavioral changes of benefit to a person's health status¹². Patient education and support are essential for enhancing self-care abilities and should be defined as all the educational activities directed to patients, including therapeutic aspects, health education and clinical health promotion³⁰. The nursing profession embraces the provision of education and information to patients and relatives as a central factor in the nursing process and as a dimension of nursing practice. In accordance with the Swedish Health and Medical Services Act, SFS.1982: 763, health care has the obligation to plan care together with the patient, but strategies regarding how knowledge should be conveyed to the patient and family are unclear³¹. According to Rankin¹², recent theories concerning new knowledge indicate that analysis and interpretation take place based on the recipient's earlier life experiences¹². This means that to a great extent education is dependent on and should be fashioned according to the patient's frame of reference, for example sex, age, educational background and social network, etc.³².

To enable the patient to take in what is taught, educational efforts should take place in the right way, at the right level and on the right occasion. This can mean that since hospital stays for acute cardiac events like pacemaker implantation are now so much shorter than in previous years, it may be more logical to institute programs on both an inpatient and an outpatient basis¹². As a comprehensive perspective is used in teaching older patients³³, nurses may need to take more time in teaching these patients and, for example, present information more slowly than usual and use a lower tone of voice¹². Educational material should be delivered in small increments, so that the material can be integrated into the patient's life situation¹². This also means that it should be possible for the person with whom the patient shares his or her life, or a close relative, to get the same information as the patient and thereby be able to provide support and in that way increase the patient's possibility for good self-care. The goal of patient education and counseling is to address self-rated skills, to teach the patient to recognize problems, and to help the patient and relative develop decision-making skills.

Pacemaker education

More than any other human organ, the heart is symbolically charged with emotions. Introducing a foreign body into the heart, even a pacemaker, could be expected to alter, if not damage, the most intimate of personal attributes, the individual's personality. Nevertheless, standard measures of emotions administered before and after pacemaker implantation revealed an improvement in psychological well-being³⁴. For some people an implanted mechanical device such as a cardiac pacemaker is readily accepted; for others it may be seen as an encroachment³⁵. Education for the patient with a newly implanted pacemaker system is intended to help the person understand that the symptoms (dizziness, fainting) that resulted in pacemaker implantation will cease, and to promote an active lifestyle. Therefore, before hospital discharge the patient will need to know both how to take his/her pulse and the base frequency at which the pacemaker is programmed in order to make sure the pacemaker is functioning correctly. The risks of electromagnetic interference, which can readjust pacemaker settings, must also be explained³⁶. Information should also be given concerning care of the operative site, when follow-up visits are planned, and the patient should be encouraged to live as actively as before pacemaker implantation, and should be told how to reach staff at the pacemaker clinic if questions arise³⁷. Earlier studies have shown that cardiac patients receive adequate education and preparation regarding return to activities, but not with respect to emotional reactions to surgery and effects on social functioning³⁸. An important aspect of the staff's supportive and educational functions also includes knowledge about the psychosocial life situation of the patients with pacemakers. Therefore the goals of education should include an evaluation of what the patient has learned, its usefulness, and the ease with which the patient has incorporated it into self-care practices.

Self-care

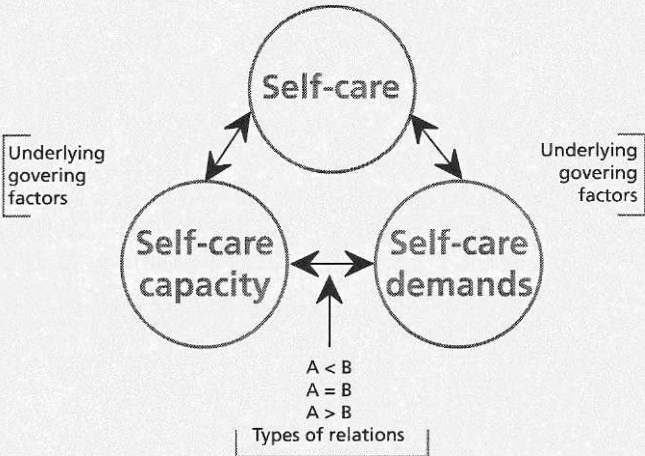
Using nursing theory to structure nursing care in a comprehensive, consistent and systematic way has considerable potential for improving the quality of care³⁹. Self-care activity is a learned and goal-centred activity, and persons who can carry out effective self-care have knowledge about their surroundings and themselves. If a person is incapable of meeting a new situation involving a deterioration in health, then a self-care deficit exists⁴⁰.

Orem defines self-care as "activities individuals initiate and carry out with the aim of maintaining life, health and well-being"⁴¹. It can unfortunately be difficult to combine an abstract nursing theory with practical nursing care. But it is important for the nurse to support, guide and educate patients with the goal of enabling them to carry out self-care in the situation in which they find themselves. Orem's nursing care model⁴¹ can be of use, as it is possible to apply the ideas of self-care to patients' experiences of their QoL⁴¹. The effects of applying Orem's self-care model were shown to distinguish between nurses with respect to evaluations of and establishment of nursing goals⁴². Campbell⁴³

demonstrated both a direct effect of abuse on health, and an indirect effect mediated through self-care agency as a protective factor when the major independent variables were the physical and emotional health of American women ⁴³. An extensive review of how Orem's self-care theory is used and how it functions comprised studies where self-care deficit nursing theory was used. There was a preponderance of descriptive studies, ranging from those using a simple descriptive correlational approach to those with a multivariate approach. Fewer than half made clear connections between the variables being examined and situations in nursing practice; in other words, they examined elements of the theory of self-care without making the link to nursing practice an explicit part of the study ³⁹. While this work increases our knowledge about self-care, further studies are needed in order to place the findings in the context of nursing practice. Most of the studies provided an enhanced or broader description of an element or component of the theory by empirically describing the relationships between or among age, gender, self-care actions, disease, and so forth. Most of them examined self-care and/or self-care deficits. While there are many studies, there is little evidence that sustained research programs are developing and expanding the theory ³⁹.

If patients with pacemakers are to practice self-care, there must be a balance between the requirement to understand and the possibility of feeling secure about the function of the pacemaker. If this feeling of security is lacking and the person is fearful about the pacemaker's activity, then a self-care deficit arises. Self-care deficit is a patient-centered concept that describes a qualitative and quantitative relation between two concepts, namely self-care capacity and self-care demand, where there can be three kinds of relations: greater than ($A > B$), the same as ($A = B$), or less than/inadequate ($A < B$) ⁴⁴ (Figure 3). When the patient cannot deal with his or her situation, anxiety and worry arise and can lead to depression and loneliness, with loss of a feeling of belonging ¹².

Figure 3. The three types of relations between self-care capacity and self-care demands. Source: Orem 1991, p 146. Reproduced with permission from Rooke and Student-litteratur ⁴⁴.



The basis of Orem's nursing theory ^{40,41} is the individual's ability to choose and to take responsibility for his/her own survival and well-being. In order to use this ability the individual needs continual stimulation both for himself/herself and those close to him/her in order to function according to his/her prerequisites. The goal of the activities the individual carries out is to maintain HRQoL. This is the core of Orem's theory and it is called self-care. In addition to the influence of sex, age and health status on the individual's self-care ability, Orem stipulated seven underlying governing factors regarding the individual: developmental status, sociocultural orientation, family factors, accessible health care resources, lifestyle, environmental factors and other resources, and capacity.

Nursing needs, which can change, are divided into three systems; ^{40, 41} 1. The totally compensating system, which means that the patient needs the nurse's help with everything in order to compensate for the inability to carry out self-care. An example would be the preoperative phase of pacemaker implantation when arrhythmias can affect the patient's mental function; 2. The partially compensating system, which means that both the nurse and the patient take part in the care together. The nurse initially carries out the care, but little by little the nurse provides assistance only with what the patient cannot do himself/herself. An example is the situation following surgical implantation of a pacemaker; 3. The supporting and educating system, which means that the patient learns to confront his/her needs and take responsibility for his/her care. At the beginning of treatment the nurse participates as teacher and supervisor, and there after as advisor. The nursing needs can change in the different stages from the totally via the partially compensatory system, to the supporting and educating system. The nurse's goal of providing the patient with the possibility of practising self-care is attained through guidance and support in situations involving choice, by providing conditions for promoting the patient's living environment, and by giving instruction in a sensitive manner. The majority of patients with pacemakers only need several of these types of support. As is the case with the other systems, the supporting and educating function is based on integrity, empathy, respect and sensitivity on the part of the nurse when caring for the patient, who is often elderly ⁴⁰⁻⁴³.

Given the relatively short history of nursing research and, more importantly, the conduct of nursing theory-based research, the amount and the quality of the work being carried out is quite remarkable ⁴⁵. A substantial number of studies have been produced and the quality of this work has improved over time. Orem has provided nurse researchers with a theoretical system comprising an ontological structure, related epistemology, and numerous models that give direction to scholarly efforts. Researchers using this theoretical system would be well-advised to use these in conceptualizing and interpreting their work ⁴⁶.

Choosing a nursing theory perspective also means that additional factors concerning quality of life are attributed to the patient in order to measure his/her HRQoL as completely as possible. Orem's nursing model ⁴⁰ can be utilised for patients with pacemakers, as the idea of self-care can be applied to their evaluation of their HRQoL ⁴⁰.

Quality of life

Quality of life is a broad, multidimensional concept that can cover many different aspects of people's lives. The term as it is often used offers hope and meaning but lacks focus and precision. The lack of clarity can be somewhat reduced if it is kept in mind that QoL can be considered on three different levels: a general evaluation where the patient estimates his/her own QoL; different dimensions or areas of QoL; and components of the different dimensions ⁴⁷.

In recent years some agreement has been reached in the area of medical research concerning which areas are of central importance for QoL. There are no obvious terms that should be used, but the areas concerned are: physical and occupational functions; mental functions; social functions; and somatic sensations ⁴⁸.

QoL is something that, like money, can be possessed by the individual in large or small amounts. The healthy individual always has a certain QoL, but the amount varies for different persons. When illness occurs this QoL is partially or completely lost. Under such conditions the task of health care is to restore the patient's original quality of life by means of appropriate medical treatment and other measures. To obtain knowledge about whether health care professionals have succeeded in doing this, the patient's QoL must be measured before and after the treatment in question.

In order to successfully measure how the patient experiences his/her QoL, health care professionals must have in-depth knowledge concerning the specific illness for which the patient is being treated. According to Wenger et al ⁴⁷, QoL in patients with cardiovascular diseases encompasses three areas. The first is functional ability, with five subgroups: daily routines, social activity, intellectual- and emotional function, and finances. The second area, experienced capability, concerns those changes the patient experiences as important in regard to health, well-being, and life satisfaction. The third area consists of symptoms, and comprises changes and impairments caused by events the patient experiences in relation to the disease such as hospitalizations, pain, respiratory problems, medication changes, and impairment in physical ability ⁴⁷.

Health-related quality of life

Over the past 30 years health-related quality of life (HRQoL) has been assessed by experts in the field of quality of life with varying viewpoints on how to define the concept. During this period a number of definitions have emerged, many based on the earlier definitions of QoL, as well as narrower definitions more specific to HRQoL ⁴⁹. Since the definitions vary depending on the aims of the studies, the goal cannot be to find a fixed definition ⁵⁰. Although there has been some debate regarding how to define HRQoL, a recent conference involving an international group of HRQoL investigators reached agreement on the fundamental dimensions essential to any HRQoL assessment ⁴⁹. These primary dimensions include physical functioning, psychological functioning, social

functioning, financial aspects, and the individual's overall life satisfaction and perceptions of his/her health status. The determinants for SRH and HRQoL focus on those domains that are closely related to health and that can be improved or harmed by medical interventions⁴⁹.

Is the idea of what constitutes QoL similar for younger and for older patients? Most conceptual frameworks of HRQoL probably include all domains that are relevant to older adults. Both older adults and younger adults consider these same aspects of HRQoL to be relevant and important. However, definitions of the domains may differ slightly for older patients because of their changing roles and living situation⁵¹. It is important that HRQoL in the elderly is examined with the understanding that the focus cannot be on daily work when most are pensioners. Instead, there should be a broader focus directed toward everyday social activities.

Patients with pacemakers are mainly individuals over the age of 65 with an acceptable QoL, and they are extremely heterogeneous with respect to their health and HRQoL, i.e. more dissimilar than similar⁵². This was also found in the Framingham Disability Study, where a majority of older adults were able to perform a variety of physical functions without help and without difficulty, even in the age category 75 to 84 years⁵³. Pacemaker treatment affects different individuals in different ways. For most of them the effect is positive, and their experience is that having a pacemaker is acceptable⁵⁴. In the search for objectivity health care professionals often try to quantify the degree of HRQoL with physiological tests like the six-minute walk test. Even when these tests are continued to their maximum workload, there is no indication that they correlate well with the patient's capacity during daily life. More subjective assessments are necessary in order to improve our understanding of the full impact of HRQoL on an individual's lifestyle.

Measuring health-related quality of life

There are different instruments, both general and disease-specific, for identifying health, quality of life and well-being. Assessment of HRQoL takes place today primarily in the context of clinical research where there is interest in studying how newly started or ongoing treatments are experienced by the patient. According to Ware⁵⁰, clinical interventions should be evaluated with a disease-specific instrument as well as with a generic instrument (Figure 4). The generic instrument should measure physical function, psychological well-being, and role limitations caused by health, pain, and general health perceptions⁵⁰. Disease-specific instruments are developed for use in particular populations and focus on special health problems and possible treatments. By including only those elements of most importance in the particular clinical situation, these measures can be constructed to include a wide range of effects without imposing a large burden on respondents⁵⁵.

