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Factors influencing patient recovery following pacemaker implantation

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# FACTORS INFLUENCING PATIENT RECOVERY FOLLOWING PACEMAKER IMPLANTATION

by

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DISSERTATION

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# FINAL REPORT FOR DNS

TO: The Dean of the Graduate Division

The Committee in charge of the dissertation for the degree of Doctor of Nursing Science of Jane G. Wilson
Candidate's Name
reports that the candidate has submitted a dissertation in proper form. This disssertation has been approved by the Committee. It therefore recommends to the Graduate Council that the degree be conferred.

Jeanne C. Hallburg — Feb. 14, 1983
Chairman — Date

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# ABSTRACT

The purpose of this study was to identify variables which might predict patient recovery following pacemaker implantation. Recovery six months following implantation was measured by resumption of presymptom work, social and leisure activities and subjective distress. Subjective distress was computed from the Anxiety and Depression scales of the Multiple Affect Adjective Check List (Today Form) (MAACL). Health perception and subjective distress preimplant and one month postimplant were selected as independent variables because they had the potential for suggesting interventions to facilitate recovery.

Data were obtained from patient interviews, the MAACL and the Current Health scale of the General Health Perceptions Questionnaire, and the patients' medical records preimplant and at one and six months postimplant.

Of the 102 patients followed for six months, 66 completed the MAACL. Seventy per cent of all patients reported that they had been able to fully resume presymptom activities by six months without major modifications. Only 15 per cent of the patients who completed the MAACL reported mild or moderate subjective distress pre- or postimplant. As a group, the patients tended to have a less positive perception of their health preimplant. By one month postimplant, their health perceptions were similar to those of the normative samples.

After controlling for the variance in clinical status, activity resumption was related to health perception at six months, for all patients ($p < .05$) and to subjective distress, for symptomatic patients only, ($p < .01$) at one month. It was not related to preimplant subjective distress or health perception prior to implant or at one month.

Subjective distress at six months was related to subjective distress preimplant ($p < .01$) and at one month ($p < .01$), and to health perception at one month ($p < .05$) and six months ($p < .01$). Age and gender did not influence the above relationships.

Preimplant subjective distress and health perception offer few clues to eventual patient recovery, but assessment of these variables at one month should assist in identifying patients "at risk" for less than optimal recovery following pacemaker implantation.

Jeanne C. Hallburg

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The patients who so willingly shared their experiences with me can never be repaid. I only hope that the finding of this study and my

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future research efforts can make some small contribution to improving the care that they receive.

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# Chapter I

# INTRODUCTION

The focus of this study was patient recovery following pacemaker implantation. The relationships between a number of demographic, clinical and psychological variables and patient recovery were explored in an attempt to identify one or more variables which might be helpful in predicting patient recovery and in giving direction to clinical interventions to optimize recovery. The variables which were considered in this study had been identified in previous studies of patient recovery following pacemaker implantation, myocardial infarction and/or cardiac surgery.

The study was stimulated by the investigator's observation that, while most patients who had pacemakers resumed their previous work, social and leisure activities without significant emotional distress about their health or the pacemaker, there were some patients who limited their activities to a greater extent than was necessary out of fear and worry about their health or the pacemaker. The investigator was not always able to predict which patients might have unfavourable reactions. If the factors which influence patient recovery could be identified then patients who were "at risk" for less than optimal recovery might be identified. Additionally, it was hoped that the identification of the variables impacting on recovery would suggest clinical interventions to facilitate patient recovery.

Any study on patient recovery following pacemaker implantation must be viewed from the perspective of the "state of the art" of cardiac pacing. The widespread clinical application of cardiac pacemakers to stimulate and/or alter the rate of myocardial contraction is a relatively new development in the long history of medicine. The first fully implantable pacing system was developed in 1958 by Elmquist and Senning in Sweden (Thalen, 1979). During the subsequent 25 years, there have been rapid advances in pacing technology resulting in smaller pacemakers, containing complex circuitry, powered by relatively long lasting power sources. The introduction of simple rate and output programmability in 1972 and multiprogrammability in 1979 allowed for noninvasive adjustment of pacemaker parameters to meet the specific needs of each patient. More recent developments include pacemakers which are able to achieve AV synchrony and physiologic rate responsiveness and pacemaker telemetry which allows for noninvasive assessment of the pacing system status.

Along with the changes in technology, over the past 25 years there have been changes in the population of patients being paced. The fixed rate pacemakers of the early 1960's were most appropriate for patients who had complete heart block. Developments in technology, including the availability of dual chamber demand pacing system, longer lasting power sources, and greater lead stability, have made cardiac pacing the intervention of choice for patients with a wide range of cardiac conduction abnormalities. As with any new development in the health field, pacemakers were initially used on a highly selected population of patients who had clearly life threatening arrhythmias. This is no longer the case. Data from the World Survey on Cardiac Pacing presented at the VIth World Symposium on Cardiac

Pacing in 1979 indicated a steady increase in the incidence of pacemaker implantation. In Canada, the implantation rate increased from 113 per one million population in 1976 to a rate of 170 per one million in 1978. In the United States, the 1976 rate was 278 per one million with an increase to a rate of 310 per one million in 1978 (Goldman & Parsonnet, 1979). Canadian data which were just gathered for the years 1979 through 1981, indicated a continued increment in the rate of implantation to 220 per one million population or 5369 new implants in Canada in 1981 (Goldman, Duncan & Wilson, submitted for publication).

In 1979, the average age of the patients at the time of initial implant was 67 years in both Canada and the United States (Goldman & Parsonnet, 1979). In the most recent Canadian survey, the average age at initial implant was still 67 years with slightly more men than women being included in the patient population. Syncope and presyncope were the most frequently reported preimplant symptoms (Goldman, Duncan & Wilson, submitted for publication).

Originally, pacemakers were implanted primarily for the treatment of complete AV block. They are now being used to treat a wide variety of conduction disturbances as indicated by the most recent Canadian data which revealed that only half of the pacemakers implanted between 1979 and 1981 were for first, second or third degree AV block. Thirty-eight percent of the patients had sinus node disease while the remaining 12 percent had a number of other conduction abnormalities. Although they are not yet widely used in Canada, pacemakers to control tachyarrhythmias are currently being developed and tested.

For many patients, the pacemaker is a lifesaving treatment. In 1978, Furman reported the survival rate for his series of 1,560 patients who received pacemakers between 1962 and 1976. The patients had a poorer survival rate than the general population (adjusted for age) in the early postimplantation period. In the first year, 14 per cent of the patients died. In the second and third years, 9 per cent died each year and thereafter about 5 per cent died each year, paralleling the statistics of the general population. About two-thirds of the patients were alive at the end of three years and more than half of the patients survived for more than five years. A recent five year follow up of patients who received pacemakers at the Toronto General Hospital in 1976 indicated that 65 per cent were alive five years later (Goldman, Wilson, Duncan & Noble, in press). The increased survival rates probably reflect improved pacer technology, advances in related medical therapies such as the use of medications, as well as the differences in the patient population.

Patients undergoing pacemaker implantation often have other chronic health problems. Furman (1978) reported that over a two year period (1975-1977), 10 per cent of the patients in his series were hospitalized each year for nonpacemaker related health problems. The total incidence of hospitalization for cardiac (pacer and nonpacer related) problems was not given, but Furman noted that in the two year period, 40 per cent of all hospitalizations were cardiac related with one-half of those being for congestive failure and one quarter for acute myocardial infarction. An additional eight per cent of the hospitalizations were for vascular lesions including major and minor cerebral vascular accidents.

Rossel & Alyn (1977) reported that only five of the 30 patients in their sample had met and talked with someone else who had a pacemaker. There is an increased likelihood that the patient undergoing a pacemaker implant today will know someone who already has one because of the increased number of individuals having pacemakers. In fact, almost all of the patients interviewed for this study knew someone else with a pacemaker. Today, prostheses to replace damaged joints, transplantation of human organs and the use of mechanical life supports, such as dialysis, are not uncommon. At the same time, the general public has become increasingly sophisticated about these medical advances since they usually receive widespread publicity in both the print and broadcast media. The personal contact, coupled with the increased sophistication of the general public about new medical technology, means that patients undergoing pacemaker implantation today usually have, at least, a vague idea of what a pacemaker is and what it does.

In summary, rapid advances in the technology for and the clinical applications of cardiac pacing have been made over the last 25 years. More and more patients with cardiac arrhythmias are being treated with pacemakers. Although the population tends to include a significant number of older individuals, many of whom have chronic health problems, a substantial proportion of the patients survive five or more years following the implantation of a pacemaker.

The extant research on patient recovery in terms of the patient's ability to resume activities and participate in a meaningful and satisfying life, is limited. This literature will be reviewed in chapter 2. Much of the research was done in the 1960's and early 1970's prior to many of the recent changes in pacing technology. The findings are frequently descriptive and do not clearly point toward possible interventions to optimize patient recovery. This study of factors influencing patient recovery was undertaken in order to address some of the limitations in the previous research.

In this prospective study, 102 patients were interviewed before implantation and at one and six months following surgery at assess current cardiac symptomatology and general health status as well as activity level. Questionnaires to assess subjective distress and perception of health were administered at the time of each interview. Only 60 percent of the patients were able to complete all questionnaires. Demographic and selected clinical data were retrieved for each patient from the computerized patient database maintained in the Pacemaker Center.

The data were analyzed to establish the association between the independent variables, subjective distress and perception of health prior to implant and one month postimplant, and the outcome variables, the resumption of presymptom work, social and leisure activity and subjective distress at six months, after controlling for the effect of the clinical status of the patient. The possible interactive effect of patient age and gender on the association between the independent and dependent variables was evaluated.

Interactionist-role theory was used as the theoretical perspective in the process of developing the study and interpreting the data.

The remainder of the dissertation will describe the study and findings in detail. Chapter II presents a review of the literature on patient recovery following pacemaker implantation along with a review of selected studies on patient recovery following myocardial infarction and cardiac surgery. In chapter III the interactionist-role perspective is introduced, and the problem focus of this study is discussed from this theoretical perspective. The operational definitions and specific research questions guiding this study as addressed in chapter IV. Chapter V includes a detailed discussion of the data collection instruments and procedures and the transformations made in the data prior to analysis. The findings are presented in chapter VI and discussed in terms of previous research and the theoretical perspective in chapter VII. The summary and conclusions including the limitations of the study and implications for nursing are included in chapter VIII.

# Chapter II

# LITERATURE REVIEW

Two bodies of literature were reviewed as a foundation for this study. The literature on recovery following pacemaker implantation was reviewed in order to gain an understanding of what was currently known about the extent of patient recovery following pacemaker implantation and the factors affecting that recovery.

The literature on recovery following myocardial infarction and cardiac surgery was reviewed with two purposes in mind: 1) to gain further insight into the operational definition and measurement of patient recovery outcomes and 2) to identify one or more antecedent variables which, if found to have significant correlation with patient outcome following pacemaker implantation, might suggest intervention(s) to optimize patient recovery. Although the population of patients undergoing pacemaker implantation differs from that of patients who have had a myocardial infarction and/or cardiac surgery, particularly in terms of demographic variables and the extent of previous cardiac problems, the populations do have many similarities. All of the patients have to cope with a diagnosis of heart disease which is frightening and anxiety provoking because of the special, often symbolic, importance placed on the heart in our society.

## REVIEW OF PACING LITERATURE

The literature on patient responses to the implantation of a pacemaker is relatively limited when compared to the vast literature on the technical aspects of cardiac pacing. This literature can be characterized as having three primary thrusts: first, a description of the various responses observed; secondly, an analysis of the extent of resumption of activities and emotional reactions and finally, an exploration of factors which might possibly be related to patient responses.

## RESPONSES TO PACEMAKER IMPLANTATION

It is anticipated that, following a pacemaker implantation, the patient should be able to resume all, or at least most, of his previous work, social and leisure activities. Few, if any, modifications in life style are required because of the pacemaker itself, although the underlying cardiac disease may require some changes or modifications. It is also hoped that the patient will not experience significant negative emotional responses, such as anxiety, depression or worry about the pacemaker or its function.

A variety of approaches have been used to define and measure the patient's responses to pacemaker implantation including: interviews (Becker, Zucker, Parsonnet & Gilbert, 1968; Greene & Moss, 1969; Rossel & Alyn, 1977; Goble, Gowers, Morgan & Kline, 1978a, 1978b) and standardized testing of psychological and mental status (Crisp & Stonehill, 1969; Lagergen, 1974; Laforet, Sidd & Waterman, 1974; Rodstein, Zarit, Savitsky & Goldfelder, 1977; Romirowsky, 1978).

Previous researchers have noted the difficulties inherent in attempting to define, describe and/or measure patient responses, including: the diversity in the ages of the population (although many of the patients are older), the possible impact of other chronic health problems on the outcome, and the problems of attempting to measure affective responses. Nonetheless, a review of previous studies does lead to a beginning understanding of patient responses following pacemaker implantation and possible factors impacting on patient outcome.

Activity resumption. Becker et al. (1967) reported that all 26 (14 of whom were women primarily involved in full time housekeeping) of the 78 patients in their series who has been working prior to implantation were able to resume their previous occupational activities after surgery. In contrast, Rossel & Alyn (1977) noted that of the 14 patients in their sample, who had been employed prior to implantation, only seven or 50 per cent had been able to return to employment. The authors commented that return to work seemed to be related, at least to some extent, to the type of employment which the patient had had prior to surgery. Although some of the patients in the Rossel & Alyn sample experienced difficulties in resuming previous occupational activities, 77 per cent of all patients in their sample described their lifestyle as "improved" following implantation since they were better able to carry on with housework, shopping, hobbies, traveling and self care.

While not specifically addressing the issue of return to work, Greene & Moss (1968) reported that 80 per cent of the patients had increased activity and 72 per cent demonstrated improved self care activities in the period from one to six months postimplant. This finding is congruent with the findings of Becker et al. (1968) cited above.

A less favourable picture was presented by Romirowsky (1978). In comparing a sample of men with pacemakers to a sample of men who had undergone coronary bypass, he concluded that the patients who had had a pacemaker implanted were more likely to self restrict their social and leisure activities than the patients who had undergone coronary bypass. Data on resumption of employment activities were not included in this study.

Psychological responses. In an early study, Greene & Moss (1968) observed that increased mental acuity followed the resumption of adequate cardiac output and cerebral blood flow after pacemaker insertion. This clinical observation was substantiated by the findings of a statistically significant reduction in confusion, as measured by the Profile of Moods Scale, following pacemaker implantation (Laforet, Sidd & Waterman, 1974) and a direct relationship between patient scores on a battery of psychometric, perceptual and psychomotor tests and the pacemaker rate setting (Lagerhan, 1974).

Some researchers have concluded that patients who have pacemakers experience increased emotional distress. Crisp & Stonehill (1969) reported that the 120 patients whom they evaluated scored significantly higher on the Anxiety, Phobic, Somatic and Depression scales of the Middlesex Hospital Questionnaire, a standardized index of psychoneurotic symptoms, than did the normative sample. A similar finding was reported by Romirowsky (1978) who concluded that patients who had had pacemakers implanted demonstrated more anxiety and inability to express aggression as measured by standardized tests than a comparison group of patients who had undergone coronary bypass surgery. Belanca (1977) in Italy and Payk-Rablaff & Payk (1978) in Germany also noted the presence of emotional disturbances in, at least, some patients following pacemaker implantation.

The above findings might lead one to conclude that there is a high incidence of emotional distress in patients who have undergone pacemaker implantation, but 70 per cent of the 78 patients followed by Becker and his colleagues (1967) and 81 per cent of the 96 patients followed by Price, Obel & Scott-Millar (1980) were judged to have "normal" emotional responses to the pacemaker.

Global recovery. The recovery assessment in the study by Goble et al. (1978a, 1978b) encompassed both activity resumption and psychological responses. Twenty per cent of the 61 patients in this study were judged to have a "disappointing" recovery, 64 per cent a "qualified success", and 16 per cent were judged to have had an "outstanding" recovery. This relatively positive view of the extent of patient recovery was supported by the observation by Blacher & Basch (1970) that, while the pattern of psychological adaptation following pacemaker implantation varied from individual to individual, eventually, most patients were able to integrate the pacemaker into their daily lives and resume previous activities.

Summary. Thus, while it appears that mental acuity increases and confusion decreases following pacemaker implantation and the restoration of adequate cerebral blood flow, the extent of resumption of activity and the emotional response is variable. Investigators in the United States, Great Britain, Italy and Germany have all found that, at least, some patients experience increased anxiety, depression, conflict about loss of control, increased somatic complaints and inability to resume presymptom activities following pacemaker insertion. Such adverse emotional responses would appear to occur in about 20-25 per cent of the patients.

## FACTORS RELATED TO THE PATIENT'S RESPONSE

Since the patient response to pacemaker implantation varies, with some individuals apparently having more difficulty in adjusting to the pacemaker than others, it would be helpful to be able to predict which patients are more likely to experience problems postimplantation. The literature to date, while not conclusive, does give some clues to possible factors influencing the recovery process. In one of the first studies done, Greene & Moss (1969) identified the following factors which they felt influenced patient adjustment: general physical status, including the presence of nonpacemaker related health problems; duration of symptoms prior to implant; adequacy of pacemaker function; social resources; adjustment to previous prosthetic devices such as glasses, hearing aids, and artificial limbs; and personality style. They did not find the age, gender or socioeconomic status of the patient to be important factors in the outcome.