Generic instruments

| | |
|---|-------|
| Sickness Impact Profile ⁵⁶ | SIP |
| Nottingham Health Profile ⁵⁷ | NHP |
| Euro-QoL ⁵⁸ | EQ-5D |

Specific instruments

| | |
|--|-------|
| Quality of life index, cardiac version III ⁵⁹ | QLI |
| Minnesota Living With Heart Failure Questionnaire ⁶⁰ | MLWHF |
| Subjective consequences of permanent pacemaker therapy in patients under the age of retirement ⁶¹ | SCOPE |

Figure 4. Taxonomy of HRQoL assessment measures: categories and examples.

HRQoL focuses on those domains that are more closely related to health and that can be improved or harmed by interventions. Are conceptualizations of these domains in HRQoL that are appropriate for younger populations also appropriate for older persons? Most conceptual frameworks of HRQoL probably include all domains that are of relevance to older individuals ⁵¹. Both older adults as well as younger adults consider the same aspects of HRQoL to be relevant and important. However, definitions of the domains may differ slightly for older persons because of their changing roles and living situations. For example, regarding limitations in usual activities (e.g. role functioning), there would most likely be less focus on problems concerning work and more on problems with a broader variety of daily activities such as volunteer work, social activities, caregiving, and recreational activities ⁵¹.

Patients with pacemakers differ regarding HRQoL depending on their sex, age, physical capacity, symptoms and pacemaker mode. Most elderly individuals today have no handicaps or physical impairment ⁶². However, women and elderly patients with pacemakers assessed their HRQoL as poorer ⁶³, which can be due to less opportunity for an active social life and possibly a poorer financial situation upon retirement. Hildingh et al also pointed out these factors as being partially responsible for a poorer HRQoL ⁶⁴. A number of studies have shown that DDD pacemakers provide better haemodynamics than VVI pacemakers, and give the patient improved physical capacity, thereby also providing an improved HRQoL ^{65,66}. In later studies little or no difference in physical capacity was found between the systems when physical tests were carried out to examine if patients' physical capacity is dependent on their pacemaker system ⁶⁷⁻⁶⁹. This may be because the physical tests used were usually either the six-minute walk test ⁷⁰ or tests where the patient estimates his/her physical capacity without any comparison with attained physical results ⁶⁷. Robbins et al ⁷¹ contend that regular physical activity is necessary for health promotion and disease prevention for all populations ⁷¹. Continued research in this important area of health behavior is

critical to identify the most effective interventions to increase physical activity among diverse populations ⁷². Therefore, maybe stairs test gives truer results, since the stairs test was much more decisive for an elderly but otherwise relatively healthy pacemaker population when physical capacity tested. Return to work may be an important component of health for patients with pacemakers, since the symptoms leading to pacemaker implantation (fainting or severe dizziness) may be an obstacle or even exclude them from the meaningful leisure time and work they have had. However, when patients reported that symptoms leading to pacemaker implantation had disappeared after implantation, the assessments of patients with DDD pacemakers indicated improved HRQoL compared to that of patients with ventricular pacing ⁷³. In contrast to the CTOPP-study ⁶⁷, there were no significant differences in HRQoL between the groups ⁶⁷. This could be due to increased understanding about the symptoms leading to pacemaker implantation obtained through education concerning causes, as well as the association between expected results and the patients' actual situation after pacemaker implantation.

AIMS OF THE THESIS

The general aim of this thesis was to describe quality of life from the perspective of patients with pacemakers, and to evaluate the effects of a nurse-led intervention regarding HRQoL in the form of a self-care program for patients with pacemakers.

The specific aims were to:

- Describe patients with pacemakers' assessments of their QoL in relation to sex, age, civil status and residence. (I)
- Describe a pacemaker populations' HRQoL in general based on the SRH-perspective regarding sociodemographic data, pacemaker mode and symptoms. (II)
- Describe patients' experiences of daily living with a pacemaker. (III)
- Evaluate the effects of a 10-month self-care program with in-depth education on patients with pacemakers and their HRQoL. (IV)

MATERIALS AND METHODS

Design and settings

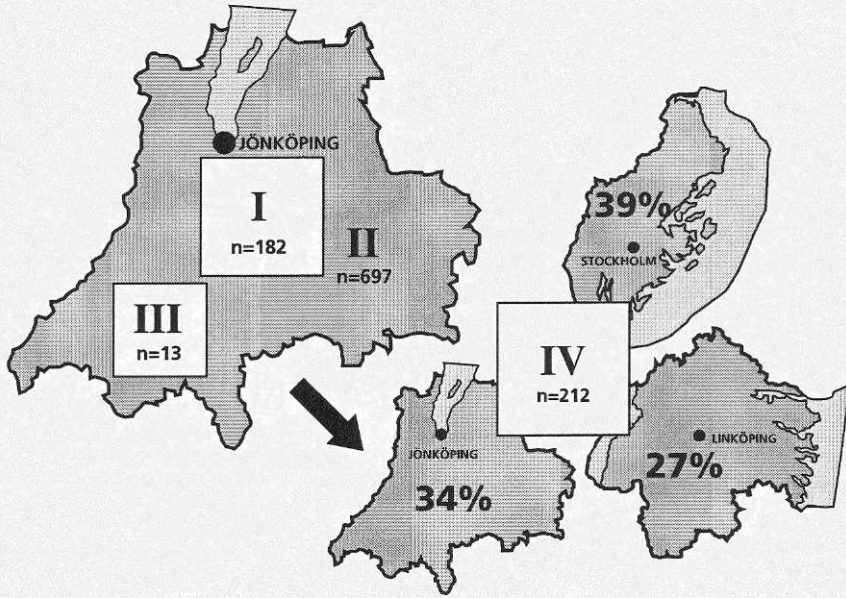


Figure 5 shows an overview of participating patients. A cross-sectional study based on a population of patients with pacemakers in a health care area in southern Sweden was conducted (II). From this population, following random selection of every fourth person in study I and 13 patients from the same population in study III, and 72 (34%) patients from the population were included in study IV. In the multicentre study (IV), 82 (39%) and 58 (27%) of the participating patients, respectively, came from university hospitals in southern and central Sweden.

This thesis had a descriptive and experimental study design comprising both qualitative and quantitative analyses. In the quantitative research, a cross-sectional (I, II) design and a randomized pretest - posttest experimental design (IV) were used. In the qualitative research, a constant comparative analysis with grounded theory (III) was applied (Figure 5, 6).

Patients with pacemakers were included in studies I, II, III and IV if they fulfilled the inclusion criteria of being Swedish speaking and > 18 years of age. The different studies also had specific inclusion criteria.

| | Aim | Design | Data collection | Data analysis |
|------------------|---|---|---|---|
| I. 1998 | To describe how patients with pacemakers assessed their QoL in general and also with respect to sex, age, civil status and occupation | Descriptive, inductive, quantitative | Questionnaires | Quantitative analysis using descriptive statistics by means of cross-tabulation and frequency and analytic statistics using Spearman's rank-order test, p<0.05 considered statistically significant |
| II. 2003 | To describe a pacemaker populations HRQoL in general based on the SRH perspective regarding of sociodemographic data, pacemaker mode and symptoms | Descriptive, inductive, quantitative | Questionnaires | Quantitative analysis using descriptive statistics by means of cross-tabulation and frequency and analytic statistics using Spearman's rank-order correlation coefficient and / or chi-square analysis, p<0.05 considered statistically significant |
| III. 2004 | To describe and generate a theory that can explain experiences of daily living for patients with pacemakers | Descriptive, inductive, constant, comparative | Semi-structured interviews | Qualitative analysis using the constant comparative method in order to generate a theory from a nursing perspective |
| IV. 2004 | To evaluate the effects of a self-care program for patients with pacemakers and their HRQoL: a 10-month randomized follow-up | Deductive, pre-post test, experimental, blinded, randomized | Pre- post test, six-minute walk test and 1½-minute stair test | Quantitative analysis using descriptive statistics by means of cross-tabulation and frequency tables and analytic statistics using the T-test and the Mann-Whitney U-test, p<0.05 considered statistically significant |

Figure 6. An overview of the studies (I-IV) comprising the thesis.

Table 1 Demographic characteristics of the patients in studies I-IV

| | No. of Patients | Mean age (range) | Men (%) | Mode AAI/DDD* VVI** (%) | Education Mean (range) | ECG SND AF Avb (n=) | Living with a partner (%) | Symptoms Gone Part.present Still present (%) |
|------------------|-----------------|------------------|---------|-------------------------|------------------------|---------------------|---------------------------|--|
| Study I | 182 | 77 years (26-95) | 51 | 9 91 | 8 years (6-18) | 91 25 66 | 59 | Not included |
| Study II | 697 | 76 years (18-98) | 51 | 13 87 | Not included | Not included | 61 | 62 31 7 |
| Study III | 13 | 59 years (22-82) | 47 | 61 39 | 11 years (6-20) | 8*** 5 | 77 | Not included |
| Study IV | 212 | 72 years (22-94) | 62 | 71 29 | 10 years (6-22) | 75 44 93 | 74 | 53 38 9 |

* Patients with inhibited pacemakers (AAI/R) were included in the dual-chamber pacing (DDD/R) group. ** Patients with ventricular rate response pacemakers were included in the VVI group, and those with atrial or dual chamber rate response were included in the AAI/DDD group. *** AF were included in SND for study III.

In study I (Table 1), a total of 216 patients with pacemakers were entered through a random selection of every fourth person with a pacemaker in order to obtain a stratified sample of all such patients with pacemakers in the catchment area. After exclusion due to moving (n=2), no interest in participating (n=4), inability to communicate (n=9), and death during the course of the study (n=19), 182 patients participated. The most common reason for pacemaker implantation was fainting due to sick sinus syndrome, resulting in the selection of a ventricular rate response (VVIR) pacemaker system. In study II, a total of 697 patients with pacemakers participated. The sample was the result of a cross-sectional survey of a pacemaker population with 869 patients, and following one reminder 832 patients were included. External exclusions due to no response (n=57) and senility (n=2) gave a dropout rate of 7%. Another 76 patients dropped out (9%) due to internal exclusions including missing data (n=69) and refusing to answer a question (n=7), resulting in a total of 697 participating patients (Table 1). In study III, 13 informants were selected according to the maximum variation sampling technique⁷⁴ (Table 2). The theoretically important variables were sex, age, years as a patient with a pacemaker, pacemaker mode, education, and if the informants lived alone or were cohabiting.

Table 2. Characteristics of the informants (n = 13)

| Age | Sex | Education no. of years | ECG** | Years with pacemaker | Pacemaker mode |
|-----|-------|---------------------------|---------|-------------------------|-------------------|
| 82* | Woman | 6 | Avb III | 26 | VVIC |
| 79* | Man | 10 | SND | 8 | VVIR |
| 73* | Man | 8 | SND | 2 | DDDC |
| 67* | Woman | 10 | SND | 3 | DDIC |
| 28 | Woman | 12 | SND | 10 | DDDC |
| 69* | Woman | 9 | SND | 3 | DDDC |
| 72* | Man | 16 | Avb III | 11 | DDDC |
| 22 | Woman | 11 | Avb III | 22 | VVIR |
| 28 | Man | 14 | SND | 9 | DDDR |
| 74* | Woman | 6 | Avb III | 33 | DDDR |
| 80* | Man | 6 | SND | 23 | VVIR |
| 47 | Man | 12 | SND | 19 | AAIR |
| 48 | Woman | 20 | Avb III | 0.5 | DDDR |

* Pensioner. ** ECG-rhythm that was the reason for pacemaker implantation.

Study IV was a pre test-post test experimental randomized multicentre study conducted in a county hospital and a university hospital in the southern Sweden and a university hospital in central Sweden. The patients underwent blinded randomization by means of a computer generated list of random numbers. Stratification based on sex, age (≤ 64 , ≥ 65), ECG (AV-block, AF, SND), and pacemaker mode (DDD/R*, VVI/R) was utilised in order to make the two groups as similar as possible. A total of 220 patients were randomly assigned to follow-up after their first pacemaker implantation. There were 1404 patients with

pacemakers from the three pacemaker clinics. After exclusion (Figure 7) of those undergoing pacemaker or electrode exchange (n=384) 1020 eligible patients remained. Of those, 801 patients were not randomized due to: administrative reasons (24%), implantable cardioverter defibrillators (ICD) or biventricular pacing (22%), complete stratum (16%), impaired physical capacity (12%), and not wanting to take part, dementia, impaired vision or hearing, problems regarding follow-up, and life-threatening illness (26%). Of the 220 randomized patients there was a dropout of eight patients during the course of the study (Figure 7). Of the 212 patients included in the study, 33% had heart failure (NYHA class I-III). The patients had atrial- dual-chamber pacing (71%) or ventricular pacing (29%); no patient had ICD pacing. The 10-month follow up was completed by 97 patients in the intervention group and 115 in the control group. There were no significant differences in sociodemographic or clinical variables at baseline between the control group and the intervention group. Table 1 provides an overview of characteristics of the patients included in the thesis.

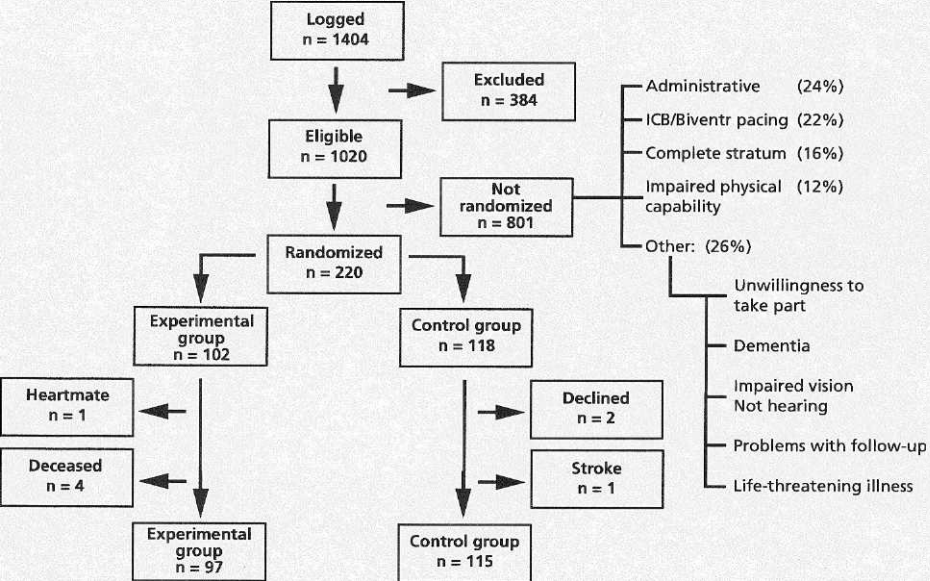


Figure 7. Flow diagram showing the logging and randomization procedure as well as dropouts in the experimental group and control group, respectively, of patients with pacemakers.

DESCRIPTIVE STUDIES (I, II, III)

Patients

Patients with pacemakers were included in studies I, II, and III if they fulfilled the inclusion criteria of being Swedish-speaking and > 18 years of age, and met the specific inclusion criteria of the respective studies. A total of 182 patients with pacemakers were entered into study I (Table 1, Figure 6) by means of a random selection of every fourth person with a pacemaker in order to obtain a stratified sample of all such patients in the catchment area. In study II a total of 697 patients with pacemakers participated. This sample resulted from a cross-sectional survey of a pacemaker population comprising 869 patients. In study III, 13 informants were selected according to the maximum variation sampling technique⁷⁴ (Table 2). The theoretically important variables were sex, age, years as a patient with a pacemaker, pacemaker mode, education, and if the informants lived alone or were cohabiting.

Instruments and interview

The instrument used in study I, the Quality of Life Pacemaker Questionnaire (QLPMQ), was developed for use in the study and it comprised a three-part instrument with questions about quality of life. The QLPMQ contained 46 items from the PGC-MAI instrument⁷⁵, 62 items from the QLI instrument⁵⁹, and 15 questions from the Living with a Pacemaker Questionnaire (LPQ), for a total of 133 items in addition to 10 questions about gender, age, etc. The LPQ instrument was developed by main researcher (DM) and was tested by an interdisciplinary team of cardiac nurses and cardiologists at a cardiology department for content validity, i.e. it was assessed in terms of whether the questions were relevant regarding content. Finally, seven factors in the instrument were identified by means of a rotated varimax factor analysis⁷⁶. The questions were allocated to eight different fields in accordance with Orem's self-care factors: developmental status, environmental factors, mental- and physical health status, family system factors, availability and adequacy, patterns of living, health care system factors and sociocultural orientation.

The instrument in study II contained items concerning socio-demographic data including sex, age, civil status, occupation, place of residence, dwelling, and five items from the EQ-5D instrument^{77,78}. Also included were pacemaker mode, i.e. VVI/R, AAI/R or DDD/R, and whether symptoms were gone, still partially present, or still present, and years as a pacemaker patient. The EQ-5D was used to measure HRQoL⁷⁹. The question in the EQ-5D with response alternatives on a thermometer scale was not considered in the analysis because of a high dropout rate.

The Philadelphia Geriatric Centre Multilevel Assessment Instrument (I)

The Philadelphia Geriatric Centre Multilevel Assessment Instrument (PGC-MAI)⁷⁵ contained 68 questions in addition to background questions concerning sex, age, occupation, education and dwelling. By means of this instrument the well-being and inherent self-care capacity of the older person could be established within different areas/domains⁷⁵. These domains are physical health, functional health (ADL), cognition, use of time, social interaction, the effect of those close to the individual (environment), psychological well-being, and agreement in accordance with Lawton with the individual's subjective experience of his/her QoL. All versions of the PGC-MAI, which is available in three different lengths, have been tested for reliability and validity using several different approaches⁷⁵. Forty-six of the total of 68 questions in the PGC-MAI were selected for use in the study. These concerned physical health, comprehension capability, self-care and activities of daily living, participation in activities, living conditions, ability to transport oneself, spirits/mood, social relationships and financial situation. The PGC-MAI assesses the individual's own understanding. Each area was divided into subgroups, which were used separately or combined into an overall index. The answers were primarily of an ordinal type⁷⁶, with the exception of some background questions. The level of reliability for this instrument according to Cronbach's alpha was 0.80.

Quality of Life Index - Cardiac III version (I)

The Quality of Life Index - Cardiac III version^{59,80} (QLI) comprised two parts consisting of 72 questions. The first 36 questions measured life satisfaction within the different areas of life, while the remaining 36 questions measured the importance of these areas of life. According to Ferrans and Powers, QoL is assessed in both sick and healthy persons, and the QLI was first developed for patients undergoing renal dialysis⁵⁹. The QLI (Cardiac III) is a modification of the original QLI, and additional versions have been developed for cardiac and cancer patients⁸⁰. Each question has answers on a six-point ordinal scale ranging from "very unsatisfactory/ unimportant" <1> to "very satisfactory/ important" <6> and consists of four subscales: health and functioning, socioeconomic, psychological/spiritual, and family. The scores range from 0 to 30 with a higher score denoting a higher quality of life. For reference, a general population has achieved mean scores of 22.9⁸¹ and 23.5 after percutaneous transluminal coronary angioplasty⁸². Criterion-related validity was established by comparing the QLI with an overall satisfaction with life question and correlations of 0.85, and 0.65 were obtained for the original version⁸³, and 0.93 was obtained for the Cardiac III version⁸¹. The level of reliability for this instrument according to Cronbach's alpha was 0.85.

Living with a Pacemaker Questionnaire (I)

The Living with a Pacemaker Questionnaire (LPQ) consists of 18 questions, 15 of which are associated with pacemaker treatment. The LPQ focuses on the

patient's experiences as a result of having a pacemaker and is divided into seven areas/dimensions: mental stability, cardiac function, physical function, need for information, giving information, complications and clinical picture. The responses are of an ordinal type. Validation of the instrument was done in three steps. The first step was carried out by six cardiac nurses and four cardiologists who assessed the content validity, i.e. judged whether the questions were relevant in regard to content and construct. After adjustments, the content validity was assessed by 10 patients with pacemakers, after which further changes were made in the instrument. Finally seven factors in the instrument were identified by means of a rotated varimax factor analysis ⁷⁶. The level of reliability for this instrument according to Cronbach's alpha was 0.57.

Euro-Qol (II)

The Euro-Qol (EQ-5D) is a multidimensional instrument for assessment of HRQoL. The EQ-5D has been found to be acceptable, feasible, valid and reliable in several population studies ^{77, 78}. In accordance with the EQ-5D, the classification of health status was defined in terms of five dimensions: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each dimension was rated using a three-point, ordered, categorical scale. The patient could be classified into 243 different health states, and each state has a reference value or score obtained from a sample of the general population ^{58, 84}. A sixth question about general level of health compared with the past 12 months completed the first part of the instrument. The second part (not used in study II), the 100-point visual analogue scale, is used to rate the current health of the patient (100 indicates the best imaginable health state and 0 the worst imaginable health state). In this thesis the internal consistency of reliability for this instrument according to Cronbach's alpha was 0.75. In order to define a global scale (II) of SRH, which would be useful in a clinical setting, the dimensions of mobility and self-care were regarded as representing the physical dimension, pain / discomfort and anxiety / depression were regarded as representing the mental dimension, and usual activities the social dimension. The criterion for a "high" level of SRH was that there were no problems in any of the activities, and hence the levels of the physical, mental and social dimensions were (111). When the social level was rated two or three, i.e. responses (112) or (113), the global index of SRH was defined as "acceptable" (Figure 8). When the median levels of the physical and mental dimensions were (23), (32) and (33), SRH was classified as "low", irrespective of the response in the social dimension. For the other combinations of the mental and physical median levels, global SRH was regarded as acceptable provided that the social level was rated one or two.

| The mental dimension | The social dimension | The physical dimension | | |
|----------------------|----------------------|------------------------|------------|------------|
| | | 1 | 2 | 3 |
| 1 | 1 | High | Acceptable | Acceptable |
| | 2 | Acceptable | Acceptable | Acceptable |
| | 3 | Acceptable | Low | Low |
| 2 | 1 | Acceptable | Acceptable | Low |
| | 2 | Acceptable | Acceptable | Low |
| | 3 | Low | Low | Low |
| 3 | 1 | Acceptable | Low | Low |
| | 2 | Acceptable | Low | Low |
| | 3 | Low | Low | Low |

Figure 8. The global assessment of Euro-qol (EQ-5D)⁷⁸ defined by the combined distribution of the overall categorical levels of the physical, mental and social dimensions in study II.

Study III had a qualitative design and used the method of grounded theory described by Strauss and Corbin⁷⁴ in order to generate a theory that could help explain how informants experience living with a pacemaker. Data were collected through semi structured interviews to enable the informants to describe their experiences of daily living with a pacemaker. An interview guide consisting of five themes was used. According to Patton⁸⁵, an interview guide gives the researcher the freedom to converse with the interviewee concerning a special theme, and the researcher is free to explore and to ask questions that will elucidate the special theme⁸⁵. The following themes were addressed: Time before implantation; Perceived function of the pacemaker; Pacemaker influence on masculinity and femininity; Perceived social problems and thoughts about the future. Protocols with introductory and additional questions are presented in Figure 9.

- Do you want to tell me how you experience having a pacemaker?
- What was it like when you got your pacemaker?
- What is the difference today compared to before you got your pacemaker?
- Has it had any effect on your life?
- How do you think your immediate family experience your having a pacemaker?
- How do you experience the responsibility your immediate family take now as compared to before you got your pacemaker?
- Do you experience that your pacemaker has affected your masculinity/femininity?
- How has your life together been affected?
- What is your relationship like with friends and acquaintances?
- Can you tell me what you know about the function of your pacemaker?
- What thoughts do you have about your future?
- Is there something you'd like to add that I haven't brought up in the interview?

More in-depth questions that were added in the course of the interviews concerned: living a natural life, a more secure life, trusting in others - in God, neglected health and therefore a pacemaker, fear of thunderstorms, what will happen when "I" die.

Figure 9. Questions posed to the informants (n = 13) in study III regarding how they experienced living with a pacemaker.

Data collection

Clinical and sociodemographic data (I, II) were collected mainly from the patients' medical records. In some cases data needed to be supplemented with information from the patient. The informants were interviewed (III) in order to collect sociodemographic data including gender, education, employment, age and marital status.

Just prior to a pacemaker check-up, the patients were informed in writing about the purpose of the study (I) and a request was going to be made that they undergo a structured interview concerning their QoL at the same time as the check-up. The main researcher (DM), who was the pacemaker nurse, conducted a pacemaker check-up, and thereafter the patient filled in QoL instruments for about 90 minutes. In study II consecutive patients with pacemakers in one county were selected and a questionnaire was mailed to them, and following one reminder the patients were included. In study III 12 interviews were conducted at the homes of the informants, while one took place at the informant's place of work, and each interview took 30 to 45 minutes. The interviews were audio-taped and then transcribed into QSR NUD.IST 4 software for analysis⁸⁶. The general interview guide approach was used (Figure 9), with an open-ended initial question, "How do you experience daily living with a pacemaker?" Notes were taken during the interviews and these were supplemented with additional notes directly afterward. Since the interviews were part of the process of generating a theory and these occurred simultaneously, the data could be coded immediately. In parallel with notes on the interviews, memos were written with ideas and statements that could be useful in the ongoing theory generation.

Data analysis

Descriptive analyses were used to describe QoL in patients with pacemakers (I, II). Several quantitative variables were not normally distributed and most variables were ordinal. Therefore non-parametric tests were used. Relationships between variables were evaluated by Spearman's rank-order correlation coefficient (I)⁷⁶ and or / chi-square analysis (II). In order to obtain an overall significance level of 0.05, adjustments for multiple tests according to Holm were performed⁸⁷.

In study III, all parts of the investigation, including data collection, data analysis and theory formation, were parallel processes including three levels, open-, axial- and selective coding, and these were usually not well differentiated, but instead overlapped one another. In the first step, open coding, each sentence in the interview protocol was analysed in order to identify descriptions of similarities and differences. Through this substantive process codes were generated that captured the content and meaning in the data. Substantive codes were compared with one another and codes that appeared to belong together were grouped into abstract concepts or categories. In the next stage in the analysis, axial coding, the aim was to find linkages or relations between the higher-level categories. However, the coding was also based on the consequences

to which it led. This part of the analysis was complex and primarily inductive, but it was also deductive when, for example, the data were examined with hypotheses by using questions to demonstrate associations between the new, more comprehensive categories. According to Strauss & Corbin, the coding must fit the story it represents⁷⁴. The last step in the process was selective coding, where the aim was to co-ordinate and “refine” the categories to obtain a tight and saturated theory. This can also explain most of the variation in the data^{74, 88}.