Clinical status variables. Several of the clinical status variables identified by Greene & Moss (1969) have received support in subsequent research.

It has been suggested that patients who have had symptoms for only a short period of time prior to implantation are more likely to have difficulty adjusting to the pacemaker (Greene & Moss, 1969; Romirowsky, 1978). The increased emotional distress is thought to result from the patients with short symptom histories needing to adjust to the diagnosis of a cardiac illness at the same time that they need to adjust to the pacemaker.

The relationship between the severity of preimplant symptoms and postimplantation responses has not been addressed in the literature, although Rossel & alyn (1977) noted that those patients with more severe symptoms which interfered with activities were more likely to seek medical attention quickly.

The adequacy of pacemaker function and the lack of complications as influencing factors in patient recovery seem to follow logically. Greene & Moss (1969) noted increased distress in the patients who had unanticipated complications. The need for pulse generator replacement, which might be anticipated, did not engender the same distress. Similarly, in Rossel & Alyn's (1977) study those patients who had experienced a number of complications or problems were more likely to have negative feelings about the pacemaker. In contrast, Crisp & Stonehill (1969) found that the patient's ratings of the "troublesomeness" of the pacemaker and pain were not significantly associated with levels of anxiety, depression or phobic responses on the Middlesex Hospital Questionnaire.

Psychological variables. The degreee of social support, while potentially an important variable in the process of patient adaptation following pacemaker implantation, has not been addressed in the literature except for the study by Galligan (1973). She reported that the degree of compliance with instructions for postimplant care was strongly related to variables "suggesting a supportive environment". The response to other prosthetic devices identified by Greene & Moss (1969) as a factor influencing outcome has not been discussed in subsequent studies, but their conclusion that the personality style of the patient may impact on outcome has been explored by other researchers. The finding of Goble and his colleagues that those patients who demonstrated higher levels of anxiety on the IPAT Anxiety Test (1978b) and greater "difficulty in establishing and maintaining mutual personal relationships as the result of personal disturbance", as measured by the Foulds PD Scale (1978a) preoperatively were more likely to have poorer outcomes at six months postimplant would support the suggestion by Greene & Moss that underlying personality patterns are reflected in the patient's adjustment to the pacemaker.

There is a suggestion in the literature that denial may be one of the mechanisms by which patients attempt to cope with anxiety about the pacemaker. Crisp & Stonehill (1969) noted the frequent and effective use of denial as a defense against anxiety by the patients in their study. Becker et al. (1967) also commented on the use of denial by 14 of the 78 patients whom they followed although they did not relate the use of denial with the extent of patient recovery.

Demographic variables. The findings regarding the influence of demographic variables are inconsistent. Among the studies which addressed the influence of these variables, Greene & Moss (1969) did not find a relationship between age, gender or socioeconomic status and patient outcome. In contrast to these findings, Crisp & Stonehill (1969) and

Rossel & Alyn (1977) found that younger patients experienced more anxiety, depression and negative life style changes. The latter researchers also described women as being more disappointed with the pacemaker.

Summary. A study done by Price, Obel & Scott-Millar (1980) in South Africa is the most recent report on patient responses to cardiac pacing. The findings of this study lend further support to some of the findings in the previous literature. In their sample of "urban white patients", most patients were able to resume previous employment and recreational activities following pacemaker implantation. Those patients who had ancillary health problems, shorter duration of symptoms or who had demonstrated higher levels of depression, as rated by the Hamilton rating scale, preoperatively were more likely to have more problems in the postimplant period.

A number of variables which might potentially influence patient outcome following pacemaker implantation have been identified in the literature. There appears to be general agreement that adequate pacemaker function and the lack of complications are positively related to patient outcome and that the patient's underlying personality will be reflected in his response. Denial of the severity of illness and the pacemaker itself has been identified as one way in which patients do cope with the anxiety engendered by the pacemaker. The findings related to the duration of symptoms seem to point to the possibility that the patients who have had symptoms for a short time will have more difficulty adjusting to the pacemaker. The findings related to the demographic variables of age and gender are inconsistent. The variable of social support identified by Greene & Moss in 1969 as significant has not been included in subsequent studies.

## CRITIQUE OF PREVIOUS STUDIES AND GAPS IN KNOWLEDGE

There are a number of limitations in the previous research studies which mean that any conclusions (such as the ones in the above summary) should be considered as tentative ones. The earliest reports by Becker et al (1967) and Greene & Moss (1969) include all of the patients who had undergone pacemaker implantation in the specific institution up until the time of the reports, but this complete representation of the total population has not been possible in later studies. Some researchers (Crisp & Stonehill, 1969; Goble et al., 1978a) were able to select subjects in a consecutive manner, while Price, Obel & Scott-Millar (1980) indicate that they randomly selected the patients for their study from among all patients having pacemaker implantation over 16 months.

Goble et al. (1978a) and Price, Obel & Scott-Millar (1980) followed patients for six to twelve months after surgery, but they did not discuss attrition from their samples. The experience of this investigator in attempting a six month follow up study, along with the usual survival statistics for patients undergoing pacemaker implantation, would make it seem unlikely that there were no patients lost from the original cohorts.

Blacher & Basch (1970), Rodstein, Zarit, Savitsky & Goldfelder (1977), Rossel & Alyn (1977), and Romirowsky (1978) did not give a clear indication of how their samples were selected out of the population of patients available to them. Romirowsky's sample is particulary biased since it included only male subjects.

Thus, the first limitation in the previous research is the lack of clarity in the descriptions of the study samples. Consequently, the reader is unable to determine the generalizability of the findings.

Secondly, the conclusions drawn by most of the researchers tend to focus on the relationships between single antecedent variables and outcome rather than considering the possible interrelationships and interactions among the antecedent variables and patient outcomes. The studies have tended to be descriptive with limited use of statistical analysis, such as multiple regression and correlation, to clarify the relative significance of the associations between the individual antecedent variables and outcomes.

The third limitation is that the studies, to date, have been empirically based rather than theoretically based. This may well have been appropriate in the beginning stages of the work in this problem area, but the lack of theoretical base inhibits a fuller understanding of the process of patient recovery as well as limiting the possibility of developing theoretically based intervention strategies.

Few of the studies have fully described the methods of data collection. Rossel & Alyn (1977) did include their interview guide. Becker et al. (1967); Greene & Moss (1969); Blacher & Basch (1970); Goble et al. (1978a); and Price, Opel & Scott-Millar (1980) indicated that data were gathered by interview and judgements on patient outcomes were based on subjective clinical assessments which makes the replication of these studies impossible and the findings difficult to assess.

There are two additional limitations which make it difficult to draw firm conclusions from the previously reported studies. The length of time between implantation and follow-up varied from study to study. Goble et al. (1978a) followed all patients for six months; Price, Obel & Scott-Millar (1980) for one year; while Becker et al. (1967); Greene & Moss (1969); Blacher & Basch (1970) and Rossel & Alyn (1977) included patients who had been followed for varying periods of time postimplant.

Finally, as was noted in the introductory chapter, the "state of the art" of cardiac pacing has changed dramatically over the last 10 to 15 years. Much of the data upon which the available published reports are based was collected in the late 1960's and early 1970's and therefore may not be representative of the patient responses to cardiac pacing now. Of the studies published in the last five years, the patients in the study by Price, Obel & Scott-Millar, which was published in 1980,underwent implantation in 1976 and 1977. There is no indication in the published reports of Rossel & Alyn (1977), Goble et al. (1978a, 1978b) or Romirowsky (1978) of when the data were collected. Rossel & Alyn noted that the patients in their study had had their pacemakers for an average of 4.7 years and the earliest of the Goble et al. reports has a notation that it was first received for publication in 1976. Thus, one can conclude that the patients in these two studies probably underwent initial implantation no later than 1975.

In summary, the previous research into the patient recovery following implantation has a number of limitations including: lack of clearly defined patient outcome criteria; lack of clarity in the descriptions of the sample, which limits the generalizability of the findings; lack of statistical analysis which would allow for the exploration of the relative significance of the association between the antecedent variables and outcome; and finally the lack of a theoretical approach to the design and/or analysis of the data.

## SUMMARY OF PACING LITERATURE REVIEW

While any conclusions from previous research into factors affecting patient recovery following the implantation of a cardiac pacemaker must be considered as tentative, the following variables have been identified as influencing patient outcomes: demographic variables, the age and gender of the patient; clinical variables, duration of symptoms prior to pacing, adequacy of the pacemaker function, presence of other health problems, and complications following implantation; psychological variables, underlying personality style, with particular mention of trait anxiety and depression, as well as the degree of social support available to the individual. If the relationships between these variables and patient outcome can be confirmed, they are potentially useful in that they would assist health care workers to identify patients who are less likely to resume previous activities and more likely to experience greater anxiety and depression postoperatively. With the exception of the variables related to the adequacy of pacemaker function and complications, these variables are not easily amenable to change through interventions by the nurses or physicians caring for the patient. Thus, it would seem that a major gap in the knowledge of patient recovery following cardiac pacing is the identification of one or more variables influencing outcome which will offer guidance to the development of interventions to increase activity resumption and decrease negative affective reactions.

## REVIEW OF SELECTED LITERATURE ON RECOVERY FOLLOWING MYOCARDIAL INFARCTION AND CARDIAC SURGERY

As noted earlier, the purpose for reviewing this body of literature was twofold: 1) to explore the definition and measurement of patient recovery outcomes and 2) to identify one or more variables related to recovery which might suggest clinical intervention.

### PATIENT OUTCOMES

As was evident in the study of recovery following pacemaker implantation, there appears to be no universally acceptable operational definition of recovery for patients who have sustained a myocardial infarction or undergone cardiac surgery. Some investigators have selected outcome variables which reflect primarily the clinical status of the patient, others have been primarily concerned with activity resumption, and others have focused on emotional outcomes.

Activity resumption. One of the most frequently utilized criteria in the study of patient outcome following myocardial infarction and cardiac surgery has been "return to work" (for example, Anderson, Barboriak, Hoffman & Mullen, 1980; Croog & Levine, 1977; Danchin, David, Bourassa, Robert & Chaitman, 1982; Garrity, 1973b; Phillip, Cay, Stuckey & Vetter, 1981 and Zyzanski, Stanton, Jenkins & Klein, 1981). Investigators have reported various aspects of "return to work" including: the percentage of patients returning, the number of hours worked each week, the time between hospitalization or surgery and resumption of employment and the required modification in previous work activity.

The apparent emphasis on "return to work" as an indication of patient recovery can be attributed, at least in part, to two reasons. First, "return to work" is relatively easy to measure, either in a questionnaire or by interview, while many of the other possible outcome variables are much more difficult to define and measure. Secondly, the population of patients sustaining myocardial infarctions or undergoing cardiac surgery tend to be men in the 40 to 65 year age range for whom continued active employment has multiple economic, social and psychological ramifications. The concern with the economic implication of incomplete recovery, for the patient and society in general is receiving increased scrutiny in the literature. (Danchin, David, Bourassa, Robert & Chaitmen, 1982; Stanford, 1982).

The resumption of other activities such as social and leisure activities and hobbies has been less frequently assessed. Garrity (1973b) and Ranshaw & Stanley (1981) are among those who included assessment of the resumption of activities other than employment in their studies. There has been a similar paucity of literature on the extent to which patients have been able to resume sexual activity, although in the more recent literature this variable is now receiving attention. (Croog & Levine, 1977; Gundle, Reeves, Tate, Raft & McLaurin, 1980; Heller, Frank, Kornfeld, Molm & Bowman, 1974, and Stern, Pascle & Ackerman, 1977).

Clinical status. Clinical outcome has been assessed in diverse ways including: survival (Prince, Frasure-Smith & Waloszyk, 1982); rehospitalization (Croog & Levine, 1977, and Prince et al., 1982); physician assessment of the patient's clinical and functional status

(Croog & Levine, 1977); patient report of symptoms (Croog & Levine, 1977; Zyzanski et al., 1981). Thus, clinical status measurement has ranged from objective measures, such as survival and the number of rehospitalizations, through physicians' assessments of physical status to the more subjective patient reports of symptomatology.

Psychological responses. In the last ten years, researchers have demonstrated increased recognition of the psychosocial sequelae of myocardial infarction and cardiac surgery. There has been relatively little consensus among those studying psychosocial outcomes on the most appropriate approach to the assessment of this ill-defined aspect of patient recovery. Consequently, a variety of approaches are evident in the literature. Brown & Rawlinson (1976), Byrne (1982), Croog & Levine (1977), Dahme (1979), and Garrity (1973b) all utilized measures of patient morale and/or satisfaction which tapped the patient's own sense of satisfaction with his life at the time of follow up. Semi-structured interviews have frequently been used. In some instances (Philip et al., 1981; Wishnie & Hackett, 1971; and Wynn, 1967), the presence and extent of psychological impairment was based on the clinical judgement of the interviewer. Heller et al. (1974) and Gundle et al. (1980) had standardized coding schemas which were used in the analysis of interview data. Standardized testing has been used to augment interview data in a number of the studies. Among the instruments which have been used are: the SCL-90, a short psychiatric symptom scale; the Psychosocial Adjustment to Illness Scale (PAIS) (Gundle et al., 1980); Cattell 16 Personality Factor Questionnaire (Heller et al., 1974); MMPI (Bruhn, Wolf & Philips, 1971; Kavanagh, Shepard & Turk, 1975; Ruskin et al., 1970); Taylor Manifest Anxiety Scale and Zung Depression Scale (Stern et al., 1977). Ranshaw & Stanley (1981) used content analysis of narratives written by the patients to assess the effects of cardiac surgery on life and life style.

Single versus multiple outcome measures. Another question which needs to be addressed is the use of single or multiple outcome measures.

Croog & Levine (1977) carried out the most comprehensive study of patient recovery following myocardial infarction. They followed 293 patients for one year and assessed patient recovery on nine "statuses". The nine statuses evaluated were: patient view of his progress, work status, physician view of progress, frequency of symptoms, patient depression, patient's perception that life had returned to normal, maintenance of preinfarct activity, satisfaction with life and patient perception of any "gains of the myocardial infarction". Only the latter status demonstrated low levels of association with the other outcome statuses. All of the other outcome statuses demonstrated statistically significant ($p < .01$) associations with each other. Even though the outcome statuses did demonstrate a high degree of association with each other, Croog & Levine decided against using a single outcome index of recovery. They felt that the multiple outcomes more fully represented the multidimensionality of patient recovery. The use of multiple outcome measures is also supported by the findings of Mayou (1979) and Brown & Rawlinson (1976, 1977) who found that some antecedent variables were related to one outcome but not to others.

Summary. There has been little consensus of the operational definition and measurement of patient recovery following myocardial infarction and cardiac surgery. Most studies have tended to focus on one or two outcomes which have been uniquely defined for the purposes of the particular study. Therefore, it is often difficult to compare results from one study with those of another study. It appears that, to adequately study patient recovery, more than one outcome measure may need to be evaluated.

## FACTORS RELATED TO PATIENT RECOVERY

Many of the variables which have been addressed in studies on recovery following myocardial infarction and cardiac surgery are the same ones which were found in the literature on recovery following pacemaker implantation. These variables can once again be divided into three general categories: demographic, clinical, and psychosocial. It is extremely difficult to summarize the findings of the extensive literature on recovery following myocardial infarction and cardiac surgery because of the diversity in the approaches taken to these studies as well as differences in the samples of patients studied. These differences have led to sometimes conflicting conclusions being drawn about the possible impact of the numerous antecedent variables. The following summary of findings on recovery after myocardial infarction and cardiac surgery will only briefly discuss the findings related to demographic and clinical variables, since the investigator's primary purpose for exploring this extensive body of literature was to identify outcome variables and new antecedent variables, which might be useful in the study of recovery following pacemaker implantation rather than an in-depth understanding of patient recovery following myocardial infarction and cardiac surgery.

Demographic variables. The age of the patient at the time of infarction does not seem to have a significant association with recovery (Bruhn, Wolf & Philips, 1971; Garrity, 1973a, 1973b; and Mayou, 1979), although Fisher (1970), and Ruskin et al. (1970) found that younger patients were more likely to return to work following a myocardial infarction. Similar findings have been reported for return to work following cardiac surgery (Anderson et al., 1980, and Brown & Rawlinson, 1977). Although most studies on postinfarction recovery have been limited to male patients, when women have been included in a study, they seem to experience more emotional distress and are less likely to resume previous activities following myocardial infarction (Mayou, 1979; Stern et al., 1977). These findings have also been found in the case of patients undergoing cardiac surgery (Brown & Rawlinson, 1976, 1977; Zyzanski et al., 1981). Patients who are of higher social class, have more education and who work at a white collar occupation are more likely to return to work (Bruhn, Wolf & Philips, 1971; Danchin et al., 1982; Mayou, 1979).