EXPERIMENTAL STUDY (IV)

Intervention

Patients were randomized to either nurse-led standard checkups (control group) where they received individualized information from a pacemaker nurse or to the nurse-led self-care program (experimental group), where in addition to the information from the nurse, patients also took part in education sessions (Figure 10).

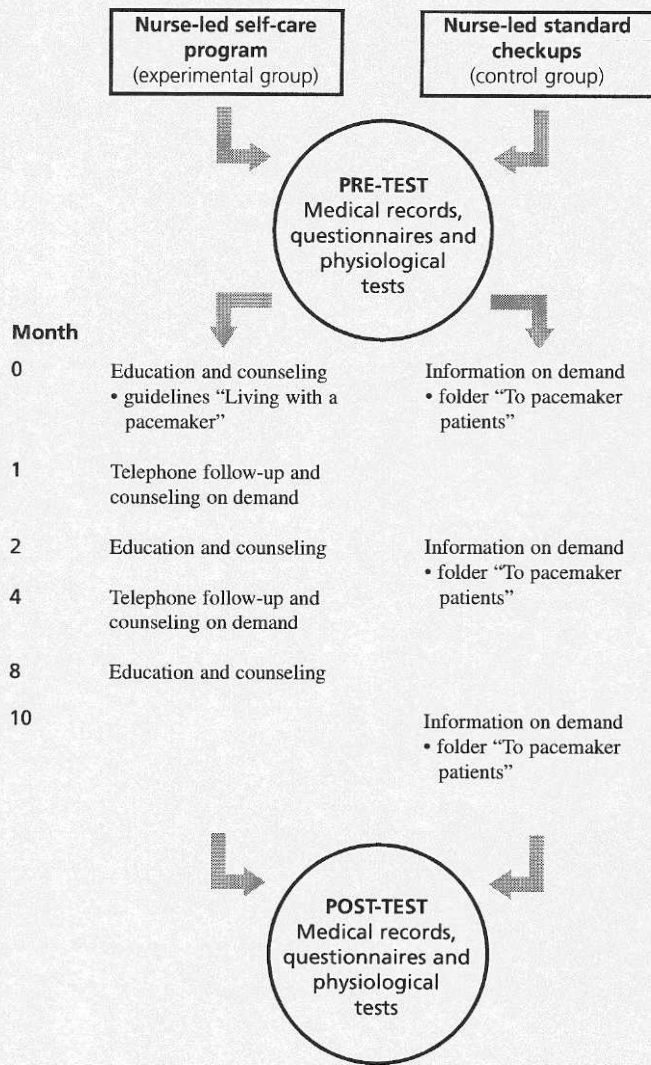
In the nurse-led standard checkups the patients were given a folder entitled “To pacemaker patients”⁸⁹ with general information for patients with pacemakers. The information was individualized regarding physiology, the heart rhythm that led to pacemaker implantation, and what it could be like to live with a pacemaker (Figure 10). Each patient received information three times on demand, for a period of 5-10 minutes at each occasion; they got information when the pacemaker was implanted, and when the pacemaker nurse checked the pacemaker system two and ten months after implantation⁹⁰ (Figure 10, 11).

In the nurse-led self-care program patients received individualized patient education from a pacemaker nurse based on information in the folder “Living with a pacemaker”⁹¹. The nurse-led self-care program consisted of three education sessions, the first when the pacemaker was implanted, and then the second and third two and eight months, respectively, after inclusion in the study. There was also follow-up by telephone, with counseling on demand, after one and four months (Figure 11). The sessions took place in the hospital, and spouses were also invited to participate. In addition to the nurse-led self-care program, the nurses also provided psychosocial support on demand. The patients could contact the pacemaker clinic during daily telephone hours. If a patient experienced anxiety that could be attributed to pacemaker implantation, or if further education was needed, the patient was scheduled for another visit to the pacemaker clinic if contact by telephone was not sufficient.

| | Aim | Procedure | Goals | Literature |
|--|--|--|--|---|
| | To give the patient knowledge about: | Together with the patient: | That the patient acquires an understanding: | Educational folder: "Living with a pacemaker" |
| Post-op. At the hospital, before discharge | <ul style="list-style-type: none"> • why pacemaker implantation is necessary • how the pacemaker system functions | In the educational folder: <ul style="list-style-type: none"> • sketch in placement of the pacemaker and electrodes • write information about the pacemaker | <ul style="list-style-type: none"> • about the reason for pacemaker implantation • about how active he/she can be up until the next appointment | Read through pages 3-7 with the patient |
| 2 months Repeat what was done on the previous occasion | <ul style="list-style-type: none"> • the pacemaker's base frequency • social activities the patient can engage in • interference from electrical equipment | Give instructions about how: <ul style="list-style-type: none"> • the patient can feel his/her own pulse • we check the pacemaker via the programmer | <ul style="list-style-type: none"> • about taking his/her pulse and also doing it- about what pacemaker check-ups will be like • about electrical equipment that can disrupt the pacemaker | Read through pages 8-10 with the patient |
| 8 months Repeat what was done on the previous occasion | <ul style="list-style-type: none"> • interval for pacemaker follow-up • interval for replacing the pacemaker • situations in which the pacemaker clinic should be contacted | Explain the interval for: <ul style="list-style-type: none"> • pacemaker follow-up and that "we" give the patient an appointment • pacemaker replacement and that "we" plan this well in advance together with the patient | <ul style="list-style-type: none"> • about the security of being able to leave check-ups of the technical function to the pacemaker clinic • about how knowledgeable pacemaker clinic staff can always be reached by telephone | Read through pages 11-18 with the patient |
| 10 months | Evaluation: Go through the self-care program again to increase self-care possibilities | | | |

Figure 10. Model for the self-care program showing aims, procedures, goals, and the time perspective.

Figure 11. Flow chart indicating how patients with pacemakers were included and randomized to either the experimental or the control group.



Patients

Consecutive patients were asked to take part in the study at the time of pacemaker implantation at the participating hospitals. Patients were included in the study if they had their pacemaker system implanted on an acute or elective basis, and had stayed at the hospital for one day, and if they fulfilled the inclusion criteria of being Swedish-speaking and > 18 years of age.

Patients were excluded if they received an ICD pacemaker, had a serious disease with an expected survival of six months, dementia or other mental illness, had seriously reduced physical capacity, suspected problems with the follow-up, were unwilling to participate, and complete stratum (Figure 7). In addition, patients with a language or communication barrier were excluded. With 120 patients in each group (experimental and control) it was calculated that a 20%

difference in the outcome variables would be detectable between the two groups (two-sided $\alpha=0.05$, a 20%). Of the 1020 patients who were listed as having a pacemaker system implanted, 801 were assessed for the study, see Figure 7. A total of 220 patients were included in the study. Thirty-eight (5%) of the 801 patients with pacemakers declined to participate. Furthermore, before discharge one patient had a stroke and two patients in the control group decided not to participate. In the experimental group one patient had a heartmate and four patients died. Only those patients who completed both the pre-test and post-test procedures were included in the study. The 10-month follow-up was completed by 97 patients in the experimental group and 115 in the control group, resulting in a total of 212 participating patients (Figure 7, 11). The physical test, which was carried out at just one of the university hospitals and at the county hospital, was performed by a total of 123 patients, 56 in the experimental group and 67 in the control group.

Instruments

Euro-Qol

The EQ-5D is a multidimensional instrument for assessment of HRQoL (page 27, EQ-5D II). The categories (1, 2, 3) resulted in an overall health state defined as a five digit number; for example, “11121”. This indicates level one, or no problem in mobility, self-care, usual activity, and anxiety / depression and moderate problems with pain. In study IV (but not in study II) the second part of the question-naire, the 100-point visual analogue scale, was used to rate the current health of the patient, with 100 indicating the best imaginable health state and 0 the worst imaginable health state. In the present study the internal consistency of reliability for this instrument according to Cronbach’s alpha was 0.72.

Psychological General Well-being Scale

The Psychological General Well-being Scale (PWBG) is intended to measure the individual’s HRQoL or self-representations reflecting a sense of subjective well-being or distress. The reliability and validity of this instrument are well documented⁹². The instrument is composed of six dimensions: anxiety (five items), depressed mood (three items), positive well-being (four items), self-control (three items), general health (three items) and vitality (four items). The PWBG consists of 22 items on a six-point Likert scale ranging from 0 to 5, and the index has a maximum score of 132 and a minimum score of 22. The higher the value, the better the well-being of the patient⁹³. In the present study the internal consistency of reliability for this instrument according to Cronbach’s alpha was 0.94.

Subjective Consequences of Pacemaker therapy

The subjective consequences of pacemaker therapy (SCOP) is a semi-structured instrument concerning subjective consequences of pacemaker therapy with five disease-specific questions for older patients with pacemakers⁶¹. These are: What symptoms do you have that indicate that you received a pacemaker? Do you have any physical discomfort from the pacemaker? Do you feel anxious or insecure because you have a pacemaker? Has pacemaker therapy affected your sex life or your quality of life? Regarding the symptom that resulted in your need for pacemaker therapy: Has it disappeared? Is it still present? Present to some extent? Are you unsure about this? The response choices were mainly dichotomous, which is why the internal consistency of reliability for this instrument could not be determined.

Six-minute walk test

The six-minute walk test⁷⁰ is a physiological test to assess exercise capacity related to activities of daily living. The patients were asked to walk at their own maximal pace along a 50-meter long hospital corridor. They were asked to walk from one end to the other, covering as much ground as they could during the allotted time without running. Encouragement was standardized⁹⁴. The distance covered in six minutes and heart rate and oxygen saturation were recorded before and immediately after the test. Heart rate (beats/minute) and oxygen saturation were recorded using a MicroO2 (Siemens MicroO2, Danvers, USA). Perceived exertion was rated on a Borg scale before and immediately after the test⁹⁵.

One and a half-minute stair test

The 1½-minute stair test is a physiological test to assess exercise capacity related to maximum capacity in activities of daily living. The patient was asked to climb stairs for 1½ minutes at a rate of about one step per second. After recovery, when the patient's resting heart rate had returned, the patient was asked to go down stairs for 1½ minutes at a rate of about one step per second. This was done following the six-minute walk test, and encouragement was standardized⁹⁴. The distance covered in 1½ minutes of climbing stars and 1½ minutes of going down stairs was determined, and heart rate and oxygen saturation were recorded before the test, every 30 seconds during the test, and immediately afterwards. Heart rate (beats/minute) and oxygen saturation were recorded using a MicroO2 (Siemens MicroO2, Danvers, USA). Perceived exertion rated on a Borg scale was recorded before and immediately after the test⁹⁵.

Data collection

Before the intervention all patients completed the instruments about well-being or distress, consequences of pacemaker therapy, and quality of life, and they did the exercise tests. The patients were asked the same questions and did the exercise tests 10 months after inclusion.

The study co-coordinators informed the patients, both verbally and in writing,

about the aim of the study. A qualified pacemaker nurse at each hospital acted as study coordinator. These nurses contacted the patients, entered patients into the study, administered the instruments, and directed the intervention program. The day after pacemaker implantation, while still in the hospital, patients answered the SCOP, EQ-5D and PWBG instruments. The study co-coordinators also administered the six-minute walk test and the 1¹/₂- minute stair test before the beginning of the nurse-led intervention program, as well as at the 10-month follow-up in the hospital. Clinical and sociodemographic data were collected mainly from the patients' medical records. In some cases data needed to be supplemented with information from the patient.

Data analysis

The analysis was quantitative in nature, using descriptive and analytic statistics (Figure 6). Basic characteristics of the patients are summarized in Table 1. Sub-grouping was done according to sex, age (≤ 64 , ≥ 65), ECG (AV-block, AF, SND), and pacemaker mode (DDD/R*, VVI/R). Patients with inhibited pacemakers (AAI/R) were included in the dual-chamber (DDD/R) pacing group. The control and experimental groups were compared using Student's t-test for normally distributed continuous variables. The Mann-Whitney U test was used for non-normally distributed continuous variables. A p-value of less than 0.05 was considered significant ⁷⁶.

ETHICAL CONSIDERATIONS

The basic ethical principles of research were adhered to in this thesis ⁹⁶. These principles are respect for autonomy, beneficence, non-maleficence and the principle of justice. Ethical issues regarding autonomy and the risk of causing psychological and emotional problems by means of instruments and interviews were considered in all these studies involving patients. All patients fulfilling the inclusion criteria received both written and verbal information, including the fact that their participation was voluntary and that they could withdraw at any time without the need to give any reason for this, before agreeing to participate. They were also informed that the information they provided would be treated confidentially.

The principles of beneficence (doing good) and non-maleficence (doing no harm) must be carefully considered before a study is conducted. The patients in the control group were not cared for in the same way as those in the experimental group (IV); they received standard care and treatment. The experimental group underwent a nurse-led individualized self-care program of pacemaker treatment which consisted of education sessions and also follow-up by telephone. Since the interventions with nurse-led self-care program were not standard before the study, the demands of doing good and not doing harm were taken into consideration. The right to privacy could be of particular interest when interviewing informants (III), and when the main researcher visits informants' homes, and hence intrusion into people's personal lives

may be a potential ethical issue. Thus, the main researcher must ensure that the research is not more intrusive than necessary. Therefore, the informants were thoroughly informed about the purpose of the study and the principle of justice was taken into consideration.

The thesis was approved by the Ethics Committee for Human Research at Linköping University, Linköping, Sweden (I-IV). The studies were conducted in accordance with the Declaration of Helsinki.

RESULTS

Health-related quality of life in patients with pacemakers (I, II)

The results of study I show that the total HRQoL for these patients was acceptable (Figure 12, Table 3). A poorer HRQoL was found with regard to physical health, the possibility of influencing one's own situation, lifestyle, health care resources and sociocultural orientation. Study II aimed to determine self-rated health (SRH) in a pacemaker population in terms of sociodemographic characteristics, pacemaker mode and symptoms. HRQoL in general according to the global scale as was defined by the joint distribution of the overall categorical levels of the physical, mental and social dimensions according to nine pairs of categorical combinations of the physical and mental dimensions (Figure 8). It can be seen in Table 4 that 30% of the patients had a high HRQoL, 59% had an acceptable HRQoL, and 11% had a low HRQoL. The findings show that a Swedish pacemaker population ($n = 697$) with a mean age of 76 years had an acceptable HRQoL. Men aged 65-84 years, persons who were cohabiting, who had their own dwelling, who had a DDD or who had a pacemaker system for more than 4-7 years experienced better HRQoL.

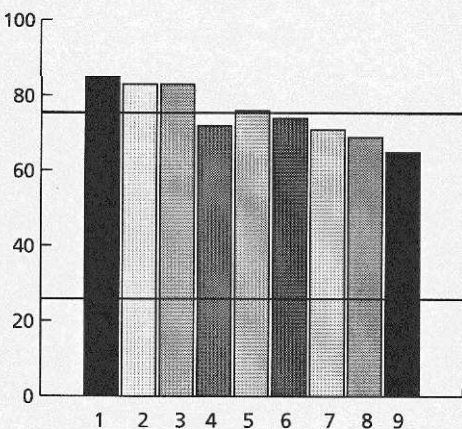


Figure 12. Health-related quality of life as reported in accordance with Orem's self-care theory⁴¹ in patients with pacemakers ($n=182$). HRQoL was regarded as acceptable in 26-75% of patients.

1 = Developmental status, 2 = Environmental factors, 3 = Health status (mental), 4 = Health status (physical), 5 = Family system factors, 6 = Availability and adequacy, 7 = Patterns of living, 8 = Health care system factors, 9 = Sociocultural orientation.

Table 3. Mean level (%) of quality of life in patients with pacemakers according to Orem's self-care theory⁴¹ as related to gender, age, civil status and occupation (n=182). Quality of life was regarded as acceptable in 26-75% of patients.

| SELF-CARE FACTORS | Gender | | Age | | | Civil status | | Occupation | | |
|----------------------------|--------|-------|-----|-------|-----|--------------|-------|------------|-----|------|
| | Men | Woman | <64 | 65-84 | 85> | Co-habiting | Alone | A* | B** | C*** |
| Developmental status | 90 | 79 | 93 | 87 | 68 | 91 | 76 | 84 | 85 | 88 |
| Environmental factors | 82 | 77 | 82 | 80 | 78 | 82 | 77 | 78 | 81 | 82 |
| Health status mental | 83 | 76 | 81 | 79 | 82 | 81 | 78 | 78 | 82 | 82 |
| physical | 74 | 68 | 71 | 71 | 71 | 73 | 68 | 70 | 75 | 70 |
| Family system factors | 76 | 75 | 78 | 75 | 73 | 80 | 75 | 76 | 74 | 77 |
| Availability and adequacy | 76 | 71 | 82 | 73 | 67 | 77 | 70 | 73 | 75 | 73 |
| Patterns of living | 73 | 66 | 72 | 70 | 68 | 73 | 65 | 68 | 76 | 72 |
| Health care system factors | 68 | 67 | 66 | 69 | 66 | 67 | 68 | 67 | 68 | 70 |
| Sociocultural orientation | 66 | 63 | 70 | 63 | 61 | 65 | 62 | 64 | 66 | 64 |

A* Blue-collar, B** White-collar, C***Manager

Table 4. Quality of life in a pacemaker population according to patient characteristics and circumstances based on information from self-rated health (SRH) questions (n=697).

| Characteristics | n | SRH | | | p-value |
|---|-----|----------|----------------|---------|---------|
| | | High (%) | Acceptable (%) | Low (%) | |
| Sex | | | | | <0.001 |
| Women | 345 | 23 | 64 | 13 | |
| Men | 352 | 37 | 55 | 8 | |
| Age | | | | | <0.001 |
| < 64 yr | 94 | 48 | 48 | 4 | |
| 65-84 yr | 478 | 30 | 63 | 7 | |
| > 85 yr | 125 | 18 | 57 | 25 | |
| Civil status the year of implant | | | | | <0.04 |
| Cohabiting | 482 | 34 | 58 | 8 | |
| Single | 215 | 19 | 68 | 13 | |
| Occupation | | | | | <0.001 |
| Employed | | | | | <0.001 |
| Day of implantation | 172 | 32 | 61 | 7 | |
| Today | 56 | 61 | 39 | 0 | |
| Old age pensioner | | | | | NS |
| Day of implantation | | | | | |
| Today | 469 | 24 | 62 | 14 | |
| Place of residence | | | | | NS |
| Urban | | | | | NS |
| Day of implantation | 559 | 28 | 60 | 12 | |
| Rural today | 7 | 57 | 43 | 0 | |
| Rural | | | | | NS |
| Day of implantation | 102 | 34 | 62 | 4 | |
| Urban today | 29 | 35 | 55 | 10 | |
| Dwelling | | | | | <0.001 |
| Own | 620 | 32 | 60 | 8 | |
| Group dwelling | 29 | 0 | 36 | 64 | |
| Nursing home | 48 | 13 | 56 | 31 | |
| Pacing mode | | | | | < 0.001 |
| VVI/R | 604 | 27 | 61 | 12 | |
| DDD/R | 93 | 49 | 49 | 2 | |
| Years with pacemaker | | | | | NS |
| ≤ 3 yrs | 240 | 29 | 62 | 9 | |
| 4-7 yrs | 208 | 30 | 57 | 13 | |
| 8-14 yrs | 185 | 30 | 60 | 10 | |
| > 15 yrs | 64 | 33 | 58 | 9 | |
| Symptoms | | | | | < 0.001 |
| Gone | 434 | 42 | 50 | 8 | |
| Still partially present | 219 | 9 | 78 | 13 | |
| Still present | 44 | 13 | 66 | 21 | |

The experience of daily living with a pacemaker (III)

The semi-structured interviews showed variations in social participation and emotional status that were related to four categories describing living with a pacemaker, and that can be seen as a preliminary theoretical model (Figure 13). A total of 13 informants with pacemakers (seven women) aged 22-82 (mean=59) years were interviewed. The informants had had a pacemaker from 0.5 to 33 (mean=13) years (Table 2).

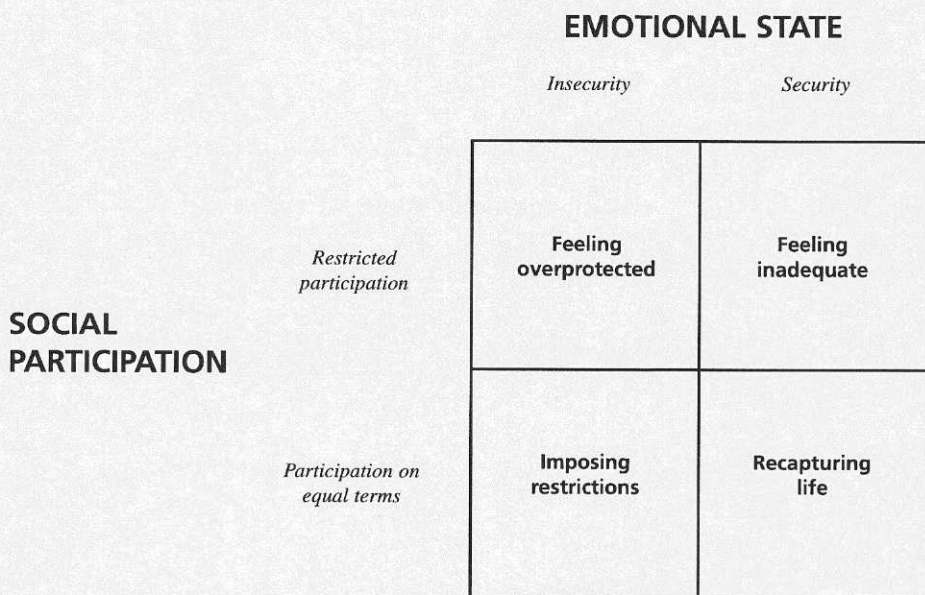


Figure 13. Preliminary theoretical model describing daily living with a pacemaker based on data from 13 informants.

Emotional state was characterized by variations between the end-points of security and lack of security. As a result of the unpredictable symptoms that led to pacemaker treatment, the informants had lived with a feeling of great insecurity for a long period of time. They began by saying that now, long after getting their pacemaker system, they felt secure in being able to trust the pacemaker. Their happiness at being alive could be experienced intensely, since falling ill had usually been acute and dramatic. Their confidence also increased successively as the follow-ups and pacemaker checkups turned out well and showed normal values.

Social participation had a central position in the data and reflected the informants' participation in social life after receiving a pacemaker. The experience of participation varied between the extremes of restricted participation and participation on equal terms. In the period soon after

implantation there was often a fear that the electrode/electrodes would loosen during physical activity such as garden work, housework, swimming, jogging or golf. The informants also had thoughts about dying because they had neglected their health, especially those who had waited many years after the start of their symptoms until the pacemaker system was implanted. But when the pacemaker system had been implanted and they received a diagnosis for their dizziness and fainting problems, they felt they were believed, and then they recovered, and with the understanding of their family they were able to resume a normal life again.

Typical quotation from a woman, aged 82 was: *I had just lain down on the bed when it happened...it was probably the worst experience I've ever had...well I looked at the ECG screen and at first I didn't understand what happened, but then I understood and I thought...well now I'm dying... but no said the doctor, you're not, we can put in a pacemaker. Well and I've had that experience with me the whole time since I got the pacemaker. So sometimes in the beginning when I felt anxious I thought it was the pacemaker. But that was mostly in the beginning, now my life as usual...*

Feeling overprotected described the informants' feeling of being treated with too much care by their close relatives. This overprotection was most common among the men in the study, and especially during the first year after pacemaker implantation. If the informant wanted to get understanding and permission to act as if he/she has recovered, the only way to do this was to do chores and work like before and thereby demonstrate that he/she could handle this exertion.

Feeling inadequate described the informants' experiences of inadequacy in different situations, both at work and in family life, after pacemaker implantation. When they were going to do similar tasks or the same tasks as before the implantation they often got help from a colleague or the colleague offered to completely take over the task from then on. In the eyes of those around them the informants had become "heart patients", and it was the judgement of employers and colleagues that for medical reasons they therefore needed considerable relief. Despite the goodwill and support, their thoughtfulness resulted in feelings of inadequacy on the part of the informant with a pacemaker.

Imposing restrictions concerns the restrictions the informants imposed on themselves. They planned their daily lives based on their understanding of what was appropriate and not dangerous for them. Electromagnetic fields were avoided as these were thought to be able to cause arrhythmias with subsequent dizziness and fainting, and this fear resulted in restrictions in different social situations. The informants were hesitant about cell phones, store alarms, airport metal detectors and microwave ovens. Atmospheric disturbances that arose in connection with bad weather with thunder and lightning could be experienced as both uncomfortable and restricting.

Recapturing life described their strong feeling of being able to return to the life they had before becoming ill. The informants, particularly those who had not become ill acutely, were quickly able to feel the return of a joy of living after a long period of medical examinations and investigations. Several years after the implantation the pacemaker was more or less forgotten, although it could be felt when touched, and it was possible to live just as actively as before the symptoms had emerged and resulted in pacemaker treatment. The summons to the yearly checkup of the pacemaker reminded the informants that they were “patients with pacemakers”.

Effects of a self-care program on health related quality of life (IV)

There were no significant differences in HRQoL between the experimental group and the control group (Table 5). One of the main findings was that patients in the self-care group (experimental group) had a significantly higher HRQoL in that symptoms like dizziness and syncope, which had been the reason for pacemaker implantation, had decreased or disappeared (Table 6). Another main finding concerned the 1½-minute stair test and patients' perceived exertion; patients in the experimental group had a significantly higher HRQoL than patients who had standard checkups (Table 7).

Table 5. Differences in HRQoL between the experimental group (n=97) and the control group (n=115) and exercise between the experimental group (n=56) and the control group (n=67).

| | Experimental | | Control | | p value |
|---|--------------|-------|---------|-------|---------|
| | pre | post | pre | post | |
| HRQoL^a | | | | | |
| EQ-5D (mean) | | | | | |
| Mobility | 1.35 | 1.38 | 1.31 | 1.41 | .93 |
| Self-Care | 1.06 | 1.07 | 1.08 | 1.06 | .55 |
| Usual Activities | 1.27 | 1.27 | 1.28 | 1.15 | .09 |
| Pain/Discomfort | 1.68 | 1.56 | 1.66 | 1.57 | .99 |
| Anxiety/Depression | 1.38 | 1.40 | 1.26 | 1.32 | .32 |
| State of health past 12 months | 2.03 | 1.69 | 2.00 | 1.70 | .75 |
| EQ VAS score (mean) | 61.45 | 68.04 | 62.43 | 69.57 | .73 |
| EQ -index | 0.745 | 0.750 | 0.755 | 0.751 | .69 |
| PWBG (mean) | | | | | |
| Anxiety | 17.10 | 19.57 | 18.42 | 10.23 | .21 |
| Depressed mood | 11.31 | 12.43 | 12.05 | 12.89 | .63 |
| Positive well-being | 10.60 | 11.99 | 11.04 | 12.41 | .75 |
| Self-control | 11.49 | 12.36 | 11.96 | 12.31 | .18 |
| General health | 8.80 | 10.93 | 9.17 | 11.10 | .49 |
| Vitality | 10.22 | 12.22 | 10.66 | 12.86 | .65 |
| PGWB-index | 69.49 | 75.95 | 73.30 | 78.22 | .49 |
| EXERCISE^b | | | | | |
| 6-minute walk test, meters (mean) | 348 | 386 | 360 | 396 | .54 |
| Heart rate per minute, at rest, 6-min walk (mean) | 67.1 | 67.1 | 71.9 | 67.1 | .68 |
| Heart rate per minute, max, 6-min walk test (mean) | 85.6 | 90.3 | 91.9 | 90.1 | .13 |
| 1½ minute stair test, perceived exertion (Borg scale 6-20) | 14.56 | 15.51 | 14.26 | 13.74 | .51 |
| Heart rate per minute, at maximum stair test, (mean) | 101.9 | 102.2 | 112.6 | 106.8 | .07 |

^a Students t-test, ^b Mann Whitney U-test p-value <0,05 taken as significant.