Clinical status variables. In terms of clinical factors, continuation of symptoms and/or the need for rehospitalization have been identified by Anderson et al. (1980) and Croog & Levine (1977) as having a negative impact on both resumption of activities and emotional responses. Nagle, Gagnola & Picton-Robinson (1971), Philip et al. (1981) and Shapiro, Weinblatt & Frank (1972) all found that the severity of the heart attack was predictive of not returning to work. These findings of the impact of clinical factors on outcome were not confirmed by Fisher (1970) or Garrity (1973a, 1973b). In contrast to the findings in the pacing studies, those patients who had had symptoms and/or who were disabled for a longer period, defined as greater than eight months by Gundle et al. (1980), prior to cardiac surgery were more likely not to return to work and were more likely to experience psychological distress postoperatively (Anderson et al., 1980; Danchin et al., 1982; Gundle et al., 1980). Gundle hypothesized that the prolonged period of disability prior to surgery resulted in the patient developing a self-image of being "damaged" which did not always abate following surgical repair.

Psychological variables. Up until this point in the discussion of the research on patient recovery following myocardial infarction and cardiac surgery, the psychological status of the patient has been viewed as an outcome or dependent variable. In the last few years there has been increasing interest in viewing aspects of the patient's psychological status as an independent variable in studies directed toward identifying variables which influence ultimate patient recovery. There has been great variation in the operational definition and measurement of the different concepts related to the patient's psychological status. The following summary is an attempt to briefly synthesize the findings of the research in this area.

A number of studies have found that those patients who demonstrated high levels of depression during hospitalization or who reported that they had had a tendency to respond to stress by becoming depressed prior to their hospitalization were more likely to demonstrate less resumption of activities and greater negative emotional responses at the time of follow-up (Brown & Rawlinson, 1976; Croog & Levine, 1977; Gundle et al., 1980; Stern et al., 1977). Both Brown & Rawlinson (1976, 1977) and Garrity (1973a, 1973b) concluded that self perception of health was an important determinant of patient outcome. Using yet another theoretical perspective, Byrne and his colleagues (1982) found that illness behaviour, which they defined as "the collective expression of the affective behavioral and cognitive meanings which particular illnesses hold for their sufferers" (p.105), was related to the patient's subjective perception of well-being at 24 months. The relationships between illness behaviour and clinical outcomes and employment status at 24 months were generally not statistically significant although they had been statistically significant at eight months following the myocardial infarction.

Other measures of psychological status which have demonstrated positive associations with recovery outcome(s) are: "psychological adjustment" in the early postinfarction period (Garrity & Klein, 1975), less "psychological vulnerability" (Mayou, 1979), greater "personality resources" (Philip et al., 1981). Brown & Rawlinson (1876, 1977) found that patients who could be characterized as "repressors" rather than "sensitizers" on the R-S scale of the MMPI reported higher morale following cardiac surgery. The R-S scale did not demonstrate the same statistically significant association with the return to work outcome.

Significant others, particularly the spouse, may influence the eventual recovery outcome. Garrity (1973a) found that the patient's perception of the degree of concern about his health by family members was a significant variable in determining the number of hours worked six months after a myocardial infarction. Reif's (1975) study clearly established the impact of family, physicians, employers and representatives of social welfare agencies on the patient's perception of himself as "healthy" or "not healthy". Taking a slightly different approach, Ruskin, Stein, Shulsky & Bailey (1970) concluded that greater feelings of adequacy and security in the spouse were associated with better medical and psychosocial adjustment in patients.

Although the question of the impact of the patient's psychological resources on ultimate recovery has been approached from a number of diverse perspectives, the above findings would seem to indicate that:

1) the underlying psychological resources of the patient do make a significant impact on the eventual patient outcome following myocardial infarction and cardiac surgery.

2) those patients who appear to be experiencing significant emotional distress in the early postinfarction period or in the preoperative and early postoperative period are more likely to continue to experience emotional distress.

3) those patients who perceive that significant others have concern about their health are less likely to return to work and are more likely to experience emotional distress.

## CRITIQUE OF SELECTED STUDIES

As was concluded after the review of the literature on recovery following the implantation of a pacemaker, the demographic and clinical variables may be helpful in identifying patients who are "at risk" for less than optimum recovery, but they do not give any guidance to clinical interventions to improve recovery outcomes. Within the variables categorized as "psychological" variables in this review of the literature, at least three emerge as possibly suggesting clinical intervention. The first of these is self perception of health. The second one is the evidence of depression in the early recovery period, but only to the extent that it reflects a state affect rather than an underlying psychological trait since the latter (underlying psychological trait) would be less amenable to short-term interventions. Finally, the impace of significant others' perceptions of the patient's health may be an important variable in the patient's perception of his health and ultimate recovery.

The remainder of this section of the literature review will be devoted to looking more closely at the studies in which a significant relationship between self perception of health, emotional distress at the time of infarction or in the preoperative and early postoperative period and/or the impact of significant others and eventual patient outcomes was found.

Garrity (1971, 1973a, 1973b) was the first researcher to consider the individual patient's perception of his own health as an antecedent variable in the study of postinfarction recovery. He followed 62 male patients for six months after their first myocardial infarction. In all, 17 different variables were considered as possible predictors of resumption of work and morale at six months. After eliminating the variables which did not correlate to the .05 level with each outcome, the remaining variables were assessed using a stepwise multiple regression. Nine variables were evaluated for the morale outcome: absence or presence of gainful employment, participation in community organizations and in informal social activities, amount of nonassociational activeness, postattack health perception, absence or presence of chronic health problems, patient's perception of the severity of the heart attack, age and socioeconomic status. Only the self perception of health measure demonstrated a statistically significant relationship with morale in the multiple regression equation (Garrity, 19731). Five variables were entered into the regression with resumption of work as the dependent variable: number of preattack hours worked, presence of chronic health problems, postattack health perception, socioeconomic index and the Rotter locus of control scale score. Self perception of health demonstrated the strongest relationship with resumption of work. The Rotter Scale score and the socioeconomic status also were statistically significant (Garrity, 1973b). Subsequent analysis demonstrated the apparent continuity of health perception since the patient's perception of his health one month prior to the heart attack (measured reptrspectively at the time of the infarction) was the strongest predictor of health perception at six months (Garrity, 1973a). Seven variables were considered in this regression: age, clinical severity of the heart attack, presence of chronic health problems, health perception one month prior to the heart attack and at the time of hospitalization, perception of the severity of the heart attack, and the frequency of visits to a physisican since hospitalization (Garrity, 1971).

Garrity concluded that the patient's perception of his health was predictive of outcome. This conclusion implies that the outcomes follow from health perception. This conclusion seems to be a bit premature based upon Garrity's data since it would seem necessary to demonstrate that health perception measured prior to the outcome had a direct correlation with outcome before drawing any firm conclusions about a predictive relationship.

Garrity utilized stepwise regression in the analysis of his data and, although this approach is frequently used, there can be very serious capitalization on chance when using this approach. This may lead to invalid conclusions being drawn from the tests of significance for the individual independent variables and the overall $\underline{R}^2$ (Cohen & Cohen, 1975).

In related studies, Brown & Rawlinson (1976, 1977) investigated the relationship of self perception of health with morale and return to work following cardiac surgery. While Garrity (1973, 1973b) asked each patient directly about his health, these investigators used two indirect measures to represent health perception: the number of symptoms which the patient reported on the Cornell Medical Index Health Questionnaire and the patient's current tendency to retain or relinquish the sick role as determined by a semantic differential instrument which they had developed. Patients who reported fewer symptoms and demonstrated greater tendency to relinquish the sick role were thought to consider themselves as healthier. The other variables which were considered were three variables indicating the patient's current health status; three variables related to the patient's condition at the time of surgery, including the duration of symptoms prior to surgery; seven social and demographic variables; and two scales taken from the MMPI, the D scale and the Sensitization-Repression (R-S) scale, as indices of predisposition to depression and coping style, respectively. Morale was judged by the Koltuv Scale. Data were collected from 150 patients who had undergone valve replacements at least 10 months previously. The approach to the analysis was similar to that used by Garrity in that stepwise regression was utilized to identify the antecedent variables which demonstrated the greatest association with the two outcomes. The data for the total sample were analyzed first, then separate analyses were carried out for the men and the women. The results of the regression demonstrated that the set of variables which best predicted morale in men differed from that which predicted morale in women. The best predictor of morale for the men was the Depression scale score, while the best predictor of morale for the women was the number of symptoms reported. Three of the top five predictors of morale were the same for both men and women. They were: coping style, current sick role and marital status. When the predictors of return to work were assessed, a different pattern was found. The men who tended to return to work had been off work for a shorter time preoperatively, reported fewer symptoms, were younger, were judged by their physician to have better cardiac function, had accepted the sick role prior to surgery and rejected the sick role after surgery. The women who returned to work (including housekeeping activities) tended to report fewer symptoms, were younger, did not have other health problems, accepted the sick role prior to surgery and rejected the sick role after surgery. The psychological variables, tendency toward depression and coping style, did not demonstrate the statistically significant association with return to work that they had with the morale outcome, but the self perception of health variables demonstrated significant relationships with both outcome variables.

The same questions about the methodology can be raised with this study as were raised with Garrity's work. It is premature to assert a predictive relationship between personality variables, such as health perception and depression, and recovery outcome when all variables are being measured at the same time. Additionally, the use of stepwise regression is open to question.

Further support for the hypothesis that the emotional responses of the patient in the early recovery period after a myocardical infarction are related to long-term emotional adjustment can be found in a study by Stern, Pascale & Ackerman (1977). These investigators followed 68 patients who had had a myocardial infarction for the first year post-infarction. A large battery of psychological testing including: the Zung Depression Scale, Taylor Manifest Anxiety Scale, Jenkins Activity Scale, Holmes-Rahe Schedule of Recent Experiences, Potter Scale and the Structured and Scaled Interview to Assess Maladjustment were administered to supplement interview data. All patients who were identified as "depressed" six weeks postinfarct were "depressed" at six months. Seventy per cent of these patients remained "depressed" at the one year follow-up. The patients who were depressed were less likely to have returned to work ($\underline{p} < .05$), less likely to have resumed sexual activity ($\underline{p} < .05$), and more likely to have been rehospitalized ($\underline{p} < .01$). Patients who reported greater depression were also more likely to report greater anxiety ($\underline{p} < .01$).

In contrast to Garrity (1973a, 1973b) and Brown & Rawlinson (1976, 1977), these investigators were able to test the relationship between the predictor and outcome variables measured at different points in time. Unfortunately, they did not utilize an analytic approach which would allow for some understanding of the relative significance of the associations of the independent variables with the dependent variables.

Along with self perception of health and early emotional reactions, it seems that the responses of the significant others play an important role in shaping the patient's recovery. Garrity (1973a) found that the degree of family concern about the patient's health, as perceived by the patient was significantly related to the number of hours worked following the heart attack. In their study of 128 postinfarction patients and spouses, Ruskin, Stein, Shelsky & Bailey (1970) noted that "feelings of adequacy and security in the spouse were associated with better medical and psychological outcome" (p.103). These authors did not present the data from which their conclusions were drawn, nor did they clearly present the methods used for data collection except to indicate that a large number of variables were considered including: 18 variables related to demographic and physical statuses and 25 MMPI scale scores. The MMPI data were available for both patients and spouses.

## SUMMARY OF THE MYOCARDIAL INFARCTION AND CARDIAC SURGERY LITERATURE

In summary, the research into recovery following myocardial infarction and cardiac surgery has been focused primarily on resumption of activities, particularly return to work, and the patient's emotional responses. The findings regarding the possible impact of antecedent variables are, at times, contradictory and the predictors of outcome may vary depending on the characteristics of the sample, the defintion and measurement of the variables, and the outcome being studied. Generally, it appears that younger, male patients who have fewer longterm physical limitations or symptoms, who are more highly educated, and white-collar workers are more likely to return to work. Those patients who have had symptoms for a shorter period of time prior to cardiac surgery are more likely to return to work. Underlying personality style, psychological responses during hospitalization and in the early posthospital period, especially the presence of depression, are related to the long term emotional adjustment of the patient. Self perception of health seems to be an important variable in predicting both return to work and emotional outcomes. Additionally, the role of the patient's spouse or other significant others in shaping the patient's responses was identified.

## CHAPTER SUMMARY

After reviewing the literature on patient recovery following pacemaker implantation and the related literature on recovery following myocardial infarction and cardiac surgery, it may be concluded that for all three groups of patients, the extent of recovery varies across the patient population. A number of demographic, clinical and psychological factors have been identified as possible predictors of patient outcome in all three groups of patients, although the actual findings do vary across studies because of the differences in methodology. The two outcomes most frequently studied have been activity resumption (including return to work) and emotional response. While these two outcomes seem to be closely related to each other, the impact of the antecedent variables does seem to be somewhat different for each outcome. Table 1 summarizes the associations between antecedent factors and patient recovery found in the literature.

Table 1

SUMMARY TABLE

VARIABLES RELATED TO RECOVERY

| Variable | Pacemaker | | MI/Cardiac Surgery | |
|---|---|---|---|---|
| | Activity Resumption | Emotional Response | Activity Resumption | Emotional Response |
| Demographic | | | | |
| Age | 0 | 0/+ | 0/- | 0 |
| Male | 0 | 0/+ | + | + |
| SES | 0 | 0 | + | 0 |
| Clinical Status | | | | |
| Short duration of symptoms | - | - | + | + |
| Severity of MI/preop symptoms | NR | NR | 0/- | 0/- |
| Continuing symptoms | - | - | - | - |
| Complications | - | 0/- | - | - |
| Other chronic illnesses | - | - | 0/- | 0/- |
| Psychological | | | | |
| Anxiety and/or depression at time of hospitalization | - | - | - | - |
| Health perception | NR | NR | + | + |
| "Repressor" coping style | NR | NR | 0 | + |
| Significant other concern about pt.'s health | NR | NR | - | - |
| Social support | + | + | + | + |

(+) = variable positively related (-) = variable negatively related

(0) = no relationship (NR) = not reported in studies reviewed

The research to date has been primarily empirical with little in the way of theoretical analysis. Research based upon theoretical approaches to understanding human behaviour would enhance the understanding of the process of patient recovery. With better understanding of factors influencing the recovery process, possible interventions directed toward optimizing recovery could be developed and tested.

Of all the factors which have been identified, some, such as the demographic variables and many of the clinical variables are not readily modifiable. Thus, while they may give health care workers clues to patients who may be "at risk" for less than optimum recovery, they do not, in themselves, suggest clinical interventions. Other variables, particularly self perception of health, the influence of significant others, and the patient's emotional response during hospitalization and the early recovery period may be potentially modifiable. If it can be demonstrated that they do have significant association with patient outcome following the implantation of a pacemaker, then some clinical interventions directed towards optimizing patient recovery might be suggested. Therefore, this study was undertaken.

## PURPOSE OF THE STUDY

This study stemmed from a concern that some patients continued to limit their activities and experience emotional distress following the implantation of a pacemaker even though their actual physical symptoms had been controlled. The investigator did not know:

1) how to predict which patients might experience such difficulties postoperatively and

2) how to intervene to prevent less than optimum recovery.

The literature on recovery following pacemaker implantation was reviewed and a number of demographic, clinical and psychological variables which seemed to influence patient recovery outcomes were identified, but no clear guides to clinical intervention emerged. The literature on recovery following myocardial infarction and cardiac surgery was then reviewed since it seemed that these two groups of patients shared much in common with patients undergoing pacemaker implantation. Many of the same independent variables were found to be related to outcome in the patients who had had a myocardial infarction or who had undergone cardiac surgery. Three variables which were potentially modifiable through clinical interventions were identified. The major purpose of this study was to test the association of these three variables with patient recovery outcomes following pacemaker implantation. The results of this study ultimately should add to the theoretical base for nursing practice and lead to additional insights into the definition and measurement of the independent and dependent variables.

The research to date had limited theoretical base so that what seemed to be needed was a study that took a consistent theoretical approach to the definition of the variables and the analysis of the findings. In the next chapter, the major independent and dependent variables will be considered within one theoretical perspective in order to develop theoretical defintiions which are consistent with each other.

# Chapter III

## THEORETICAL PERSPECTIVE

The theoretical perspective that was selected for this study was the interactionist approach to role theory. Meleis (1975) has argued that this theoretical framework is a useful one for nursing practice and research since it offers an excellent theoretical basis for developing nursing diagonoses and for planning appropriate nursing interventions. Meleis & Swendsen (1978), using this framework, developed and tested the efficacy of role supplementation interventions with couples at the time of the birth of their first child. Dracup & Meleis (1982) recently applied the interactionist approach to role theory in exploring the problems of patient noncompliance. Turner (1970) and Burr, Leigh, Day & Constantine (1979) were able to devlop hypotheses regarding many aspects of family interaction from the concepts and propositions of this theoretical framework.

The interactionist approach to role theory is rooted in the theoretical tradition of the symbolic interactionsts (Cooley, 1909; Mead, 1934; Blumer, 1969). Sarbin & Allen (1968), Turner (1959, 1962, 1968) and Burr et al. (1979) have subsequently explicated the concepts of symbolic interaction in relationship to role behaviour. In discussing this theory, the investigator will address only the major assumptions and concepts of the theory which have particular relevance to this study.

Three assumptions underlying the theory begin to differentiate this approach from other theoretical approaches which assume that behaviour is influenced by forces such as unconscious instincts, stimulus-response, or inherent physiological and psychological drives. These assumptions are:

1) Humans live in a symbolic world and they respond to the environment by constructing meanings for the various symbols which they perceive.

2) The meaning and values which each person learns to attach to various symbols are established through interaction with others.

3) In order to understand human behaviour it is important to understand the meaning and values which each person has attached to the symbols. (Burr, et al., 1979) Thus, in contrast to other theoretical perspectives, the focus within this perspective is on the meanings constructed by each person.

Other basic assumptions of this theory are related to the development of the "self":

1) Individuals are capable of introspection and through this process they begin to differentiate a "self" from other objects in the environment.

2) The process of defining the "self" is ongoing as one continues to interact with others.

3) There are at least two parts to the "self": the "me" which consists of a generally well-organized representation of the various roles one may play and the "I" which includes the more spontaneous and impulsive aspect of the "self". (Burr et al., 1979)

The above assumptions underlie the interactionist approach to role theory which can be contrasted to the more structuralist approach represented by the work of Linton (1936) and Parson (1958). Generally, the structuralists have viewed roles as structured social expectations for a person occupying a particular position or status. In contrast, Turner (1956) working from the interactionist perspective defined a role as:

> a collection of patterns of behaviours which are thought to constitute a meaningful unit and deemed appropriate to a person occupying a particular status (e.g. doctor or father), occupying an informally defined position in interpersonal relations (e.g. leader or compromiser), or identified with a particular value in society (e.g. an honest man or patriot) (p. 316).

Further a role:

> refers to behaviour rather than position so that one can enact a role, but not occupy a role (p. 317).

In a later work, Turner (1959) further clarified the definition of "role" by indicating the the focus in understanding a role was the recognition of the underlying goal, sentiment or value.

The existence of any role can be validated by both external and internal criteria. Among the possible external criteria is the presence of a name which is in general use to designate a role, such as "mother" or "sick role". The naming of a role does not mean that there is agreement on the content of the role, but only that there is agreement that the role exists (Turner, 1962).

Roles are always enacted in interaction with an other role. This concept is clearly stated by Turner (1962):

> the idea of role-taking shifts emphasis away from the simple process of enacting a prescribed role to devising a performance on the basis of an imputed other-role. The actor is not the occupant of a position for which there is a neat set of rules - a culture or set of norms - but a person who must act in the perspective supplied in part by his relationship to others whose actions reflect roles that he must identify. Since the role of alter can only be inferred rather than directly known by ego, testing inferences about the role of alter is a continuing element in interaction (p. 23)

The various roles which the individual has learned to enact are organized into a self conception. The self conception is developed through interaction with others as the person is forced to evaluate the succession of self images (those pictures of himself which he sees at a particular moment) in light of his ideal goals and values (Turner, 1968). Thus the self conception has at least some degree of reality orientation, as defined by the interactions with others, while still retaining elements of the individual's picture of his ideal self.

The subjectiveness of the self conception has presented difficulties for researchers who have attempted to operationalize and measure this concept. In an attempt to cope with this problem, Turner (1978) has proposed the concept of role-person merger. Since the self conception is the repertoire of roles of the person, then behavioural evidence of role-person merger could be seen as a reflection of the person's self conception. Role-person merger can be said to occur when: 1) there is lack of role compartmentalization, i.e. the person continues to enact the role although it does not apply; 2) one does not relinguish the role even though there are advantageous or viable alternative roles available; and 3) there is evidence of the acquisition of attitudes and beliefs appropriate to the role. The individual is more likely to merge the role(s) by which significant others identify him; that maximize autonomy and favourable evaluations and those in which he has the greatest investment of time and effort in role learning or achievement.

There are a number of difficulties which can occur in the process of role enactment, including: role strain (Goode, 1960); lack of consensus on role expectations; difficulties either moving into or out of a role; role insufficiency (Meleis, 1975); or lack of self-role congruence (Sarbin & Allen, 1968). In describing the lack of self-role congruence, Sarbin & Allen (1968) say that:

> such extreme incongurence between values or beliefs about self and role expectations creates severe psychological effects on the individual, recognizable through somatic dysfunction, lack of concentration and the like (p.524).

While Sarbin & Allen are describing the person's response to extreme difficulty, varying degrees of subjective distress can be experienced in any situation in which difficulty(ies) in role enactment is being experienced. In their study, Meleis & Swendsen (1978) considered "anxiety" and "depression" to be affective responses to the experiencing of role insufficiency.

It seemed that the assumptions and concepts of the interactionist approach to role theory might be helpful in extending the understanding of the problem focus of this study.

## EXPERIENCE OF PACEMAKER IMPLANTATION FROM AN INTERACTIONIST ROLE PERSPECTIVE

The individual undergoing a pacemaker implantation brings to this experience his own self concept with his unique way of interpreting his environment. This self concept and the meanings and values given to various aspects of his world emerged from his past experiences. For some patients, the onset of symptoms and the subsequent hospitalization for pacemaker implantation are entirely new experiences. For others, physical symptoms and hospitalization are not new occurrances.

Having to lie in a hospital bed attached to a cardiac monitor, under constant observation and care by nurses and physicians and the need for a pacemaker might be interpreted by one individual as meaning that he is now a "sick man". Another individual might reject this interpretation saying that he is not really "sick", but that the need for hospitalization for pacemaker implantation and the symptoms are only temporary or transient changes in his usually healthy self. Using the role-person merger concept, one might say that there is variation in the extent to which the "sick role" has been merged with the individual's self concept. In using the term "sick role", the interactionist definition of role is being used with the emphasis on the underlying goals, values, and sentiments rather than the more structured meaning of "sick role" as set forth by Parsons (1958). In his discussion of role-person merger, Turner (1978) noted that not all roles are firmly incorporated into the self concept and that among the factors which influence the process of role-person merger is the extent to which significant others identify the person in the role. Thus, it might be expected that, if the patient perceives that his spouse, family, and/or other significant others perceive him to be "sick", he is more likely to see himself as "sick" rather than temporarily incapacitated.

After discharge from the hospital, many physical and interactional cues which supported the patient's perception of himself as "sick" are withdrawn. The nurses and physicians are no longer enacting the direct caregiver roles which required the individual to respond in the "patient" or "sick" role. After the implantation, symptoms, such as syncope, resulting from the conduction defect, are usually eliminated, although the occurrence of complications or symptoms from other illnesses might continue to support the individual's perception of being "sick". For some individuals, the presence of the pacemaker itself could be interpreted as a continuing indication that the "sick role" is an appropriate one. Interactions with significant others may either facilitate merger or lack of merger of the "sick role" with the patient's self conception.

It is not clear what impact the incorporation of the "sick role" within the self conception will have on the enactment of other roles. Some writers such as Parsons (1958) have said that the incumbent in the "sick role" is not required or expected to fulfill other roles. Many studies have used resumption of previous activities as an indicator of recovery.

Researchers and caregivers have frequently observed that individuals exhibit varying degrees of emotional distress when confronted with physical illness and hospitalization. Various labels have been applied to this experienced distress, such as "anxiety" or "depression". In research and practice, different theoretical perspectives have been used to explain the nature and sources of the individual's emotional response to illness. Whenit is viewed from an interactionist role perspective, the experience of emotional distress might be seen as a subjective state arising from a perceived difficulty in role enactment. This difficulty in role enactment could be characterized in a variety of ways, such as inadequacy in role enactment; self-role incongruence; role insufficiency or role strain. Physical illness and hospitalization for pacemaker implantation may impinge upon the individual's opportunity and/or ability to enact one or more of his previously valued roles. For some individuals, this experience might also call forth new role(s) which need to be merged with other previously existing roles. The extent to which the invididual perceives difficulties in role enactment in this situation will vary, thus individuals will vary in the degree of emotional distress which they experience at the time of hospitalization and pacemaker implantation.

As the phsyical symptoms abate and the restrictions of hospitalization are eliminated, it would seem that many of the factors which hampered the enactment of previous roles would be eliminated and the need to enact other new roles, such as the "patient role", would be diminished. It seems to follow then, that if the emotional distress were a consequence of perceived difficulties in role enactment and if the environmental constraints on the enactment of previously established roles were removed, thereby facilitating resumption of previous roles, then emotional distress should decrease. It is entirely possible, though, that an individual might continue to perceive that he is not able to resume previous role adequately and consequently would continue to experience emotional distress. For the purposes of this study the key variables are viewed within this theoretical perspective in the following manner:

Self perception of health: the extent to which the sick role has been merged into the self conception.

Subjective distress; the emotional response of the individual to perceived difficulty(ies) in role enactment. The specific nature of the difficulty need not be defined.

Resumption of activity following implantation: the resumption of previously enacted roles.

Patient's perception of the significant other's perception of his health: the extent to which the patient perceives that the significant other(s) see the "sick role" as appropriate for the patient at that time.

## METHODOLOGICAL IMPLICATIONS OF THE INTERACTIONIST ROLE PERSPECTIVE

The use of this perspective as the theoretical base for this study has implications for the approach to data collection. The basic assumptions of symbolic interactionism stated earlier clearly lead to the conclusion that, in order to understand human behaviour, the investigator must attempt to learn about the behaviour and feelings directly from the individuals involved rather than imputing meanings to behaviour without varifying these meanings with the individual. There is controversy among the various researchers working within this framework regarding the most appropriate methodology to employ in collecting data. As described by Burr, et al. (1979), at the one extreme are those scholars who:

> emphasize the indeterministic, subjective, spontaneous aspects of the human mind and tend to have fairly qualitative research methodology. At the other extreme are scholars who concentrate on the more objective aspects of role, selves, and interaction. They tend to have a more quantitative methodology and to emphasize the predictable rather than unpredictable, the repetitious rather than the spontaneous, the measurable rather than the unmeasurable and the objective rather than the subjective (p. 51).

Burr et al. indicate that those researchers who incorporate the interactionist approach to the study of roles tend to focus on the more objective, measurable aspects of behaviour. Nonetheless, even if a more quantitative approach to data collection is used, the data of interest are those which reflect the individual's own perceptions of self, role behaviour or the interaction.

## Chapter IV

## DEFINITION OF VARIABLES AND STATEMENT OF THE RESEARCH QUESTIONS

This chapter will include a discussion of the following: the selection of the dependent and independent variables, the operational definitions and the statement of the research questions.

### SELECTION OF VARIABLES

### DEPENDENT VARIABLES

Three questions needed to be addressed in selecting the dependent variables: 1) What patient outcomes should be considered? 2) Should the outcomes be evaluated separately or combined into a single outcome? 3) Should the outcomes be viewed as categorical (e.g., "good" versus "poor" outcome) or as continuous variables?

The use of previously studied outcome variables would facilitate comparisons of the findings of this study with those of previous research. Resumption of activity and emotional responses have been the most commonly studied patient outcomes. Therefore, these two outcomes were selected as the outcome of interest for this study.

The following arguments would support the use of multiple outcomes. Assessment of multiple outcomes acknowledges the complexity and multidimensionality of recovery. It is possible that the extent of recovery for any one individual may vary across the outcomes. This difference might be lost in a single combined outcome. As noted in the review of the literature on recovery following a myocardial infarction, the relationship with the independent variables may vary from one outcome to another.

There are counter arguments to the use of multiple outcome measures. One might argue that the ultimate interest is in recovery on all dimensions taken together, if man is to be considered as a totality, and that the interest should be in a global representation of recovery. From a statistical point of view, multiple outcome variables necessarily increase the number of statistical tests being done. As the number of tests increases, the chance of finding a statistically significant result, purely by chance alone, also increases.

After considering the arguments for and against the single outcome, the decision was made to evaluate each outcome separately, since the two outcomes might demonstrate differing relationships with the independent variables.

The third decision which needed to be made was whether the outcome should be viewed as categorical or continuous variables. The use of categorical outcomes would imply that there were valid and identifiable criteria for categorizing the outcomes. An additional difficulty with categorical outcomes would be that subtle differences between individual patients would be lost. If the objective of the research were only to discriminate between those patients who had "good" versus "poor" recovery and these categories could be clearly defined, the categorical outcomes would suffice. Because of the lack of clearly defined criteria for establishing the categories and the wish to more fully understand the relationship between the independent variables and the outcomes, the decision was made not to categorize the outcomes.

## INDEPENDENT VARIABLES

The independent variables were selected from among those that had previously demonstrated significant relationships with patient outcomes following pacemaker implantation, myocardial infarction, or cardiac surgery (See Table 1, p.37). The variables which were selected for this study were:

a) demographic variables - age and gender

b) clinical status variables - duration and symptoms prior to surgery, preoperative cardiovascular symptoms, presence of other cardiovascular and/or chronic illnesses, adequacy of pacemaker function, pacemaker complications, continuation of cardiac symptoms and general health status postoperatively.

c) psychological variables - anxiety and depression prior to implant and in the early postimplant period, health perception, and the patient's perception of significant others' concern about the patient's health.

In addition to the above independent variables, data were collected on the following variables in order to more fully describe the sample: marital status, socioeconomic status, the limiting preoperative symptom, primary ECG indication for pacing and the etiology of the conduction disorder.

## OPERATIONAL DEFINITIONS OF VARIABLES

At the Pacemaker Centre, where this study was carried out, a comprehensive computer database of patient information has been developed (MacGregor, Covvey, Noble, Smardon, Wilson & Wigle, 1980). The database data were used for this study since they were readily available and in a standardized format. Consequently, the operational definitions of the clinical variables reflect the format of the data on the database. The database data were verified by the interviews and/or with the patient's charts.

## DEPENDENT VARIABLES

Emotional response - emotional distress as measured by the Anxiety and Depression scales of the Multiple Affect Adjective Check List (Today Form) (MAACL). The score on the two scales, Anxiety and Depression, were calculated using the scoring key supplied by the developers (Zuckerman & Lubin, 1965). Later in the study the two scales were combined into a single emotional distress scale which was labelled "Subjective Distress". (See chapter 5, p.75).

Resumption of activity - the extent of resumption of presymptom activity at six months as reported by the patient during the follow up interview. The patient was asked to compare both the kind and amount of activity for each of three categories of activity: work (either employment, housekeeping, school or organizational activities), if applicable; social activities, such as visiting with family and friends, attending senior citizen's groups, or going out to dinner with friends; leisure activities (which were done for pleasure, but which did not necessarily involve social contact with other people) such as gardening, sports, going for walks or hobbies. Each of the three categories were equally weighted to derive a total activities resumption score. See Appendix A, Card 3, #40-44 for coding and the computation of the total activity resumption score.

## DEMOGRAPHIC VARIABLES

Age - the age of the patient in years at the time of implantation. Age was calculated using the patient's birthdate recorded on the patient's record on the database.

Marital status - the marital status of the patient as reported by the patient during the preoperative interview.

Socioeconomic status (SES) - socioeconomic status (recorded as Class 1 through 6, with Class 1 being the highest)was determined using the Blishen classification of occupations in Canada (Blishen & McRoberts, 1976; Blishen & Carroll, 1978). Occupation was reported by the patient during the preoperative interview. SES was based upon:

a) current occupation for men and single or divorced women, who were currently employed

b) previous occupation for men and single or divorced women, who had retired or been disabled

c) husband's current or previous occupation for married or widowed women. In the case of a married woman who was also employed, the husband's occupation was used to determine the SES. While it was recognized that the use of the husband's occupation, alone, for all married or widowed women might not adequately reflect SES in every case, the investigator was not able to identify any alternative approach which would be more adequate. The development of the Blishen scale is discussed in the next chapter.

## CLINICAL STATUS VARIABLES

Preoperative cardiovascular symptoms - the number of cardiovascular symptoms recorded by the physician on the preoperative assessment section of the database. The following symptoms are included on the database: syncope, presyncope, fatigue, dyspnea, angina, other chest pain, palpitation, and decreased mental acuity.

Preoperative limiting symptoms - the one symptom from the above list which was identified as most limiting for the patient and recorded by the physician on the database.

Duration of symptom(s) - the duration (recorded in terms of weeks or months) of the symptom(s) which the patient believed indicated the need for a pacemaker, as determined during the preoperative interview.

ECG indication for pacing - the ECG indication which was listed as the major indication for pacing on the database as determined by the physician prior to implant. See Appendix A, Card 1, #22-23 for the coding.

Etiology of the conduction disorder - the etiology of the conduction disorder as determined by the physician and recorded on the database. See Appendix A, Card 1, #24-25 for coding.

Preoperative history of other cardiovascular illness - the diagnosis and treatment of cardiovascular illness prior to the onset of current symptoms as reported by the patient during the preoperative interview. Hypertension, peripheral vascular disease and stroke were not included as cardiovascular illnesses, unless the patient described these as being related to the heart. Treatment included: medication, special diet, hospitalization or surgery. Self imposed diet or exercise regimens were not considered as treatment. See Appendix A, Card 1, #19 for coding.