Table 6. Differences in symptoms between the pre-test and the post-test according to sex, age, ECG and pacemaker mode between the experimental group (n=97) and the control group (n=115).

| Characteristics | Sex | | Age | | ECG | | | Mode | |
|-----------------|-------|-------|-------|-------|-------|-------|-------|--------|-------|
| | Men | Woman | <64 | >65 | Avb | AF | SND | DDD/R* | VVI/R |
| Experimental | 54.55 | 29.07 | 14.26 | 69.79 | 35.69 | 20.43 | 27.37 | 57.51 | 25.30 |
| Control | 68.84 | 35.34 | 22.44 | 78.29 | 48.40 | 19.55 | 31.23 | 76.39 | 23.63 |
| P value | NS | NS | 0.016 | NS | 0.015 | NS | NS | 0.004 | NS |

* Patients with inhibited pacemakers (AAI/R) were included in the dual-chamber pacing (DDD/R) group. ** Mann Whitney U-test p-value <0,05 taken as significant.

Table 7. Difference in perceived exertion (Borg)⁹⁵ in the 1½-minute stair test between the pre-test and the post-test according to sex, age, ECG and pacemaker mode between the experimental group (n=56) and the control group (n=67).

| Characteristics | Sex | | Age | | ECG | | | Mode | |
|-----------------|-------|-------|------|-------|-------|------|-------|--------|-------|
| | Men | Woman | <64 | >65 | Avb | AF | SND | DDD/R* | VVI/R |
| Experimental | 35.92 | 22.17 | 9.83 | 47.94 | 30.00 | 8.50 | 21.13 | 46.00 | 12.04 |
| Control | 25.33 | 16.00 | 8.06 | 33.68 | 17.31 | 8.50 | 15.37 | 31.02 | 10.85 |
| P value | 0.016 | NS | NS | 0.006 | 0.001 | NS | NS | 0.003 | NS |

* Patients with inhibited pacemakers (AAI/R) were included in the dual-chamber pacing (DDD/R) group. ** Mann Whitney U-test p-value <0,05 taken as significant.

There were no significant differences in baseline demographics between the experimental and control groups. As shown in Table 5, neither the experimental group nor the control group had a significant improvement in HRQoL between baseline and the 10-month follow-up. Overall, the self-care program was well tolerated, and no serious adverse events occurred while exercising. Table 6 shows significant improvement in experienced symptoms in the experimental group compared to the control group between baseline and the 10-month follow-up in the stratified groups according to age: ≤ 64 years ($p=0.016$); ECG rhythm: AV-block ($p=0.015$); and pacemaker mode: DDD/R ($p=0.004$). Perceived exertion in the 1½-minute stair test improved significantly in the experimental group compared to the control group in the stratified groups according to sex: men ($p=0.016$); age: ≥ 65 years ($p=0.006$); ECG rhythm: AV-block ($p=0.001$); and pacemaker mode: DDD/R ($p=0.003$) (Table 7).

DISCUSSION

Result issues

Health-related quality of life

The HRQoL in studies I and II was acceptable, although it emerged that measures should be taken on behalf of women, those living alone, the elderly, those with a low level of education, retired persons, and those with single chamber systems (VVI/R), all of whom had a lower HRQoL. Acceptable HRQoL in study I was found based on assessments using Orem's self-care factors when the patients rated their HRQoL using the PGC-MAI⁷⁵, the LPQ (I) and the QLI cardiac version⁵⁹. Comparison with a study with a normal population would have been desirable but this was unfortunately not possible, as such studies have not been carried out with these instruments. Instead, study I was compared with a study where the population had received a pacemaker as treatment after catheter ablation due to AF⁹⁷. Using the QLI cardiac version⁵⁹ instrument, paired t-tests showed that the overall HRQoL in the population in study I was significantly higher ($p < 0.05$ - $p < 0.001$) except in the psychological/spiritual state dimension (Table 8). The demographic characteristics of the patients in study I (n=182) compared to the reference population in the ablate and pace trial (n=156)⁹⁷ were: men 51% vs 57%; age (mean) 77 vs 66 years; pacemaker mode AAI/R+DDD/R vs VVI/R, 9% vs 42% and 91% vs 58%; ECG SND+AF vs Avb, 64% vs 100% initially and 36% vs 99% after 12 months.

Table 8. Quality of life scores (mean \pm SD) from the Quality of Life Index, Cardiac Version⁵⁹ in patients with pacemakers implantation for treatment of AF⁹⁷ compared with study I.

| Category | The ablate and pace trial | Study I |
|---------------------------------|--------------------------------|--------------------------|
| | 12 months follow up (n=156) | Cross-section (n=182) |
| Health / functioning | 21.1 \pm 6.8 | 25.1 \pm 3.6*** |
| Socioeconomic status | 24.6 \pm 5.4 | 26.3 \pm 2.9** |
| Psychological / spiritual state | 24.1 \pm 5.2 | 24.8 \pm 3.3 NS |
| Family | 25.6 \pm 5.4 | 28.2 \pm 2.9*** |
| Total QLI | 23.0 \pm 5.2 | 25.4 \pm 5.5*** |

t-test; * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

These results suggest that HRQoL might be experienced as better (study I) when non psychosocial factors such as work and income determine the patient's well-being, which can be in accordance with the fact that most patients in study I were pensioners. The requirement to be physically active when one is older affects, but is not decisive for, a good life (II), which also indicates that the type of pacemaker system, VVI/R vs DDD/R, is not experienced as being of decisive importance regarding good health. A number of studies have shown that

implantation of a permanent pacemaker improves HRQoL, but benefits associated with dual-chamber pacing as compared with ventricular pacing are observed principally in patients with SND, and not in those with AVb², or with symptoms and perceived exertion in the stair test (IV), or in older patients, as little or no difference between systems was demonstrated when physical tests were carried out to examine if patients' physical capacity was dependent on their pacemaker system^{67-69,98}. This may be due to the fact that the physical tests used were usually the six-minute walk test⁷⁰ or tests where the patient estimated his/her physical capacity without any comparison with attained physical results⁶⁷. This may indicate that the stair test was more reliable and much more decisive for an older but otherwise relatively healthy pacemaker population when physical capacity was tested (IV).

No significant differences between study I and the ablate and pace trial⁹⁷ were found when the patients assessed their psychological / spiritual state. The explanation for this may be that these patients had similar questions about the pacemaker's functions and whether the symptoms they had before implantation will cease or if they have to live with anxiety about whether palpitations, dizziness and fainting can suddenly recur. This anxiety about symptoms that no longer recur can be caused by the self image the patient has or gets through interaction with others⁹⁹. With a self image of being an anxious, sick heart patient who has waited a long time for treatment, such as ablation with pacemaker implantation, the anxiety that previously characterized the patient's life can remain for a long period of time, even when the patient is healthy^{99,100}.

The fact that there are strong associations with a number of sociodemographic predictors means that different studies can obtain different results concerning which factors influence patients with pacemakers' rating of their HRQoL (I, II, III, IV,)¹⁰¹. It is therefore of greatest importance to consider a large number of factors in the individuals' lives that affect how each person rates his/her HRQoL, and these factors can vary among different individuals and groups¹⁰¹. However, functional health is of importance to the experience of good HRQoL, which was also found in the case of those men with the greatest physical exertion in the stair test (IV). Theorell et al¹⁰² found that increased demands in general were also associated with increased possibilities for control for men, while this was not the case for women. There was also a correlation between age and possibilities for control for men, but not for women^{101,102}. In study III it was found that men, in particular, felt overprotected by their family, especially the first year following pacemaker implantation, but the reason for this is unclear. The men themselves perceived that they had recovered well from their illness, but their families were worried that the symptoms that had brought about the implantation would recur. The family's attitude was characterized by extra support and care, although they did not know what was actually allowed for an informant. It was obviously unclear to them whether their relative could perform everyday tasks such as going to the store to shop, cleaning the apartment or driving the car.

The demands on health care are increasing due in part to progressive medical and technological developments and the changing demographic structure of the population, with a steady increase in the number of elderly individuals. This means that the need for pacemaker implantation will increase, since the cause is abnormalities in the heart's conduction system, which is mainly an age-related condition ¹⁸. However, there are priorities to be set in the encounter between caregiver and patient: the amount of time that should be devoted; the level of competence of the caregiver the patient encounters; what care efforts should be undertaken and to what extent ¹⁰³. QALYs (quality adjusted life years) could be of use in handling these difficult concepts ¹⁰⁴. This measure is based on health care costs and the patient's subjective assessments, and takes into account how an improvement in health state is assessed before and after treatment. If a treatment increases HRQoL and/or length of life, this can be expressed in gained QALYs ¹⁰⁵. Health economic assessments of nursing care have been criticised to some extent because the best imaginable state of HRQoL is freedom from illness rather than good health, and because it is complicated and not always relevant, since nursing care focuses more on a process than on the results and effects of a treatment ¹⁰⁶. The health effects (number of life years) of different medical interventions such as coronary artery disease, heart failure, and pacemaker and ICD treatment have been evaluated over a long period of time, and it has been found that there is usually a positive effect on survival but that side effects can result in a deterioration in HRQoL ^{18, 107-112}. QALYs is a measure of results that takes into account both costs and survival as well as how HRQoL is affected. It would be of value to be able to express the results of nursing care interventions as a whole for patients with pacemakers, including the value of care time, costs, complying with patients' wishes, in-depth education, and more technical efforts carried out for and through the patient.

Patient education

The majority of patients with pacemakers experience their HRQoL as satisfactory, but for those who experience poorer HRQoL, women and those with a low educational level (I, II), providing more in-depth patient education (IV) might improve HRQoL. Female patients with myocardial infarctions experience more dissatisfaction with care and they are also more anxious than men about how things will be when they go home ¹¹³. The health paradox (the sex paradox) indicates the following fact: that women are sicker than men but that they live longer. Women visit a doctor more often, consume more medication, and are sick-listed more. They report more health problems than men. The differences are especially great for symptoms like anxiety, fear, sleeping difficulties, headache and fatigue. But women nevertheless live longer than men ¹¹⁴. This indicates how important it is to take sex differences into account in health care ¹¹⁵. It was found in this thesis that consideration should be given to women's health, as they experience poorer HRQoL than men (I, II, IV). The women who participated in the self-care program including in-depth patient

education and an increase in health care contacts did not assess their HRQoL as significantly higher in comparison with those who received the usual follow-up (IV). This is somewhat surprising, since it is well-known that there is a greater association between psychosocial factors and mental health for women than for men ^{64, 101}. However, as a result of the unpredictable symptoms that led to pacemaker treatment, the patients with pacemakers had lived with a feeling of great insecurity for a long period of time. The fear of dying before having a pacemaker system implanted was found in both the informants and their families (III). Since it was found in study II that poorer HRQoL was experienced by those who still had the same symptoms after pacemaker implantation as they had before, and a significant decrease in symptoms was found in the experimental group in study IV, a progressive concentrated effort should be made for all patients in connection with the decision for pacemaker implantation.

In order to try to reach women, particularly with a preventive aim in connection with pacemaker implantation, the psychosocial environment including leisure time should be analysed. In this regard the idea of self-care can be utilized in the same way as the so-called demand-support model that is used to see the association between psychosocial factors and risks for coronary artery disease. In the demand-support model, psychological demands interact with possibilities for control and the support the individual gets ¹¹⁶. Alfredsson et al. ¹¹⁷ reported that only 20% of women felt they had time for rehabilitation after a myocardial infarction because problems at home and at work overshadowed everything else ¹¹⁷. Furthermore, in a Swedish population study it was found that older women, often with a low educational level and an extensive social network, had a greater risk than other women of the same age of dying from cardiovascular disease. It may be the case that for certain women their total life situation with a large social network involves psychosocial stress that is difficult to handle ¹¹⁸.

It has been recognized for some time that individualized goals set the course for patient education intervention ¹¹⁹. According to Rankin ¹², the benefit of setting up goals is that they constitute a motivation for learning that also promotes communication between the patient and nurse ^{12, 119}. If the patient has the expectation that his or her own experiences are needed in order to reach the goal - improved HRQoL, then it is necessary to understand the patient when he/she puts thoughts into words.