Preoperative history of chronic illness - diagnosis and treatment for other chronic illness prior to the onset of the current symptoms, as reported by the patient during the preoperative interview. Acute illness episodes or accidental injuries not requiring ongoing medical supervision were excluded. Patients who had cataracts, glaucoma or hearing loss were considered to have a chronic illness. Treatment meant any diet, medication, exercise or assistive device which was prescribed by a physician or other health care worker. See Appendix A, Card 1, #20 for coding.

Pacemaker function - the extent to which the pacemaker was pacing and sensing normally as determined by the physician in the Pacemaker Center at the one and six months follow up visits.

Pacemaker related complication(s) - the diagnosis of a complication made by the physician and recorded on the database. The following were considered as pacemaker complications: neuromuscular stimulation (either lead or pack related); wound hematoma; lead fracture; other lead problems (including dislodgement, malposition, penetration or "exit block"); phlebitis; thrombosis or embolism; infection or erosion (pack or lead related); pulse generator migration; electrical or myopotential interferences; and pacemaker induced arrhythmias. The complications were categorized according to the treatment required. See Appendix A, Card 2, #10 for coding.

Continuation of cardiac symptoms - cardiac symptoms reported by the patient during the follow up interviews. The continuation of symptoms was coded in terms of whether or not the preoperative limiting symptom continued. See Appendix A, Card 2, #9 for coding.

Postoperative general health status (nonpacemaker related) - patient report of general health in terms of changes in symptoms and need to seek medical care. The data were obtained during the follow-up interviews. See Appendix A, Card 2, # 14 for coding.

## PSYCHOLOGICAL VARIABLES

Perception of health - the patient's perception of his current health status as reflected by his reponses on the Current Health scale of the General Health Perceptions Questionnaire (Appendix B) and scored according to the directions given by Ware et al. (1978). The questions for the Current Health scale are: 1, 2, 9, 12, 17, 22, 26, 30, 32.

Patient's perception of his significant other's perception of his health - the patient's perception of his spouse or other significant other's assessment of his current health as reflected by the patient's responses to the nine questions on the Current Health scale of a questionnaire adapted from the General Health Perceptions Questionnaire by the investigator (Appendix C). The Current Health scale is comprised of questions: 1, 2, 7, 10, 14, 18, 22, 25, 26. During the pretest, this questionnaire was deleted from the study when the investigator found that most of the patients had difficulty completing the questionnaire.

Emotional distress prior to implant and in the early postoperative period - emotional distress as measured by the Anxiety and Depression scales of the Multiple Affect Adjective Check List (Today Form). The score on the two scales, Anxiety and Depression, were calculated using the scoring key supplied by the developers of the test (Zuckerman & Lubin, 1965). The two scales were later combined into a single emotional distress score and labelled "Subjective Distress". (See chapter V, p. 75.)

Table 2 summarizes the variables in the study and the sources of the data.

Table 2

SUMMARY TABLE OF VARIABLES

| Variable | Source | When Collected |
|---|---|---|
| Outcome Variables | | |
| Activity Resumption | patient interview | 6 months |
| Emotional Response | MAACL Anxiety & Depression scales | 6 months |
| Independent Variables | | |
| Age | database | preoperative |
| Gender | database | preoperative |
| Duration of symptoms | patient interview | preoperative |
| Cardiovascular symptoms prior to implant | database | preoperative |
| Other cardiovascular illnesses | patient interview | preoperative |
| Other chronic illness | patient interview | preoperative |
| Adequacy of pacemaker function | database | 1 and 6 months |
| Pacemaker complications | database | 1 and 6 months |
| Continuation of cardiac symptoms | patient interview | 1 and 6 months |
| General health status | patient interview | 1 and 6 months |
| Psychological Variables | | |
| Health perception | General Health Perception Questionnaire - Current Health scale | preoperative<br>1 and 6 months |
| Emotional distress | MAACL Anxiety & Depression scales | preoperative and 1 month |
| Descriptive Variables | | |
| SES | patient interview | preoperative |
| Marital status | patient interview | preoperative |
| Limiting symptom | database | preoperative |
| ECG indication | database | preoperative |
| Etiology | database | preoperative |

## RESEARCH QUESTIONS

The research questions were focused on the relationship between the patient's perception of his health or the extent of emotional distress prior to surgery and at one month postimplant and the recovery outcomes at six months. These two independent variables were selected as the independent variables of primary research interest because they seemed to offer the greatest chance of suggesting possible clinical interventions to facilitate patient recovery. The initial proposal included another variable, the patient's perception of the significant other's perception of his health. The study of the impact of this variable was deferred when it was found in the pretest that the instrument, which had been developed to measure this variable, was not appropriate for this patient sample.

Previous research on recovery following pacemaker implantation indicated that clinical factors such as the adequacy of pacemaker function, continuation of symptoms, occurrence of complications and general health status affect patient recovery. It is also possible that they might impact on the patient's perception of his health and the emotional distress early in the patient's course. Therefore, it seemed to be appropriate to control for the relationship between the clinical variables and the independent and dependent variables. The clinical variables were used as covariates with any variance in both the independent and dependent variables which was associated with the covariates being controlled prior to assessing the association between the independent (health perception or emotional distress) and the recovery outcomes.

In previous research on recovery following pacemaker implantation, the age and gender of the patient had not consistently demonstrated a statistically significant relationship with outcome, but it is possible that the demographic variables might influence the relationship between perception of health or emotional distress and the recovery outcomes. The interest in the demographic variables was not so much in their direct association with the outcomes, but in any influence which they might have on the relationship between the independent and outcome variables, i.e. an interactive effect.

The following research questions were addressed in this study. In each analysis the influence of patient age and gender on the relationship between the independent variable and outcome was assessed.

1) To what extent does the patient's preoperative health perception explain the variance in resumption of presymptom activity six months following the implantation of a pacemaker when controlling for the association with preoperative clinical status?

2) To what extent does the patient's preoperative health perception explain the variance in emotional response at six months when controlling for the association with preoperative clinical status?

3) To what extent does the patient's health perception at one month after implantation explain the variance in resumption of presymptoms activity six months following the implantation of a pacemaker when controlling for the association with the patient's clinical status at one month?

4) To what extent does the patient's health perception at one month following implantation explain the variance in emotional response at six months when controlling for the association with the patient's

clinical status at one month?

5) To what extent does the patient's preoperative emotional distress explain the variance in the resumption of presymptom activity at six months when controlling for the association with the patient's preoperative clinical status?

6) To what extent does the patient's preoperative emotional distress explain the variance in emotional response at six months after controlling for the association with the patient's preoperative clinical status?

7) To what extent does the patient's report of emotional distress at one month explain the variance in the resumption of presymptom activities when controlling for the association with the patient's clinical status at one month?

8) To what extent does the patient's report of emotional distress at one month explain the variance in emotional response at six months when controlling for the association with the patient's clinical status at one month?

While the study was primarily focused on the relationship between the preoperative and early recovery independent variables and recovery outcomes, the following questions were also answered in this study:

9) What is the relationship between the patient's health perception at six months following the implantation of a pacemaker and the resumption of presymptom activity when controlling for the association with the patient's clinical status at six months?

10) What is the relationship between the patient's health perception at six months following the implantation of a pacemaker and

the emotional response at six months when controlling for the association with the patient's clinical status at six months?

# Chapter V

# METHODOLOGY

The following topics are discussed in this chapter: the design of the study, the setting, the criteria and procedure for sample selection, the instruments used for data collection, the actual method of data collection and data transformation and reduction.

## DESIGN

The purpose of this study was to assess the ability of preoperative and early recovery variables to predict patient recovery at six months after pacer implantation. A prospective follow up design was chosen in order to obtain more accurate preoperative and early recovery data than would be available in a retrospective design.

The resumption of activity and anxiety and depression six months following pacemaker implantation were selected as the outcome variables. This time frame was selected because it is one that has been utilized in other research on recovery following pacemaker implantation (Goble et al., 1978) and myocardial infarction (Garrity, 1973a, 1973b). The investigator's own clinical observation that most patients had achieved maximal recovery by this time supported the use of this time frame.

## SETTING

The study was carried out in a Pacemaker Center which is located in a large Canadian university teaching hospital. The hospital serves only an adult population since there is a specialized children's hospital in the city. In 1981, 209 initial implants and 116 replacements were done in this Center, making it one of the largest pacing centers in North America. The Pacemaker Center acts as a referral center for patients from other hospitals within the metropolitan area and a number of community hospitals, some of which are 500-600 miles away. Many of the approximately 1,500 patients being followed by the Pacemaker Center are seen routinely in the follow up clinic. Others are followed primarily in a network of satellite clinics located in local hospitals or by transtelephone monitoring and come to the follow up clinic only when there are specific problems related to the pacemaker which need evaluation and/or treatment (Goldman, Heller, Noble, Covvey, MacGregor & Morrow, 1974; MacGregor, 1978).

The Center is staffed by a nurse and two technicians who have all been associated with the Center for a number of years, along with two cardiologists and a cardiovascular surgeon, who are directly responsible for the medical and surgical care of the patients. There is an active program for the evaluation of new pacemaker technology, consequently, pacemakers which are not routinely used in the larger community are frequently available there. This was true in the latter part of this study when a new dual chamber pacemaker was introduced.

All patient data related to the pacemaker are maintained on a computerized database. Thus, standardized information on the patient's clinical status and the pacemaker are readily available (MacGregor, Covvey, Noble, Smarden, Wilson, Goldman & Wigle, 1980).

Inpatients are generally hospitalized in the specialized cardiology unit, which is an intermediate care unit and has the facilities for continuous cardiac monitoring. The nursing and medical house staff on this unit are very familiar with pacemakers and the routine preoperative and postoperative care of patients. There is a regular preoperative teaching program, including an information booklet which was written for patients and their families. With the help of the clinic staff, a Pacemaker Club has been organized by individuals with pacemakers. Among the activities of this club is a visitation program,in which individuals who have a pacemaker visit patients preoperatively. At the time of this study,the visitation was sporadic and not all of the patients in the study were visited prior to surgery.

The setting was selected because of the large patient population, the organized follow up program, as well as the interest in and support for this study, which was expressed by the staff. The very size of the Center and the active follow up program and the consequent familiarity of the staff with the implantation procedures and patient follow up does make it atypical. Only about one-third of the new pacemakers in Canada are implanted in large university teaching hospitals and the majority of patients in Canada are followed by their own physician rather than a specialized follow up clinic (Goldman, Duncan & Wilson, submitted for publication).

## SAMPLE

All patients who underwent an initial pacemaker implantation in this Center between February 1, 1980 and July 31, 1981, were considered for inclusion in this study with the following exceptions:

a) patients who were not able to give informed consent, including those who had a diagnosis of chronic brain syndrome, retardation, senility or psychiatric illness recorded on their Kardex or hospital chart; (Patients whom the nurses on the unit described as "confused" or "unable to follow directions or answer questions" were also excluded);

b) patients who were not able to understand written and/or spoken English;

c) patients with diminished hearing to the extent that the interview could not be carried out;

d) patients who were not able to see well enough to complete the questionnaire;

e) patients who were critically ill requiring treatment in the Coronary Care Unit, Cardiovascular Surgery ICU, or other intensive care units;

f) patients who received their immediate preoperative and postoperative care in other hospitals;

g) patients residing out of the province or for whom follow-up at another center was anticipated.

In addition to the above exclusions, some patients were excluded over the 18 month period of intake because of delays in scheduling operating room time which meant the investigator was unaware of the patient's impending surgery. Some patients were also missed when the investigator was unavailable to interview the patient before surgery.

All patients received an explanation of the study (Appendix E) and were asked to sign a written consent (Appendix F). Over the 18 months, nine patients declined to participate. Patients, particularly older patients, often discussed their participation and the signing of the consent with their family prior to agreeing to participate.

## DATA COLLECTION INSTRUMENTS

### INTERVIEW GUIDE

An interview guide was developed for the three interviews (Appendix D). The interview guide was pretested by the investigator with ten patients in order to test the clarity of the questions, the ease of coding the responses, and the patients' reactions to the interview. The pretest indicated that the questions in the interviews were understandable to the patients, and the answers could be easily coded using the coding format developed by the investigator (Appendix A). The necessary information could be gathered in about 20 minutes, but many interviews lasted longer since the patients seemed to want to elaborate on their answers to the investigator's questions.

Data gathered during the preoperative interview included the patient's description of the symptoms which he believed were related to his need for the pacemaker, the duration of symptoms, previous history of other cardiac or chronic health problems, his usual work activity (employment, housekeeping, organizational or school activity), social and leisure activities prior to and following the onset of symptoms. Current and previous employment history, which was used to determine socioeconomic status, was also collected.

During the follow up interviews at one and six months following implantation, the patient was asked to describe any present symptoms, problems he was having with the pacemaker, visits to any physician and/or hospitalizations since he was last interviewed, and the extent of resumption of previous activity.

## PACEMAKER DATABASE

The patient's age and gender, major ECG indication for pacing, the etiology of the conduction disorder, preoperative cardiac symptoms, the limiting symptoms, pacing mode, and specific pacemaker complications were retrieved from the computer database. These data were verified with data from the interview and/or the patient's hospital chart.

## BLISHEN SCALE

The Blishen scale (Blishen & McRoberts, 1976; Blishen & Carroll, 1978) is an index of socioeconomic class in Canada. The index, available for all occupations listed in the 1971 Statistics Canada *Classification and Directory of Occupations*, is based upon the following regression scale:

Index $(Y) = B_1X_1$(income) + $B_2X_2$(education) + C. Index scores for men (Blishen & McRoberts, 1976) and women (Blishen & Carroll, 1978) with differential weighting for education and income have been developed. The indexes used in this study were developed using data from the 1971 Canadian census. As an example, the index for male psychologists is 62.26 and for female psychologists it is 67.61. The index for a male accountant is 67.41, while a female accountant has a socioeconomic index of 58.16.

Socioeconomic class was assigned based upon the index for the current or previous occupation reported by the patient during the pre-operative interview, in the manner suggested by the developers (Blishen & McRoberts, 1976):

| Class | Blishen Index |
|---|---|
| class 1 | above 70.00 |
| class 2 | 60.00 - 69.99 |
| class 3 | 50.00 - 59.99 |
| class 4 | 40.00 - 49.99 |
| class 5 | 30.00 - 39.99 |
| class 6 | below 30.00 |

While the scale includes approximately 500 different occupations, some difficulties were still encountered in attempting to use the scale in the study. There are fine differentiations in the occupations listed in the manufacturing sector, for example, six different occupations are listed in textile manufacturing; but there were no specific designations for other occupational categories. The major problem was encountered with small business owners. The investigator placed small business owners in the related manager or supervisor occupation. For example, an owner of a fabric store was classified as "supervisor sales occupations, commodities".

## MULTIPLE AFFECT ADJECTIVE CHECKLIST

The following criteria guided the selection of an instrument for measuring anxiety and depression:

a) easily administered and not requiring special equipment, since the data were to be collected at the patient's bedside and in the clinic;

b) required no more than 10 to 15 minutes maximum to complete, since the total time required to complete the interview and questionnaires needed to be controlled in order to prevent patient fatigue;

c) provided objective data rather than subjective data based upon the investigator's observations or interpretations;

d) acceptable to the patient population.

The first and third criteria pointed to the use of a self administered written inventory or check list. After reviewing the most frequently used self report inventories for anxiety (Taylor Manifest Anxiety Scale, State-Trait Anxiety Inventory, IPAT Anxiety Scale Questionnaire and the Multiple Affect Adjective Check List (Levitt, 1980) and the Self Rating Depression Scale), the investigator selected the Multiple Affect Adjective Check List for use in this study. This test incorporates measurement of both anxiety and depression in one instrument. A single test for both anxiety and depression limited the number of different data collection instruments which needed to be introduced to the patient, thereby decreasing the complexity of the task for the patient and limiting the time needed for completion. It is focused on subjective assessment of mood only and does not incorporate physiological responses, such as fatigue, which could be related to the patient's disease state rather than to his emotional status. The adjectives used to describe mood are common ones, consequently, it seemed likely that it would be more acceptable to the patient sample than some of the other tests which contained more psychologically oriented items.

The Multiple Affect Adjective Check List is a self administered test designed to measure three negative affects: anxiety, depression and hostility. Affect is defined by the developers of this test as "the psychological aspects of emotion or the emotional response which is assessed by means of verbal report" (Zuckerman & Lubin, 1965). It consists of 132 adjectives presented in alphabetical order. The adjectives are all at,or below,an eighth grade reading level. The test usually requires less than five minutes to complete. The respondent is asked to check all of the adjectives that describe the way he feels.

The time frame for responses can be modified by the directions given to the respondent. Directions to check all adjectives describing the way he feels "today" or "right now" should yield a state measure of the affect, while directions to check all adjectives which describe the way he feels "generally" should result in a trait measure of the affect. The patients in this study were directed to check all adjectives that reflected the way they felt "today".

The distinction between state and trait anxiety is frequently made in the literature. The distinction between state and trait depression is less frequently discussed. An underlying assumption in the use of the Multiple Affect Adjective Check List (Today Form) as a state measure of affect is that this distinction is also a viable one for depression. State affect is described by Spielberger (1975) as a transitory emotional condition or feeling state which may vary in intensity and fluctuate over time, while trait affect is "impervious to situational stress and relatively stable over time" (p.719).