In the area of ICD treatment it has been determined that setting goals in terms of the patient having the task of familiarizing himself/herself with his/her situation, which is discussed with a knowledgeable nurse, within a certain time, is of great importance in supporting the patient's efforts to understand his/her new life situation ¹¹¹. However, health care professionals are not automatically proficient in setting goals. Berkowitz et al ¹²⁰ used goal formulation in connection with continued medical education and found that without special training, goals are often set that fall outside the individual's control and that cannot be evaluated or followed up, which impairs the patient's possibilities of attaining self-care

balance¹²⁰. This was also the case when the self-care program was tested by four nurses and 10 patients and changes were made before start of the intervention in order to improve understanding (IV) (Figure 10). Because the goals of the self-care program were formulated from a comprehensive patient perspective, it was also possible to evaluate and, when necessary, support the patient in the self-care program for the experimental group (IV).

Good patient education conveys ideas and skills that help patients cope with immediate medical and technological problems, maintain health and avoid disease. Patient education is increasingly important as hospital stays are shortened, elderly patients become more active health care consumers, and there is increased need to document informed consent for treatment^{121, 122}.

Continuous technological advances are being made in the area of pacemakers, and it is difficult to provide consistent high quality individualized patient education, and reimbursement is problematic. Computers may provide a solution as they have unique attributes for individualized, effective instruction including a variety of lessons controlled by the patient and the ability to accurately track the level of patient understanding in order to document informed consent¹²¹. In a study of heart failure patients, patients reported that the program was not sufficiently extensive and did not adequately clarify various aspects. Consequently, it might be a good idea to have two or more levels in the education program, ranging from basic to advanced, in order to satisfy heart failure patients¹²³. The ability of the computer to persuade as well as inform could help motivate the patient to live life as he/she did before pacemaker implantation. The unrealized potential of computer-based patient education makes clear the need for further research on how to effectively use this unique tool for patient education^{121, 123}.

The focus is currently on making patient education realistic, and basing it on the patient's length of stay and the self-care skills that will be needed^{119, 124, 125}. Suggestions for developing and evaluating both printed patient education materials and practical teaching are included in study IV and good results were obtained. A climate for promoting adult learning should take the physical and emotional needs of the learner into account. A problem-centred learning approach should be used in which the nurse relates educational material to the life situation and concerns of patients with pacemakers. These learning activities include opportunities for an exchange of ideas between nurse and patient and for applying what is learned in simulated or real exercises^{119, 124}. Study III confirmed the well-known finding that informants with pacemakers can impose restrictions on themselves as a result of their anxiety about experiencing dizziness or fainting when in the vicinity of electromagnetic fields such as store alarms, mobile telephones, and in connection with bad weather with thunder and lightning, which can be experienced as both uncomfortable and restricting. A number of studies have shown that this anxiety is unfounded¹²⁶⁻¹²⁸. Consequently, there is a need for more problem-centred learning and knowledge, as well as the ability to provide information in a correct way by taking each patient's habits and

physical capacity into account and ensuring that the patient can put this knowledge into practice in his/her daily life (III, IV) ^{12, 99, 129}.

Nursing and self-care

Internationally, there are many definitions or descriptions of nursing, but apart from the one given by the International Council of Nurses (ICN) there is no overall agreement ¹³⁰. In this thesis, the term nursing is used in relation to supporting and developing the patient's self-care abilities in order to manage daily activities as well as possible based on the patient's own prerequisites ¹³¹. This is also the basis for Orem's ⁴⁰ self-care theory, but prevention is an underlying concept; prevention of ill health is superordinate to the other two parts of the theory, self-care deficit and self-care capacity ⁴⁰ (Figure 3). Self-care encompasses the concrete measures the individual carries out in daily life and comprises behaviour introduced into the context of the individual's life, and self-care demands are also related to the situation in which the individual finds himself/herself ⁴⁰. This also emerged in studies I and II, where the majority of patients were elderly and approximately one third lived alone, but depending on a functioning social network and good family relations most experienced a sense of satisfaction in their lives. However, patients with pacemakers experienced their ill health differently, which could mean that elderly recovered patients could feel inadequate in different situations, i.e. in family life they had become a "heart patient", and when they were going to do similar tasks or the same tasks as before implantation they often got help they did not need. And despite the fact that they had recovered, they could have the same restrictions in their social life as before pacemaker implantation. In contrast, another informant in the same situation could feel he/she was recapturing life and could do everything he/she had done when healthy. Those who had not become ill acutely were quickly able to feel the return of a joy of living after a long period of medical examinations and investigations (III).

Since the underlying concept in the self-care theory is prevention, and people have unique common needs that must be met, the theory can also be seen as a theory of needs ^{132, 133}. It is the nurse's responsibility to evaluate the degree of nursing care needed by each pacemaker patient. The support nurses give to patients and relatives concerning pacemaker treatment and its consequences can be expected to increase and improve possibilities for self-care and the learning of self-care skills and prevent the occurrence of self-care deficits (IV). The shortening of hospitalization time for pacemaker implantation will reduce the already limited amount of time the nurse has for the psychological care of the patient and family. There is a danger that the two-way therapeutic relationship between patient and nurse will be lost in the constant endeavour to increase the flow of patients ¹³⁴. However, studies have shown that early discharge programmes for elderly patients result in earlier recovery ^{135, 136}. Other important benefits of shorter hospitalization times are a decreased risk for hospital-related

infections, shorter waiting times, and more effective use of the dwindling resources health care has at its disposal today²¹. Another initiative for supporting patients with CVD in attaining improved self-care is telephone support by which comprehensive information can be provided IV¹³⁷, and by which the nurse can give the increasingly older patients, who often live alone, the possibility of attaining increased understanding about their new situation. This kind of support will no doubt increase in coming years¹³⁸. Its benefits include the opportunity to reinforce health education, answer questions about physical problems, provide emotional and psychological care and, when appropriate, to refer patients with pacemakers to other departments/agencies such as cardiology, psychology, physiotherapy, or to primary health care. Studies in the primary health care sector have shown that nurse-led telephone consultations are effective with respect to understanding and dealing with the patient's problems¹³⁹.

However, training in telephone consultations with follow-up have demonstrated inadequacies in these consultations such as difficulties in talking with those who have communication problems due to impaired hearing, language difficulties, or if they have no telephone. Training and specific information is required to compensate for the fact that the nurse does not see the patient during the telephone conversation, since it has been found that in 2/3 of information in health care it is important that the nurse can observe the patient's condition, including such factors as paleness, posture and behaviour, in order to provide individualized patient education that is kind, supportive, safe and effective¹⁴⁰. The most important strategies for the nurse involve being clear about these deficiencies and being able to individualize the achievement of goals, planning in order to deal with possible obstacles, i.e. prevention (I, II, III), and being able to make revisions based on a comprehensive perspective.

In addition, evidence-based nursing will augment this approach by demonstrating a structured and logical approach to helping patients with pacemakers attain a self-care balance¹²⁴. If the patients are elderly but otherwise healthy, or younger with chronic illnesses, the nurse should obtain information that addresses their own situation. In this way good conditions are created for returning to the life that is made possible by pacemaker treatment. The goal is to live a normal life (III) by practicing self-care, with good HRQoL. Living a normal life means that the individual returns to the physical, psychological/spiritual, and socioeconomic life he/she was living before pacemaker implantation. To attain this goal, the standard for pacemaker treatment should be that health care professionals provide goal- and need-focused patient education where the physiological reasons for pacemaker implantation and the treatment measures are addressed in an individualized manner. In addition, a physiological test (the stair test) should be carried out where the patient is subjected to exertion similar to what he/she did normally prior to pacemaker implantation.

Methodological issues

The methodological design and the scrutiny of the studies can be discussed within the areas of applicability, validity and reliability based on a quantitative approach, and within the areas of applicability, reasonableness and trustworthiness based on a qualitative approach ¹⁴¹.

Applicability: In order to draw general conclusions based on study results, the patient selection should be representative of the population, and the selection is therefore of decisive importance with respect to the aim of the thesis and interpretation of the results ⁷⁶. In this thesis the samples were: a total population (II), randomised (I, IV), or participants were selected to achieve maximal variation (III) in order to obtain results that could be generalised. The first two studies (I, II) had a cross-sectional design which enabled data collection to be done without any great difficulty. The disadvantage was that changes in HRQoL over time did not appear in these cross-sectional studies. This could have been of interest, since the primary information about physiological pacing is based mainly on studies with 10-20 patients. In study II a large population was investigated regarding the normal everyday conditions of their daily life, and this provided new knowledge for use in the future treatment of patients with pacemakers. A considerable weakness in study I was the absence of a comparison group, which made it difficult to assess the results. Results from the QLI instrument were therefore compared with a reference group. The reference group consisted of patients who had received a pacemaker system due to catheter ablation, and the results showed that patients with pacemakers (I) have an equally good or better QoL compared with the reference group, confirming that patients with pacemakers have acceptable QoL.

In-depth interviews were conducted in accordance with grounded theory (III) with 13 informants, which is too small a number to be representative for other than the interviewed group. Nevertheless, the informants comprise a variation of experiences, which makes results of importance in a clinical context, such as the way informants are received, education and empathetic treatment. The results of the intervention study (IV) showed significant positive effects for participants in the self-care program, but they were nevertheless not totally convincing. Part of the self-care program was telephone follow-up on two occasions (at 1 month and 4 months). To provide better continuity with an increased sense of security and the possibility for better self-care balance, telephone follow-up can be increased so that patient are contacted by phone on two additional occasions (at 6 months and 9 months). At the same time, follow-up time that is 6-8 months longer could point towards significantly improved results for the experimental group as compared to the control group - with better HRQoL. When the risk for increased dropouts was considered, along with the demand for more participants and a longer study time, it was decided that the study was not feasible due to imposed time limitations.

In study IV one third of the patients with pacemakers were from the same area as

patients in studies I, II and III (Figure 5). A total of 1281 patients were included and 1104 patients participated in the study, for a dropout of 14%. None of the informants discontinued their participation in study III. If the response rate is high, the risk for serious response bias may be negligible. A response rate greater than 60% is probably sufficient for most purposes, but lower rates are common¹⁴². In Scandinavia today this rate is considered sufficient¹⁴³. According to Dillman et al.¹⁴⁴, response rates in large questionnaire studies have decreased by 10% in the past decade¹⁴⁴, which should mean that a rate of 80% (II) can be considered as good. In study III the mean age was 59 years, which is about 10 years younger than the age of patients in studies I, II och IV, and this can be seen as a weakness. On the other hand, however, patient access and being able to interview informants with an active social life were of great importance. One risk in using statistical methods is that of an α error, or the risk of obtaining false positive findings. In particular, the risk of an α error increases in line with the number of statistical analyses performed⁷⁶, as in the case of studies with an explorative design where numerous statistical analyses are necessary for the generation of new hypotheses. In an explorative study a balance has to be found between identifying the unknown that is relevant to the phenomenon under study and significant results due to α errors. To avoid getting type I α errors with false positive results, the significance level was set at 0.05, and to try to assure that false negative results (type II β errors) would not be obtained, a power analysis using 0.80 was carried out.

Study III was conducted using patients from the same area as in studies I and II. The informants with pacemakers were selected according to maximum variation sampling technique^{74, 97} in order to get as broad a range of informants experiences as possible, and they also had different levels of theoretical knowledge about pacemakers. Classical grounded theory emphasises the emergence of theory from empirical data by means of analysing the social processes within the area being studied⁸⁸. This writing can be considered abstract and theoretically difficult to understand, and therefore inaccessible to many readers. Strauss and Corbin reformulated and tried to demystify classical grounded theory⁷⁴, and consider the theory to be a construct co-created by the researcher and participants, while Glaser believes that theory emerges from the actual data¹⁴⁵. The difference between the ideas in Strauss and Corbin's⁷⁴ text and the original theory development lies in the way in which concepts are generated and relationships explained⁸⁸. They also introduced new procedures for analysing data such as axial coding, dimensionalizing and conditional matrix with the aim of making the resulting theory more dense, composite and exact. Hartman¹⁴⁶ considers that the large differences between the original grounded theory and Strauss and Corbin involve the openness with which the researcher studies his/her problem area, management of data analysis, how faithful the researcher is to the empirical data, and how theory is allowed to develop or is forced into the matrix¹⁴⁶. Charmaz¹⁴⁷ suggests a constructivist version of grounded theory that builds upon the theses of ontological relativity. This means that the researcher should seek the real nature of existence based on the picture

subjects have of reality rather than seeking the truth, and constructionists commonly assume that humans do not have direct access to a singular, stable, and fully knowable external reality⁸⁵. Since the systematisation of grounded theory in accordance with Strauss and Corbins⁷⁴, a more easily accessible and, for many, possibly more credible use of the method has come to hand. This can result in the use of the method by more so-called quantitative researchers who will obtain in-depth knowledge about the psychosocial life of informants.

Validity and reasonableness: This is the second important criterion for evaluating the adequacy of what is being measured; validity shows the degree to which the instrument measures what it is intended to measure¹⁴². Content validity is affected if the questions are unclear and if it is difficult to choose between different responses. The content of the questions in the LPQ instrument was therefore tested on 10 patients, as well as on six cardiac nurses and four cardiologists. Finally, the construct validity was confirmed by rotated varimax factor analysis, where seven factors emerged with loading > 0.40 (0.43-0.93), and with Eigenvalues > 1.0, explaining a total variance of 58.5% and with the remaining 41.5% due to possible additional common factors besides those seven and/or measurement errors. This construct validity was satisfactory but it also indicated the need for further development. The other seven well known and generally recognised instruments were tested and they had good content and construct validity. It is known that patients with pacemakers constitute an older but relatively healthy population, and this affects the ability of the instruments to verify positive and negative findings. QLIs have been criticised for having less sensitivity than other instruments regarding health states, but they have a good ability for agreement regarding changes in scores over time for serious conditions like cardiac arrhythmias and heart failure^{97, 148, 149}.

The PGWB has identified primarily through its relationships with negative conditions rather than conditions indicating more positive life events⁹³, and it is not oriented solely towards discriminating psychiatric cases from healthy individuals. It is possible that the EQ-5D is too blunt an instrument to be able to detect small differences between the experimental group and the control group as a result of the self-care program. Additional studies have also shown that the EQ-5D is less sensitive to health states than other instruments, and there is poor agreement regarding a change in scores over time^{150, 151}. Consequently, a significantly better HRQoL was found in the subgroups in terms of experiencing the symptoms that were the reason for pacemaker implantation as having decreased or disappeared, and a higher level of perceived exertion in the one and a half minute stair test compared with the patients who had standard checkups, but the PWBG and the EQ-5D were not able to discern any significant changes in HRQoL between the experimental group and the control group in study IV. This indicates that in similar studies more specific instruments should be used in order to clarify the results of treatment.

The different perspectives of gender, age, educational level and the course of events in connection with pacemaker implantation affect the interview results

(III). In order for the experience to emerge as deeply and extensively as possible through a small number of interviews, a strategic patient selection is required⁷⁴. Semi-structured interviews, followed by additional interviews, were chosen for the data collection (figure 9). Grounded theory involves alternating between data collection, analysis and verification of categories⁷⁴, which implies confirmed concordance. The content of the interviews and the categories correspond to the researchers' understanding of what the informant situation is in reality. The researcher has a large amount of theoretical and clinical knowledge of many years duration in the world of pacemakers, and the co-researcher commands both professional and methodological knowledge, which strengthens the security of the analysis. The categories that needed saturation were supplemented with data that had already been collected, or by collecting new data. When the categories were saturated after 10 interviews, another three interviews were then performed in order to confirm that all conceptual holes and gaps in the developed model were filled, and this also increased the reasonableness in the study.

Reliability and trustworthiness: This involves how well the instrument measures the characteristics it is designed to measure¹⁴². If reliability is affected by chance, the instrument's trustworthiness is affected in that the number of points the patient gets, for example, is not in accord with the patient's true number of points, but also that the information within the instrument is not in accord. This is due to flaws in the reliability of the instrument. To strive for a reliable instrument and to decrease the risk that the instrument measures incorrectly, the homogeneity (internal consistency) can be checked. Cronbach's alpha is one of the most frequently used methods for testing internal consistency and showing how a number of questions in an instrument work together in the study of a particular phenomenon or characteristic. An acceptable level of Cronbach's alpha should be greater than 0.70¹⁴², which would mean, for example, that if the reliability coefficient were .85, then 85% of the variability in obtained scores could be said to represent true individual differences, and 15% of the variability would reflect random, extraneous fluctuations. Cronbach's alpha values in this thesis (0.87(I), 0.75(II), 0.72+0.94 (IV) indicate that there is an acceptable level of internal consistency or homogeneity.

Because indirect methods of measurement were used in the form of instruments (I, II, IV) or in-depth interviews (III), the results are consequently dependent on how the patients functioned as informants - whether they wanted to provide exact descriptions. Since patients seldom have anything to win or lose in such situations, it is assumed that they answered honestly and gave a true picture concerning what they were asked about. Experience has shown that when participating in studies where HRQoL is addressed in relation to medical treatment, patients are without exception eager to help in attaining scientific knowledge¹⁰¹. This also indicates a high level of reliability.

In the grounded theory method (III) the process of analysis is carried out in parallel with interviews, and is repeated in a constant comparing analysis, in

which concepts and categories of concepts are compared with one another until saturation is attained ⁷⁴, which is termed confirmed concordance. The risk for wrong interpretations (III) can be considered minimal since the main researcher tape-recorded all the interviews, and then listened to and transcribed them. In each interview situation it is up to the researcher to achieve good contact with the informant in a short period of time so that the interaction is more than a polite conversation. To obtain good contact, the researcher must create an atmosphere in which the informant feels secure enough to talk freely about his/her experiences and feelings. With this in mind the interviews were carried out in the informants' homes, and they began with conversation concerning everyday matters in the respondent's life as well as an explanation about the aim of the interview. The main researcher was a cardiac nurse with pacemaker knowledge experienced in talking with informants and he achieved good contact by listening attentively, and showing interest, understanding and respect for what the informant said. In addition, all interviews were concluded with a follow-up question by the main researcher. This gave the informant an opportunity to raise questions that had not come up during the interview or that he/she had not thought about previously.

Generalisability: The use of multiple methods, or triangulation, reflects an attempt to secure an in-depth understanding of the phenomenon in question. Objective reality can never be captured. A thing can be known only through its representations. Triangulation is the process by which several methods (data sources, theories, data collection, researchers or analysis) are used in the study of one phenomenon ⁸⁸. For the first time, studies including intervention and a constant comparative method have been used in patients with pacemakers; the results comprise a large amount of data, and the different methods have together provided a greater breadth and depth of understanding concerning the daily life of these patients. The thesis shows that patients who undergo a self-care program have significantly improved mental and physical HRQoL and they can attain emotional and social rehabilitation under the condition that there is understanding, empathetic treatment and insight concerning the patients' new situation. The basis and the prerequisite for valid results and the possibility for generalisability is correct selection with adequate methods, and therefore the data were collected in cross-sectional (I, II), randomised, experimental (IV), constant comparative (III) studies using quantitative and qualitative methods. The data collection methods that were used were instruments (n=1091), which gave broad information focusing on HRQoL, and in-depth interviews (n=13) that shed light on the daily lives of patients with pacemakers from a deeper perspective. The researchers included a cardiologist, a psychologist, a biostatistician, a cardiac nurse and a cardiac nurse with pacemaker knowledge in order to use different perspectives in the hope of assuring a correct course of action. Different theoretical approaches were used to shed light on the patients based on a comprehensive perspective where the instruments were focused on: the elderly (PGC-MAI); pacemaker treatment (LPQ, SCOP); CVD (QLI), physical

ability (exercise test); emotional-physical-social well-being (PWBG, EQ-5D). By using the different instruments, the possibility of triangulation emerged as a way of confirming data from a source with the help of another source and discovering conflicts between them.

In summary, by means of all the different methods in this unique material it was found that the self-care program is representative for the treatment of patients with pacemakers in the general European and American population where there are nurse-led pacemaker clinics.

CONCLUSIONS

- The health-related quality of life among patients with pacemakers was at least as good as that of patients with pacemakers as a treatment after catheter ablation due to AF.
- Measures should be taken on behalf of women, single persons, those who are very old, retired persons, and blue-collar workers, all of whom have a lower health-related quality of life.
- Patients with pacemakers can attain emotional and social rehabilitation under the condition that they encounter understanding, empathetic treatment and insight concerning their new situation.
- Older but otherwise healthy patients, and younger patients with chronic illnesses should get information that addresses their own situation in order to return to a normal life made possible by pacemaker treatment.
- Patients with pacemakers should be actively included in a self-care program while still hospitalized and in the acute phase.
- The self-care program improves HRQoL in that the symptoms that resulted in pacemaker implantation decrease or disappear and for men a high level of physical exertion according in a 1 1/2 minute stair test compared with patients who had standard checkups.
- Training and continued education for health care professionals is necessary so that their efforts will be based on the patient perspective.

IMPLICATIONS

Clinical implications

More emphasis should be placed on increasing opportunities for physical activity such as daily walks and dancing, or any activities that patients with pacemakers enjoy and feel motivated to participate in, keeping in mind that many of them are old, single and retired. An important initiative would be telephone support, possibly once every month for the first year, when everyday issues can be discussed, such as the effects of the electronics that surround patients daily, like theft alarms in stores and mobile telephones, as well as medical treatment and physical activities - everything that can create anxiety and doubt about a normal psychosocial life. After a year, the telephone support was discontinued and the patients were requested to contact the pacemaker nurse whenever necessary. The importance of physical activities for the elderly is urgent, and self-care abilities in patients with pacemakers may be reinforced by the self-care program and physical training with the stair test, rather than simply informing them about the importance of patient education and exercise training. Patients with pacemakers can attain emotional and social rehabilitation by actively participating in a local heart-lung association for patients, and social rehabilitation by taking part in activities like language courses, genealogy, bowling and golf. Training and continued education for health care professionals is required so they can support the patient and family by providing clear and relevant information in a kind, professional manner, and plan a self-care program based on a professional assessment of the patient's needs.

Research implications

The findings in this thesis revealed that self-care program and a strenuous physical test resulted in significantly improved health-related quality of life. But to understand why the self-care program was not as effective for women, patients with AF/SND, and those with VVI/R systems, qualitative studies of men and women in separate groups should be conducted, with more questions about heart rhythm and one and two-chamber systems. It could be that the self-care program for women should focus more on emotional and social aspects, since it has been found that effective pacemaker function may depend, in part, on the patients' successful emotional attachment to the device. In order to understand and counteract psychosocial restrictions, family support is also of great importance. Therefore family members of both sexes and of different ages should be included and compared in quantitative and qualitative studies to obtain increased understanding about the way they deal with the patient's and their own psychosocial situation.

Another target group that should receive greater attention in research comprises children with pacemakers and their families. These patients want to be able to play, run and bicycle just like other children, but many are restricted and run the

risk of feeling like outsiders. Further research involving surveys and in-depth interviews is needed to delineate the level of physical activity required for both elderly and young patients with pacemakers in order to enhance their self-care possibilities in their daily lives. When these questions have been answered, it would be of interest to improve the self-care program with respect to self-care effects and good HRQoL for all patients with pacemakers, and then to conduct further studies to evaluate the long-term effects of such programs.

More research is needed to develop and test a general instrument with a psychosocial focus that can, by means of a small number of questions, guarantee the quality of care the patient is offered.

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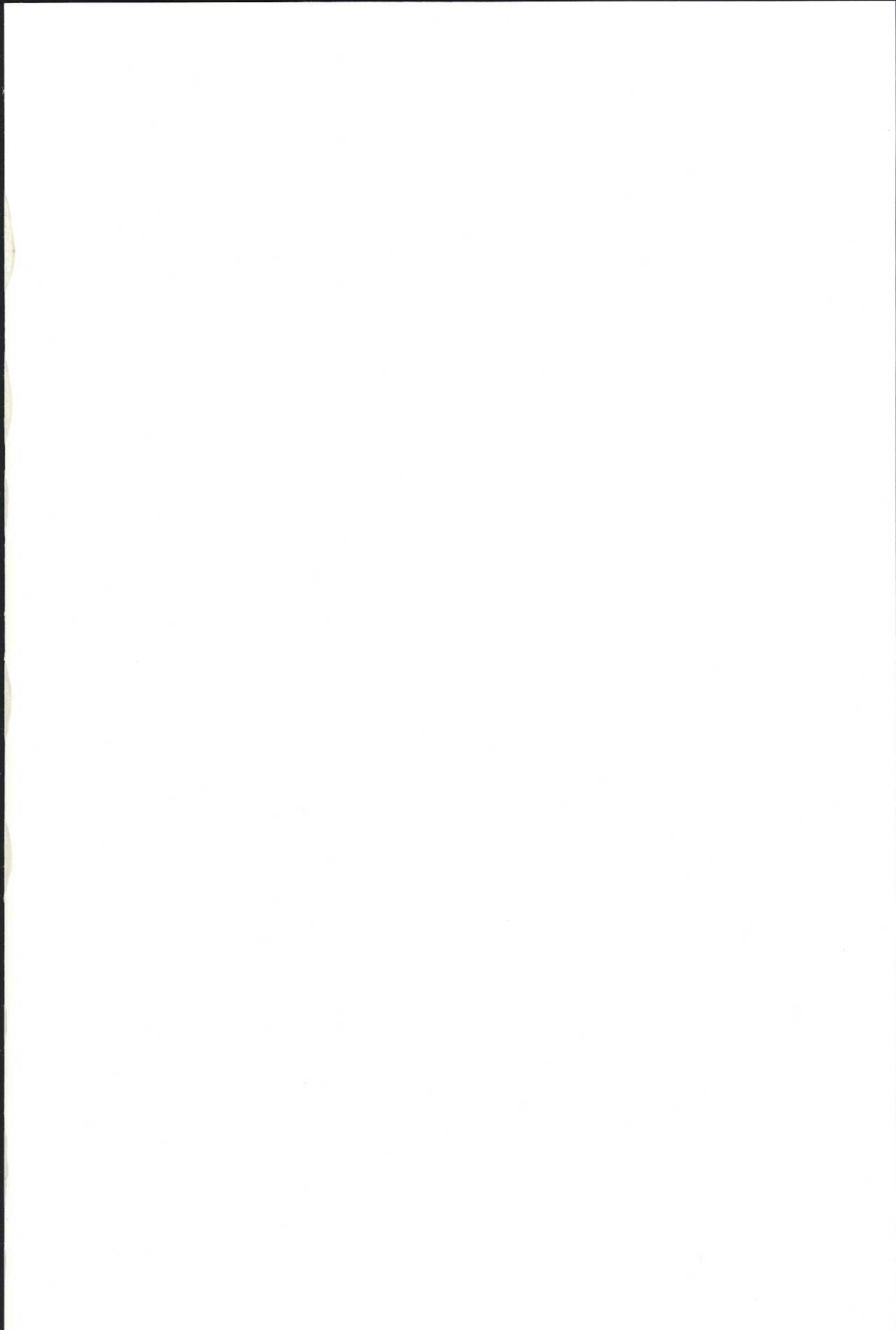
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