The emotional response of the patient served as both an outcome variable and an independent variable in this study. Since the outcome of interest was the patient's emotional response to the experience of pacemaker implantation at the time of follow up, the use of a state affect measure seemed to be most appropriate. Some of the previous investigators (Greene & Moss, 1969; Price, Obel & Scott-Millar, 1980) who had identified "underlying personality" as a key variable in predicting outcome following pacemaker implantation seemed to be referring to trait affect. While admitting that trait affect may well influence the outcome, the investigator wished to maintain the focus of this study on variable(s) that were potentially amenable to modification through nursing intervention. Consequently, the decision was made to use a state affect measure before surgery and at the one month follow up as independent variables, since such affective states might be modifiable through short-term nursing interventions.

Of the 132 items, 21 items are included on the Anxiety scale, 40 items on the Depression scale and 28 items on the Hostility scale. The remaining 43 items are not included on any scale. No adjective appears on more than one scale. Each scale consists of plus and minus items. Plus items are scored if the respondent checks the adjective. Minus items are scored if the respondent does not check them. There are approximately the same number of plus and minus items on each scale.

Only the Anxiety and Depression scales were scored for the purposes of this study.

The validity of the MAACL Anxiety and Depression scales has been tested in a number of studies which were reviewed in the test manual (Zuckerman & Lubin, 1965). One of the key issues in considering the validity for a measure of state affect is whether or not the scores do vary with experimently or naturally occurring alterations in mood states, such as hypnotically induced mood states, or stress inducing situations. The MAACL (Today Form) Anxiety scale scores have generally reflected the expected alteration in anxiety level with experimentally induced anxiety or relaxation states and with naturally occurring stress situation. The Anxiety scale (Today Form) has also demonstrated statistically significant correlations with clinical observations of anxiety. These correlations ranged from .30 to .53. The correlations between the MAACL Depression scale (Today Form) and clinical observations of depression have ranged from .35 to .47 (Zuckerman & Lubin, 1965).

The internal reliability coefficients for the Anxiety and Depression scales (Today Form) in nonpsychiatric populations were reported to range from .85 to .92. The test-retest reliability for a seven day interval for the Today Form ranged from .21 to .31 while the General Form had test-retest reliability of .68 (Zuckerman & Lubin, 1965). The test-retest data reflect the fact that the Today Form is attempting to measure the day to day fluctuations in affect and consequently, one would not anticipate significant test-retest reliability correlations.

Because the Multiple Affect Adjective Check List has been widely used with multiple diverse populations in previous research, the investigator did not attempt to establish the internal reliability of this test for the specific samples in this study.

Review of the literature on this test did identify two potential difficulties which might affect the interpretation of the Anxiety and Depression scale scores. A possible response set effect in terms of the total number of items checked was reported by Herron (1969) and Johnson (1970). Statistically significant correlations between the two scales were described by Panderwitz et al. (1972). The scores of the two scales in this sample were examined to determine if either, or both, problems might be influencing the scale scores.

The correlation between the total number of adjectives checked and the scale scores ranged from -.37 to -.56 for the Anxiety scale ($\underline{p} < .01$) and -.52 to -.59 for the Depression scale ($\underline{p} < .01$). These correlations are similar to those reported by Herron (1969) and Johnson (1970). Zuckerman (1969) in his discussion of the potential for response set effect in the MAACL (Today Form) noted that the effect varied and recommended that "users are advised to examine the response set influence in their own data and to remove it, if necessary, with covariance or partial correlation techniques" (p.774). The correlations made to the data in this study will be discussed later in this chapter.

Zuckerman & Lubin (1965) argued that, although the Anxiety and Depression scales did demonstrate substantial correlations with each other, the two scales did show different patterns in response to stimuli. They believed that the different response patterns supported the contention that the scales measured different affects. Pankrantz et al.

(1972) believed that all three MAACL scales were measures of a single affect. Examination of the correlations between the Anxiety and Depression scale data in this study revealed correlations ranging from .56 to .83 with a mean of .73. These correlations are similar to those reported by both Zuckerman and Pankrantz. Plots of the change in the scale scores over the three times of testing indicated almost parallel change in the mean scores. Plots of the scores for randomly selected individual patients yielded similar results. Therefore, it was decided that it was likely that the scores on the two scales reflected a single negative affect rather than two distinct affects, anxiety and depression. The two scores were combined into a single affect score. This single affect was labelled "subjective distress" by the investigator.

## HEALTH PERCEPTION QUESTIONNAIRE

In reviewing 40 studies which had included health perception as either an independent or dependent variable, Ware et al. (1978) noted that in 33 of the studies, health perception was measured by a single item. In the other studies, multi-item scales were used to measure health perceptions. Since self perception of health was a major independent variable in this study, it seemed important to search for an instrument which had established reliability and validity. Ware et al. (1978) noted that none of the researchers who had used the single item measure had reported reliability estimates. The multi-item scales which had been used previously and reviewed by Ware et al. included items relating to the actual use of health care services, such as hospitalization or physician visits as well as perceptions about current health status. Therefore, they did not seem suitable for use in this study. In an attempt to answer the deficiencies in the previous approaches to the meausrement of self perception of health, Ware and his colleagues at Rand Corporation devloped the General Health Perceptions Questionnaire for use in their study on the impact of different approaches to health care funding on the use of health care services, quality of care, satisfaction with care and health status.

The Health Perception Questionnaire, Form II (Appendix B) is a 32 item, self administered questionnaire consisting of favourably and unfavourably worded statements of opinion about general health. There are five possible responses: "definitely true", "mostly true", "don't know", "mostly false" , and "definitely false". Six scale scores can be obtained from the Health Perceptions Questionnaire: Current Health, Prior Health, Health Outlook, Resistance/Susceptibility, Health Worry/ Concern, and Sickness Orientation.

The reliability data on the six scales on the Health Perceptions Questionnaire indicated internal consistency reliabilities, as measured by Conbach's alpha, ranging from a low of .45 for the Health Worry/ Concern scale to a high of .92 for the Current Health scale. Test-retest reliability ranged from .42 on the Sickness Orientation scale to .86 on the Current Health scale. Ware et al. (1978) concluded that the reliability coefficients for all scales were sufficient to warrant the use of this questionnaire with groups. According to Helstadtler (1964), internal consistency coefficients should be .90 or above for use of a scale to test individual differences. Only the Current Health scale meets this standard.

Of the six scales of the General Health Perception Questionnaire, the Current Health scale seemed to be most closely related to the concept of self perception of health as it had been defined in previous research. Consequently, a decision was made, based on both psychometric and conceptual criteria, to use only the Current Health scale in this study. The patients did complete the entire 32 item questionnaire.

The Current Health scale consists of nine items, five of which are positively worded and four negatively worded. After field testing with over 2000 respondents, Ware et al. (1978) reported an internal consistency coefficient (Cronbach's alpha) ranging from .89 to .92 with a median of .91 in five different test sites (p.42). The test-retest reliability obtained approximately six weeks apart was .76 and .86 in two sites (p.42). Ware et al. noted that the scale scores appear to be slightly less reliable for respondents reporting less education, lower income, and older age. There appeared to be no difference in the reliability for men and women.

The scale scores demonstrated construct validity in an analysis of the associations among the six different scales. Additionally, the correlation between the scale scores and 21 health related variables (11 other measures of health, seven measures of health and illness behaviour and age) supported the validity of the questionnaire as a measure of health perception. The Current Health scale demonstrated positive and statistically significant correlations with variables defining favorable ble health states, and statistically significant negative correlations with those variables defining unfavorable health states. The correlations ranged from .21 to .80. Current Health had a -.26 correlation with age (Ware et al., 1978, p.53).

In this study, the Cronbach's alpha for Current Health ranged from .86 to .89 over the three times of testing. These values were slightly less than those demonstrated by Ware et al. (1978). The median age in Ware's five field tests ranged from 32 to 51 years. The median age in this study sample was 70 years and Ware had noted that there might be slightly less reliability with older aged respondents.

The preoperative one and six months Current Health scale scores in this study demonstrated statistically significant negative correlations of -.23 to -.51 with variables indicating unfavourable health such as the more cardiovascular symptoms, and poorer general health status at follow up. In conclusion, the findings related to validity and reliability of this scale in this study were quite similar to those of Ware et al. (1978) and indicated that the questionnaire could be considered a valid and reliable measure of health perception for this study.

## DATA COLLECTION PROCEDURE

Prior to the beginning of data collection, the research proposal was reviewed and approved by the university committee on research with human subjects and the Nursing Department and Medical Advisory Committee of the hospital. The investigator discussed the proposed study with the staff of the Pacemaker Center and the nursing staff of the in-patient units, which were going to be used, in order to introduce the purpose and procedures of the study. Approval of the medical staff in the Division of Cardiology and Cardiovascular Surgery Department was received through the departmental chairmen.

The names of the patients who were scheduled for pacemaker implantation were obtained from the surgeon's office. The investigator then checked with the nursing staff regarding the patient's suitability for inclusion in the study. It was also necessary to be sure that the patient had been informed of the scheduled surgery. The patients were visited during the afternoon on the day prior to surgery. After the study was explained (Appendix E) and the consent signed (Appendix F), the interview took place at the patient's bedside. The actual length of the interview varied from 20 minutes to an hour, since some patients seemed to want to elaborate on their answers to the investigator's questions. After the interview, the investigator read the instructions for each questionnaire and answered any questions that the patient had. After making sure that the patient understood the instructions, the questionnaires, a pencil and an envelope were left with the patient. The patient was asked to complete the questionnaires that afternoon or evening and place them in the envelope for the investigator to pick up the following day. The decision to leave the questionnaires with the patient to complete at his convenience was made after testing the data collection procedure during the pretest. Many patients found that the best time to complete the questionnaires was in the evening after visitors had left and other activities such as physical examinations and x-rays were finished for the day.

As will be noted later in the discussion of the results, 37 per cent of the patients who originally agreed to participate in the study, including completing the questionnaires, subsequently did not complete them. The reasons given by the patients for not completing the questionnaires were usually that they were too tired by the end of the day or that they did not like to fill in written forms.

The investigator picked up the completed questionnaires the next day. At that time she reminded the patients that she would talk with them again during their clinic visit in one month. The actual date and time of the clinic appointment were arranged by the Center staff before the patient's discharge. The investigator obtained the appointment time from the clinic appointment book.

In the clinic, patients frequently had to wait to have the electrocardiogram done or to be seen by the physician. Therefore, most follow-up interviews and questionnaires were completed while the patient was waiting. This was done so that the patients were not required to spend extra time in the clinic.

Throughout the patient intake period, the investigator maintained a log of all patients undergoing pacemaker implantation. If a patient was excluded from the sample, the reason for excluding that patient was recorded in the log book. Basic demographic and clinical data for all patients (including the patients who were not included in the study) were available from the database. This enabled the investigator to compare the patients who were included in the study with the total patient population undergoing pacemaker implantation during the 18 months intake period on the basic demographic and clinical parameters.

## DATA REDUCTION AND TRANSFORMATION

In the process of data analysis, a number of data reduction and/or transformations were required. Transformations in the scores on the Anxiety and Depression scales of the MAACL were done because of the significant interscale correlations and the apparent response set for the total number of adjective checked.

Two clinical status variables, cardiovascular symptoms and general health, were developed from the larger number of specific clinical variables in order to increase the statistical power of the regression analyses.

## DEVELOPMENT OF THE SUBJECTIVE DISTRESS SCORE

The rationale for combining the Anxiety and Depression scale scores has been presented earlier (p. 75). There were 21 items on the Anxiety scale and 40 items on the Depression scale. It seemed conceptually appropriate to weight the two scales equally in computing the single affect score. Therefore, it was necessary to transform the raw scores of each scale into Z scores prior to adding the two scores together to create the single affect scale score, which was labelled Subjective Distress by the investigator.

Herron (1969) reported that it was likely that the total number of adjectives checked on the MAACL (Today Form) acted as a response set. In response to Herron's report, Zuckerman (1969) reported that the correlation between the total adjectives checked and the scores varied and that each researcher using the MAACL should "examine the response set influence in their own data and remove it, if necessary, with covariance or partial covariance or partial correlation techniques" (p. 774). In scoring the MAACL, the respondent receives a score for not checking ceratin items as well as for checking other items. The overall result is that those respondents who check fewer items are more likely to receive higher scores on the affect scale. The investigator first became concerned about the possibility of this response set when scoring the MAACL. The scores for Anxiety and Depression scales for some of the patients seemed to be higher than the investigator anticipated, based upon her observations during the interview. In many of the cases where the scores were incongruent with the investigator's observations, the patient had checked fewer items than usual. (The mean number of adjectives checked ranged from 29 to 32 over the three times.) The number of adjectives checked demonstrated low correlations with the demographic and clinical variables, ranging from .04 to .24. The correlations between the number of adjectives checked and the Subjective Distress score were highly significant, ranging from .48 to .62 ($\underline{p} < .01$). This seemed to indicate that the number of items checked was introducing a response set bias into the affect score.

On the other hand, it is entirely possible that the number of adjectives checked reflected the underlying negative affect and that by correcting for the number of items checked one might be "discarding" part of the affect being measured. The investigator's clinical observations did not support the latter argument. Consequently, the investigator decided to correct for the apparent response set bias. As suggested by Zuckerman (1969), a regression analysis was done with the Subjective Distress score as the dependent variable and the total number of adjectives checked as the independent variable. A residual dependent variable was computed and the residual Subjective Distress score was substituted for the raw Subjective Distress score in all subsequent analyses.

## COMPUTATION OF THE CLINICAL STATUS VARIABLES

Data were collected on several clinical status variables prior to surgery and at one and six months postimplant. The use of all the variables in the regression analyses would have been costly in terms of statistical power. If the variables are correlated with each other, a single combined variable is likely to be more focused and statistically powerful than two or three variables.

Preoperative clinical status variables. Since the correlation between the number of cardiovascular symptoms and the duration of symptoms demonstrated a substantial correlation, these two variables were combined. Each variable was divided by its standard deviation so that each would be equally weighted. A subsequent check on the regression analysis showed that the single variable alone, and the two original variables, taken together, accounted for similar variance in the outcomes. The combined variable was labelled "cardiovascular symptoms".

The second preoperative clinical status variable which was labelled "preoperative general health status" was computed using the variable indicating a preoperative history of cardiovascular illness and the variable indicating a preoperative history of other chronic illness. Each of the original variables was divided by its standard deviation in order to weight the variables equally. A check on the regression with the outcomes indicated that the single combined variable and the two separate variables accounted for similar variance.

Clinical status variables at one and six months. The same procedure as described above for the preoperative clinical status variables was followed in combining the cardiovascular symptoms and pacemaker complications at one and six months into a single variable.

The data for general health status at follow up reflected changes in symptoms and the need for medical care for nonpacemaker related health problems. Among those patients who had not required medical care for nonpacemaker related health problems, some patients had no history of prior chronic illness, while others had a history of chronic illness. It seemed appropriate to differentiate these patients from each other in the scoring of the general health status at one and six months. Therefore, general health status at follow up was determined in the following way:

a) If the patient had received medical care during the follow up period, the variable was scored according to the original coding (see Appendix A, card 2, #14). Five (5) was then added to this score.

b) If the patient had not sought medical care during the follow-up period, the score on the preoperative general health status variable, as described above, was substituted in the coding for general health status at follow up.

The scores on this variable then ranged from two (2) for a patient who had not sought medical care during the follow up period and who had no history of cardiac or chronic illness to 11 for a patient who had been hospitalized during the follow up period.

## STATISTICAL ANALYSES

All statistical analyses were carried out using the programs of the Statistical Package for the Social Sciences (SPSS), Release 9 (Nie, Hull, Jenkins, Steinbrenner & Bent, 1975; Hull & Nie, 1981). Tests of significance were considered to be statistically significant if $p = .05$ or less.

# Chapter VI

# FINDINGS

In this chapter the findings of the study will be described and the analyses directed by the research questions will be presented. The meaning of the findings and the implications for practice will be discussed in the next chapter.

The demographic and preoperative clinical status characteristics will be presented. The study sample will be compared to the population of patients who underwent initial pacemaker implantation in Canada from 1979 through 1981, and with the patients who underwent initial pacemaker implantation at the Pacemaker Center used in this study, during the study period, but who were not included in the study. The clinical status following implantation, activity before and after implant, and the findings on the health perception and subjective distress questionnaires will be described.

Some patients were lost to follow up over the course of the study and some patients did not complete all of the written questionnires. The possible effects of this attrition and incomplete data will be included in the description of the sample data. Finally, the analyses described by the research questions will be presented.

## SAMPLE

From February 1, 1980 to July 31, 1981, 313 patients underwent initial pacemaker implantation in this Center. Of the 313 patients, 136 met the criteria for the study and were interviewed prior to surgery.

## ATTRITION

Over the course of the study, there was attrition from the original cohort of 136 patients who were interviewed preoperatively. One hundred and twenty-three patients (123) were interviewed in the Pacemaker Center one month following implantation. There were three patients who were not seen at one month who were interviewed at six months. At six months, an additional 24 patients were lost to follow up. Thus, 102 patients were interviewed at six months following implantation.

The reasons for attrition at one and six months are indicated in Table 3.

Table 3

REASONS FOR ATTRITION FROM THE STUDY

| Reason for Attrition | N lost to follow up | |
|---|---|---|
| | one month | six months |
| Follow up elsewhere | 6 | 7 |
| Transtelephone follow up | 2 | 7 |
| Investigator missed | 3 (2)[a] | 4 |
| Patient did not return | - | 3 |
| Death | 1 | 3 |
| Hospitalized | 1 (1) | - |
| Total | 13 (3) | 24 |

[a] the number in the parentheses indicates the number of patients not seen at one month, but seen at six months

The major reasons for attrition were follow up at another center and follow up by transtelephone ECG transmission. While it was originally planned that the patients who were entered into this study would return to the Pacemaker Center for follow up for, at least, the first six months, alternate plans were made for some patients because of the difficulties which some patients had travelling long distances to the clinic. Travel was a particular problem during the winter.

## INCOMPLETE DATA

Some patients did not complete one or both of the written questionnaires at each interview. Thirty-six (36) of the 102 patients who were interviewed at six months did not complete the MAACL. Consequently, complete outcome data, i.e. activity resumption and subjective distress at six months, were available for only 66 patients. The data for these 66 patients were used in all of the analyses directed by the research questions.

In the discussion of the preoperative sample data, the findings for these 66 patients will be presented along with the findings for the 136 patients seen prior to surgery. The findings for the 66 patients and either the 123 patients or the 102 patients who were interviewed at one or six months, respectively, will be the basis for the follow up data presented in this chapter.

## DEMOGRAPHIC CHARACTERISTICS

The demographic characteristics of the 136 patients interviewed prior to surgery, and the 66 patients, for whom complete outcome data, were available are presented in Table 4. The age of the patients ranged from 20 to 88 years, but most patients were over 65 years. When percentages are used in this and subsequent tables, the column total may not equal 100 per cent because of "rounding error". The sample of 66 patients was significantly younger than the other 70 patients who were interviewed prior to surgery, but who did not have complete outcome data because they were lost to follow up or did not complete the MAACL at six months.

Table 4

DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE

| Characteristic | % of Patients | |
|---|---|---|
| | Interviewed Preoperatively (a) | For Whom Complete Outcome Data Were Available (b) |
| Age: | | |
| Mean age | 69.02 | 65.94** |
| Median age | 70.30 | 68.50 |
| Range | 20 - 88 | 20 - 88 |
| Gender: | | |
| Male | 59% | 67% |
| Female | 41% | 33% |
| Marital Status: | | |
| Married | 63% | 74% |
| Widowed | 27% | 20% |
| Divorced | 4% | 2% |
| Single | 5% | 5% |
| Socioeconomic Class: | | |
| Class 1 | 11% | 19% |
| Class 2 | 13% | 12% |
| Class 3 | 17% | 17% |
| Class 4 | 15% | 15% |
| Class 5 | 24% | 20% |
| Class 6 | 19% | 17% |

[a] $n = 136$ [b] $n = 66$

** $t\ (134) = 2.83$, $p < .01$ for comparison between patients for whom complete outcome data and those for whom complete data were not available.

Pearson correlations among the demographic variables indicated that the women in the sample tended to be older than the men, and were more frequently widowed, single or divorced (see Table 5).

Table 5

PEARSON CORRELATIONS AMONG THE SAMPLE DEMOGRAPHIC CHARACTERISTICS

| | Age in Years | Gender | Marital Status | SES |
|---|---|---|---|---|
| Age in Years | 1.000 | .253** | .269** | -.083 |
| Gender | .253** | 1.000 | .371** | .008 |
| Marital Status | .269** | .371** | 1.000 | .114 |
| SES | -.083 | .008 | .114 | 1.000 |

_n_ = 136

** _p_ $<$.01

## CLINICAL STATUS

### PREOPERATIVE CLINICAL STATUS

ECG indications and etiology. As indicated in Table 6, sinus node disease (Sick Sinus Syndrome) and complete heart block were the most frequent electrocardiographic indications for pacing. These two conduction defects had approximately equal incidence and together they accounted for over 80 per cent of the pacemakers implanted.

Table 6

MAJOR ECG INDICATIONS FOR PACING

| ECG Indication | % of Patients Interviewed Preoperatively (a) | % of Patients For Whom Complete Outcome Data Were Available (b) |
|---|---|---|
| Sinus Node and Inta-atrial: | | |
| Sinus bradycardia | 12% | 11% |
| Sinus arrest | 23% | 21% |
| Brady-tachycardia | 8% | 6% |
| SA exit block | 1% | 2% |
| AV Node: | | |
| $1^0$ AV block | 1% | - |
| Mobitz I | 2% | 3% |
| Mobitz II | 4% | 5% |
| Complete heart block | 39% | 43% |
| AF with slow ventricular response [c] | 9% | 8% |
| Ventricular Blocks: | | |
| Right bundle branch block | 1% | 2% |
| Left bundle branch block | 1% | 2% |
| Other: | | |
| Bradycardia due to drug therapy | 1% | - |

[a] n = 136

[b] n = 66

(c) atrial fibrillation with slow ventricular response

The etiology of the conduction defect was primarily either idiopathic or chronic ischemic heart disease (see Table 7). A small percentage of the patients had recently had a myocardial infarction or undergone cardiac surgery. The low incidence of congenital conduction disorders reflected the exclusively adult patient population of this hospital. The ECG indications and etiology of the conduction disorder were very similar in both the total sample of 136 patients interviewed prior to surgery and the 66 patients for whom complete outcome data were available.

Table 7

ETIOLOGY OF CONDUCTION DISORDER

| Etiology | % of Patients | |
|---|---|---|
| | Interviewed Preoperatively (a) | For Whom Complete Outcome Data Were Available (b) |
| Idiopathic | 36% | 39% |
| Chronic Ischemic | 27% | 21% |
| Degenerative | 17% | 17% |
| Surgery - recent | 7% | 11% |
| Surgery - remote | 2% | 3% |
| Myocardial Infarction - recent | 6% | 5% |
| Cardiomyopathy | 2% | 3% |
| Congenital | 2% | 2% |
| Other | 2% | - |

$^{a}\underline{n} = 136$

$^{b}\underline{n} = 66$

<u>Cardiac symptoms</u>. The most frequently identified preoperative symptom was syncope. Presyncope was the next most frequently named symptom as indicated in Table 8.

Table 8

LIMITING CARDIOVASCULAR SYMPTOMS
PRIOR TO SURGERY

| Limiting Symptom | % of Patients | |
|---|---|---|
| | Interviewed Preoperatively (a) | For Whom Complete Outcome Data Were Available (b) |
| Syncope | 35% | 35% |
| Presyncope | 29% | 27% |
| Dyspnea | 15% | 17% |
| Asymptomatic | 7% | 9% |
| Fatigue | 4% | 3% |
| Angina | 4% | 6% |
| Palpitations | 4% | 3% |
| Chest Pain (other) | 4% | 3% |

[a]$\underline{n}$ = 136

[b]$\underline{n}$ = 66

The total number of cardiac symptoms reported by the patients ranged from zero to seven with most of the patients reporting one to three symptoms (see Table 9).

Table 9

NUMBER OF CARDIOVASCULAR SYMPTOMS
PRIOR TO SURGERY

| Number of Symptoms | % of Patients Interviewed Preoperatively (a) | % of Patients For Whom Complete Outcome Data Were Available (b) |
|---|---|---|
| Asymptomatic | 7% | 9% |
| One | 31% | 32% |
| Two | 28% | 26% |
| Three | 20% | 21% |
| Four | 12% | 9% |
| Five | 2% | 2% |
| Six | - | - |
| Seven | 1% | 2% |

[a] *n* = 136

[b] *n* = 66

Duration of symptoms. The duration of symptoms reported by the patients during the preoperative interview varied from those who reported that they were asymptomatic to those who reported experiencing symptoms for more than two years. Table 10 indicates the distribution of duration of symptoms for the patients who were interviewed prior to surgery and for those for whom complete data were available. The 66 for whom complete data were available were more likely than the 70 patients for whom complete outcome data were not available, to have had symptoms for less than one month prior to implant ($\chi^2(1) = 8.5$, $p < .01$) The reason for this difference is not clear.

Table 10

DURATION OF SYMPTOM(S)
PRIOR TO SURGERY

| | % of Patients | |
|---|---|---|
| Duration | Interviewed Preoperatively (a) | For Whom Complete Outcome Data Were Available (b) |
| Asymptomatic | 7% | 9% |
| Less than 1 week | 10% | 6% |
| One week to 1 month | 34% | 47% |
| One month through 3 months | 12% | 9% |
| Four through 6 months | 7% | 5% |
| Seven through 12 months | 13% | 9% |
| Greater than 12 but less than 24 months | 8% | 5% |
| Twenty-four months or more | 10% | 11% |

[a] _n_ = 136

[b] _n_ = 66

Previous cardiac illnesses and other chronic illness. Sixty-three per cent of all patients interviewed prior to implant reported that they were receiving treatment, usually medication and/or diet modification, for previously diagnosed cardiovascular problems prior to the pacemaker implantation. An additional 7 per cent indicated that they had been told previously that they had some form of cardiovascular disease which did not require treatment at that time. Sixty-two per cent of the 66 patients for whom complete outcome data were available were receiving treatment for other cardiovascular illness and an additional 9 per cent had cardiovascular illness not requiring treatment.

Almost half of all patients interviewed preoperatively and a subsample of 66 patients for whom complete outcome data were available had other chronic illnesses such as diabetes, arthritis or cancer, which required treatment.

Eighty per cent of all patients were receiving some type of treatment for either cardiovascular or other chronic illness prior to the pacemaker implantation. The proportion of patients receiving treatment was the same in the subsample of 66 patients.

## PACING MODE

Most of the patients included in the study received a programmable VVI pacemaker. In January, 1981, a DVI, dual chamber ventricular inhibited pacemaker was introduced at the Center and by the completion of the patient intake period in July, 1981, was frequently being implanted. Twenty per cent of the patients interviewed preoperatively received a DVI pacemaker, 2 per cent were paced with AAI pacemakers and the remaining 78 per cent received a VVI pacemaker. The distribution of pacing mode was different for 66 patients for whom complete data were available. Seventy per cent of this subsample had VVI pacemakers; 2 per cent had AAI pacemakers and 29 per cent had DVI units. When the 66 patients for whom complete outcome data were available were compared to the 70 patients who did not have complete outcome data, the difference in pacing mode was statistically significant ($\chi^2$ (2) = 6.55, $\underline{p} < .05$). The increased proportion of patients with DVI pacemakers in the subsample of 66 patients probably resulted from the more intensive follow-up of patients with these units. They were less likely to be referred out to satellite follow-up centers.

## COMPARISON OF THE SAMPLE WITH THE CANADIAN POPULATION OF PATIENTS UNDERGOING PACEMAKER IMPLANTATION

When one compared the patients in this study with the population of patients who underwent pacemaker implantation in Canada between 1979 and 1981 (Goldman, Duncan & Wilson, submitted for publication), the following observations could be made. The preoperative sample of 136 patients was slightly older with a mean age of 69 years versus a mean age of 67 years for all Canadian patients, but the subsample of 66 patients was younger with a mean age of 66. There was approximately the same distribution of men and women in the study sample and the Canadian population of patients. The electrocardiographic indications for pacing and the etiology of the conduction disorders were similar.

The mode of pacing for the preoperative sample was similar to that of the Canadian population, but the proportion of patients in the subsample of 66 patients, who had DVI pacemaker was greater than was indicated in the general Canadian data. All of the patients in this study had programmable pacemakers. These units are not as frequently used in some other centers in Canada.

## COMPARISON OF THE SAMPLE WITH PATIENTS NOT INCLUDED IN THE STUDY

In the 18 months of patient intake into this study, an additional 177 patients underwent initial pacemaker implantation in this hospital. The reasons for not including these 177 patients in this study are presented in Table 11.

Table 11

REASONS FOR NOT INCLUDING A PATIENT IN THE STUDY

| Reason | % of Patients (a) |
|---|---|
| Late transfer to this Center[b] | 38% |
| Did not speak English | 13% |
| Late addition to the OR list | 11% |
| Critically ill | 10% |
| Diminished mental status | 10% |
| Patient declined | 5% |
| Follow up planned elsewhere | 4% |
| Other | 8% |

[a] $\underline{n} = 177$

[b] includes patients admitted for surgery only and receiving all pre- and postoperative care in another hospital

The patients included in the study did not differ from those who were not included in terms of gender, limiting symptom, ECG indications for pacing or pacing mode used. The mean age of the patients who were not included (71.5 years) is higher ($\underline{t}$ (316) = 1.74, $\underline{p} < .10$, two tailed test) than the 136 patients who were interviewed preoperatively. The difference between the subsample of 66 patients and the patients who were not included is even greater. This difference reflects the number of very elderly (above 85 years of age) patients in the population from one of the hospitals that referred patients for surgery only. These patients received all of their pre- and postoperative care in the other hospital.

## CLINICAL STATUS AT ONE MONTH

Pacemaker function and complications. For 122 of the 123 patients interviewed at one month, the pacemaker was judged to be functioning normally. The other patient was found to have a lead displacement, although he was asymptomatic. Seventeen patients (14%) of the 123 patients had had some unexpected complication during the first postoperative month. Half of these complications occurred during the patient's initial hospitalization. Two of the complications which occurred after discharge from the hospital required readmission to the hospital. The remaining problems were corrected by pacemaker programming and/or reassurance in the clinic. The incidence of complications in the subsample of 66 patients paralleled that of the total sample interviewed at one month (see Table 12).

Table 12

COMPLICATIONS BETWEEN IMPLANTATION AND THE
ONE MONTH CLINIC VISIT

| Complications | % of Patients | |
|---|---|---|
| | Interviewed at One Month (a) | Complete Outcome Data Available (b) |
| None | 86% | 83% |
| Required office visit only[c] | 5% | 5% |
| Extended Original Hospitalization[d] | 7% | 11% |
| Required rehospitalization[e] | 2% | 2% |

[a] _n_ = 123

[b] _n_ = 66

[c] included neuromuscular stimulation, failure to sense, acute threshold rise (failure to pace), pain at site

[d] included lead malposition, wound hematoma, wound infection and pulmonary embolus

[e] included lead dislodgement

Thus, 86 per cent of all patients interviewed at one month and 83 per cent of the subsample of 66 patients for whom complete outcome data were available had an uneventful postoperative course in the first month.

Cardiac symptoms. Sixty-six per cent of all patients interviewed at one month reported that they were not experiencing any cardiac symptoms. Twenty-three per cent reported at least one cardiac symptom, but denied experiencing the symptom which had been described as the major limiting symptom preoperatively. The limiting symptom was still present for 10 per cent of the patients with 8 per cent of the patients reporting that symptom alone, while 2 per cent reported the limiting symptom along with other cardiac symptoms. Once again, the incidence of symptoms at one month in the subsample of 66 patients approximated that of the total sample of 125 patients interviewed at one month.

The patients who reported symptoms did not differ from those who were asymptomatic at one month in terms of the previously identified limiting symptom, the ECG indications for pacing, pacing mode employed, or the gender of the patient. Older patients did report more symptoms.

General health status. Thirty-three per cent of the 123 patients interviewed reported that they had not seen a physician between the time of the implantation and the one month clinic visit other than for care related to the pacemaker. Twenty-eight per cent reported visiting their physician for "routine or continuing care" while 11 per cent of the patients reported an increase or change in symptoms. Five per cent of the patients reported new symptoms which required medical attention. Thirty patients (25%) of the 123 patients who were seen at one month reported being hospitalized in the preceding month for a nonpacemaker related health problem. The reasons for hospitalization are indicated in Table 13.

Table 13

## REASONS FOR HOSPITALIZATION IN THE FIRST POSTOPERATIVE MONTH

| Reason for Hospitalization | % of Sample of 123 Patients |
|---|---|
| Other cardiac problems (MI, angina, IHSS) | 5% |
| Regulations of cardiac medications | 4% |
| Cardiac surgery related | 2% |
| Vascular (CVA, TIA, femoral by-pass, anticoagulation) | 4% |
| Other surgery (TURP, hernia repair, hysterectomy) | 3% |
| Other (stasis ulcer, diabetes, pneumonia | 7% |

Forty-three per cent of the hospitalizations were for cardiovascular related problems; 17 per cent were for vascular problems and 13 per cent for surgery. The surgeries had frequently been delayed until after pacemaker implantation. The remaining 27 per cent of hospitalizations were for a variety of medical problems.

The incidence and reasons for physician visits and hospitalization in the subsample of 66 patients for whom complete outcome data were available were similar to that reported for the total sample interviewed at one month.

## CLINICAL STATUS AT SIX MONTHS

Pacemaker function and complications. The pacemaker function was judged to be normal in 100 of the 102 patients who were followed at six months postimplantation. Two patients had questionable pacemaker function, i.e., it was not clear if the pacemaker was pacing and/or sensing normally without further testing. Between the one month and six months clinic visits, four patients had complications which required rehospitalization. Two patients required clinic visits in the interim period for programming because of myopotential inhibition or the need for change in the pacing mode. Two patients were found to have neuromuscular stimulation at the time of the six months clinic visit. The complication rate in the subsample of 66 patients for whom complete outcome data were available was similar to that of the total 102 patients interviewed at six months. The complications are noted in Table 14.

Table 14

PACEMAKER COMPLICATIONS BETWEEN ONE AND SIX MONTHS

| Complication | % of Patients Interviewed at One Month (a) | % of Patients For Whom Complete Outcome Data Were Available (b) |
|---|---|---|
| None | 92% | 93% |
| Required office visit only[c] | 4% | 4% |
| Required rehospitalization[d] | 4% | 3% |

[a] n = 102

[b] n = 66

[c] included symptomatic myopotential inhibition, neuromuscular stimulation, change of pacing mode from DVI to VVI

[d] included lead dislodgement, lead fracture, change of pacing mode from AAI to VVI

Note: asymptomatic myopotential inhibition was not considered as a complication

Cardiac symptoms. Seventy-one per cent of both the 102 patients interviewed at six months and the subsample of 66 patients, for whom complete outcome data were available, reported that they were asymptomatic at the time of the six months interview. Sixteen per cent of the 102 patients and 15 per cent of the 66 patients reported at least one cardiac symptom other than that which was identified as the limiting symptom prior to implant. Fourteen per cent of all patients seen at six months reported that the limiting symptom persisted. The incidence of the limiting symptom in the subsample of 66 patients was also 14 per cent.

General health status. Between one and six months,most patients, 83 per cent of the 102 patients interviewed at six months saw their physician for some reason other than for pacemaker evaluation. Forty-seven per cent of all patients interviewed at six months reported that the visits were for "routine or continuing care", for example, routine blood pressure checks. Sixteen per cent of the patients experienced an increase or change in symptoms and 5 per cent experienced new symptoms necessitating medical care. Sixteen per cent of the patients had been hospitalized during this period. The findings for the subsample of 66 patients parallel those for the total sample. The reasons for hospitalization are in Table 15.

Table 15

REASONS FOR HOSPITALIZATION BETWEEN ONE AND SIX MONTHS

| Reason for Hospitalization | % of 102 Patients |
|---|---|
| Other cardiac problems (angina, CHF) | 2% |
| Regulation of cardiac medications | 4% |
| Cardiac surgery | 1% |
| Vascular (CVA, TIA) | 6% |
| Other surgery (hip replacement) | 1% |
| Other (injury, back problem) | 2% |

There were fewer hospitalizations during the five months from the end of the first month to six months than there were in the one month period immediately following the pacemaker implantation. This might well reflect the multifaceted nature of the patients' illnesses at the time of the implant. The reasons for hospitalization continue to be primarily related to cardiovascular problems. Of note are the number of hospitalizations for cerebralvascular problems, such as strokes or transient ischemic attacks.

## ACTIVITY STATUS

### PREOPERATIVE ACTIVITY

Prior to the onset of symptoms, 28 per cent of all 136 patients interviewed preoperatively were employed. With the onset of symptoms, 61 per cent of the employed patients decreased both the amount and kind of work activity. Patients who were immediately hospitalized upon the onset of symptoms were included in this group. Housekeeping was described as the major presymptom activity for 43 per cent of the patients, including 13 men. A greater proportion of the patients (76%) who were primarily engaged in housekeeping descreased activities following the onset of symptoms. ($\underline{\chi}^2(1) = 3.4$, $\underline{p} < .10$ for kind, and $\underline{\chi}^2(1) = 4.13$, $\underline{p} < .05$ for amount of activity).

One patient was a full-time graduate student and two patients reported that organizational activities (for example, being president of a national voluntary organization) were their major activities prior to the onset of symptoms. Because of the small number of patients in the student or organizational categories, these two categories were combined with the work category for the purposes of subsequent data analysis.

Twenty-seven per cent of all patients interviewed prior to implant were retired prior to the onset of symptoms.

Only 3 per cent of the 136 patients said that they did not usually have some social activity prior to the onset of symptoms. Of the 97 per cent of patients who were socially active, 70 per cent reported a decrease in social activity with the onset of symptoms.

Ninety-eight per cent of the 136 patients reported that they had some type of leisure activity prior to the onset of symptoms. Sixty-seven per cent of these patients described a change in the kind of activity or a decrease in the amount of leisure activity with the onset of symptoms.

The percentage of patients who decreased activity in each of the three activity categories (work, social and leisure) is similar. Thus, the onset of symptoms seemed to have an overall effect on the patients' lives.

The subsample of 66 patients for whom complete outcome data were available differed from the original cohort of 136 patients in terms of preoperative activity. Forty-six per cent of the subsample were either employed, or engaged in full-time study or organizational activities as compared to 28 per cent of the total sample. Thirty-three per cent were primarily involved in housekeeping and the remaining 21 per cent were retired, compared to 43 per cent involved in housekeeping and 23 per cent retired in the total sample. When the subsample of 66 patients, for whom complete data were available, was compared with the 70 patients, who were interviewed prior to implant but who did not have complete outcome data, the final subsample of 66 patients included significantly more patients who were working and fewer homemakers and retirees ($\underline{\chi}^2(2) = 14.25$, $\underline{p} < .01$). The increased proportion of patients who were employed in the subsample of 66 patients, may reflect the increased attrition of women from the original cohort of patients, since the women in this study tended not to be employed outside the home.

The presymptom social and leisure involvement of the subsample of 66 patients was the same as the total patient sample who were interviewed preoperatively.

## ACTIVITY RESUMPTION AT ONE MONTH

The extent of presymptom activity resumption by one month as reported by all 123 patients interviewed at that time and the subsample of 66 patients, for whom complete outcome data were available, is indicated in Table 16. The extent of activity resumption varied from "the resumption of no presymptom activities with no plans to resume activities" to "resumption of all presymptom activities". For the total sample of 123 patients interviewed at one month, 25 (or 29%) of the 87 patients who were not retired prior to the onset of symptoms had not resumed any of their work or housekeeping activities by one month. Eighteen (or 72%) of the 25 patients who had not resumed activities, indicated that they did have plans to resume these activities.

One hundred and twenty-one of the 123 patients interviewed at one month had indicated, at the preoperative interview, that they had been involved in social and leisure activities prior to the onset of symptoms. Of these 121 patients, only 2 per cent reported that they had not resumed any social activities and 4 per cent said that they had not resumed any of their presymptom leisure activities.

On the other hand, over 50 per cent of the 87 patients who were not retired prior to implant, had resumed more than half of their presymptom or housekeeping activities and over 60 per cent of the 121 patients reporting presymptom social and leisure activities had resumed more than half of these activities.

The findings for the subsample of 66 patients,for whom complete outcome data were available, are very similar to those for the total sample of patients interviewed at one month. Fifty-two of these 66 patients had been employed or primarily engaged in housekeeping prior to the onset of symptoms. Sixty-four of the 66 patients had reported presymptom social and leisure activities. Two of the 66 patients who had complete outcome data at six months were not interviwed at one month, so their activity resumption at one month is unknown.

Table 16

SELF-REPORTED ACTIVITY RESUMPTION AT ONE MONTH

| Extent of Activity Resumption (b) | % of Patients Resuming Activity[a] | | |
|---|---|---|---|
| | Employment or Housekeeping | Social | Leisure |
| No activities, with no plans | 8% ( 8%) | -- | 1% (--) |
| No activities, with plans | 21% (23%) | 2% ( 3%) | 3% ( 3%) |
| Less than half, with no plans | 1% (--) | 8% ( 6%) | 10% ( 8%) |
| Less than half, with plans | 14% (12%) | 24% (20%) | 29% (27%) |
| More than half, with no plans | 7% ( 6%) | 2% ( 2%) | 2% ( 2%) |
| More than half, with plans | 24% (23%) | 27% (30%) | 37% (43%) |
| All activities | 25% (25%) | 36% (36%) | 21% (16%) |
| Unknown | ( 4%) | ( 3%) | ( 3%) |
| Number of patients (c) | 87 (52) | 121 (64) | 121 (64) |

[a] activity resumption expressed in terms of presymptom activities

[b] the % in parentheses is the % of the subsample of 66 patients for whom complete outcome data were available

[c] see text for an explanation of the number of patients in each column

## ACTIVITY RESUMPTION AT SIX MONTHS

In assessing the extent of activity resumption at six months, two aspects of the presymptom activity were considered: the kind of activity and the amount of activity (see Appendix A, card 3, #40-44 for the coding of the activity outcome). A score of two (2) indicated no resumption of the presymptom activity while a score of eight (8) for the activity category indicated full resumption of both the kind and amount of presymptom activities.

As indicated in Table 17, in the total sample of 102 patients who were interviewed at six months, of the 73 patients who were not retired prior to the onset of symptoms, 49 (67%) had completely resumed their employment or housekeeping activities by the time of the six months follow up interview. An additional 8 patients (11%) of the 73 patients had made some minor modification in either the kind or amount of activities as indicated by a score of six or seven in the employment or housekeeping category. Seven patients (10%) had not resumed their presymptom work or housekeeping activities.

One hundred of the 102 patients interviewed at one month had reported presymptom social and leisure activities.

All patients had resumed some presymptom social and leisure activities with only 12 per cent of the 100 patients who had reported presymptom social activities, reporting that they had made major adjustments in either the kind or amount of social activities as indicated by a score of four or five. Sixteen per cent indicated that they had made some major change in their previous leisure activities. Seventy-seven per cent of the 100 patients reported full resumption of social activities and 61 per cent of the patients reported full resumption of leisure activities.

Fifty-two of the 66 patients, for whom complete outcome data were available, had been employed or actively involved in housekeeping prior to the onset of symptoms. Sixty-four of the 66 patients had reported presymptom social and/or leisure activities.

The findings for the subsample of 66 patients for whom complete outcome data were available are indicated by the percentage in parentheses in Table 17. The patients in the subsample reported activity resumption which was very similar to that reported by the total sample.

Table 17

SELF REPORTED RESUMPTION OF PRESYMPTOM ACTIVITIES
SIX MONTHS FOLLOWING PACEMAKER IMPLANT

| Activity Score[a] | % of Patients Resuming Activity | | |
|---|---|---|---|
| | Employment or Housekeeping | Social | Leisure |
| <u>No Resumption</u> | | | |
| Two | 10% (10%) | --- | --- |
| Three | --- | --- | --- |
| <u>Major Modification</u> | | | |
| Four | 10% (10%) | 8% ( 6%) | 8% ( 6%) |
| Five | 3% ( - ) | 4% ( 6%) | 8% ( 9%) |
| <u>Minor Modification</u> | | | |
| Six | 3% ( 2%) | 9% ( 5%) | 13% (12%) |
| Seven | 8% (10%) | 3% ( 3%) | 11% (12%) |
| Full Resumption | 67% (69%) | 76% (80%) | 60% (60%) |
| Number of Patients (c) | 73 (52) | 100 (64) | 100 (64) |

<u>Note</u>. column totals may not equal 100% because of "rounding error"

[a] see text for explanation of activity score

[b] the % in parentheses indicates % of subsample of 66 patients for whom complete outcome data were available

[c] see the text for an explanation of the number of patients in each column

The total activity score at six months was then computed by adding the major work activity, social and leisure activity scores. The three scores were equally weighted. Those who had retired prior to the onset of symptoms, or those who denied having social or leisure activities prior to the onset of symptoms, were given a score of eight for the respective category. Table 18 describes the distribution of the total activity scores as reported by the 102 patients who were interviewed at six months and the subsample of 66 patients, for whom complete outcome data were available. The scores ranged from a low of 11 to a high of 24 with most of the scores clustered at the upper end of the scale. The median for the total sample interviewed was 23.2 and the mean for that group was 21.6, indicating that most of the patients reported that they had been able to resume most presymptom activities without major adjustments by six months following the pacemaker implantation.

The median activity score for the subsample of 66 patients was 24 and the mean score was 22.06, indicating that the extent of presymptom activity resumption in the subsample was quite similar to that of the total sample interviewed at six months.

Table 18

SELF-REPORTED ACTIVITY RESUMPTION AT SIX MONTHS FOLLOWING PACEMAKER IMPLANTATION

| Total Activity Score[a] | % of Patients | |
|---|---|---|
| | Interviewed at Six Months (b) | For Whom Complete Outcome Data Were Available (c) |
| 11 | 1% | — |
| 12 | 1% | — |
| 13 | 2% | 2% |
| 14 | 1% | 2% |
| 15 | 3% | 3% |
| 16 | 5% | 2% |
| 17 | 2% | 4% |
| 18 | 4% | 3% |
| 19 | 2% | 3% |
| 20 | 8% | 4% |
| 21 | 1% | 2% |
| 22 | 13% | 12% |
| 23 | 11% | 12% |
| 24 | 47% | 51% |

[a] see text for explanation of activity score

[b] n = 102

[c] n = 66

## QUESTIONNAIRE FINDINGS

### SUBJECTIVE DISTRESS

The distribution statistics for the Subjective Distress scale scores which were developed following the procedure described in chapter 5, pp. 81-82, are presented in Table 19. Preoperatively, 97 patients completed the MAACL. At one month, 73 patients completed the questionnaire and at six months 66 patients completed it. Since the six months Subjective Distress scale score was one of the two outcomes of research interest, these 66 patients have been identified throughout the earlier presentation of findings as the subsample with complete outcome data. Not all of the 66 patients who completed the questionnaire at six months did so prior to and one month following implant. Within the subsample of 66 patients, 61 completed the MAACL prior to surgery and 54 completed it at one month.

Table 19

DISTRIBUTION OF THE SUBJECTIVE DISTRESS SCALE SCORES OVER TIME

| | Time of Testing | | |
|---|---|---|---|
| | Preoperative | One Month | Six Months |
| Range | -2.43 to 5.60<br>(-2.43 to 5.60)[a] | -2.34 to 4.42<br>(-2.34 to 4.42) | -2.07 to 5.31 |
| Mean | 0.00 (-.07) | 0.00 (-.21) | 0.00 |
| Median | -.34 (-.32) | -.33 (-.52) | -.56 |
| Std. Dev. | 1.64 (1.70) | 1.50 (1.51) | 1.60 |
| No. of Patients Completing[b] | 97 (61) | 73 (54) | 66 |

[a] figures in parentheses indicate the data for patients within the subsample of 66 who completed the MAACL preoperatively and at one month

[b] see text for an explanation of the number of patients in each column

Examination of frequency tables of the scores showed that the distribution of scores was relatively symmetrical at each of the three times.

The mean scores for subjective distress cannot be compared across the three times of testing since they were computed from the Z scores on the MAACL Anxiety and Depression scales each time.

The preoperative Subjective Distress scale score had $r$'s of .48 and .45 with the one and six months Subjective Distress scores, respectively. One month Subjective Distress had an $r$ of .54 with six months Subjective Distress.

It is possible to get some sense of the variation in subjective distress by comparing the mean scores on the underlying scales. The mean Anxiety and Depression scale scores did decrease over time, but the change was not statistically significant for the mean Anxiety score. There was a significant ($t$ (60) = 2.01, $p < .05$) decrease in the mean Depression score from the preoperative testing to the testing at six months, but the decrease from preoperative to one month and one month to six months was not statistically significant. Although the mean Anxiety and Depression scale scores did not change significantly over time (with one exception), plots of the scores of individual patients did demonstrate variation over time.

Not all patients completed the MAACL. Preoperatively, 97 (71%) of the patients completed the questionnaire. The patients who completed the MAACL prior to surgery were younger ($\chi^2$ (5) = 7.74, $p < .05$) than those who did not complete it. There were no statistically significant differences between those completing and those not completing in terms of the gender or socioeconomic class of the patient, the limiting symptom, the number of cardiac symptoms or the duration of symptoms.

Seventy-four of the 123 patients seen at one month completed the questionnaire for a completion rate of 60 per cent. There were no statistically significant differences in age, gender, socioeconomic class, or the incidence of complications, cardiac symptoms or the patient's general health status at one month between those who completed the questionnaire and those who did not complete it.

The 66 patients who completed the questionnaire at six months represented a completion rate of 64 per cent. There were no statistically significant differences in the age, gender, socioeconomic class, or the incidence of complications, cardiac symptoms or the patient's general health status at six months between those who completed the MAACL and those who did not complete the questionnaire. The drop in the completion rate at the two clinic visits when compared to the preoperative interview likely reflects a lack of time during the clinic visit when many of the patients had family or friends waiting to drive them home, in contrast to the hospital setting when the patients usually had more time.

In summary, with the exception of the age difference at the preoperative time, there were no statistically significant differences between those patients completing the MAACL and those who did not complete the questionnaire.

Supplemental analyses indicated that women consistently reported higher subjective distress ($\underline{p} < .01$). Subjective distress was also higher in those patients who had had symptoms for a longer time prior to implant ($\underline{p} < .01$), for those reporting more cardiovascular symptoms at follow up ($p < .01$), and those who reported poorer general health status at follow up ($p < .01$). The level of subjective distress was not related to age, the number of preoperative cardiovascular symptoms or a history of chronic illness prior to implantation.

## CURRENT HEALTH PERCEPTION

The distribution statistics for the scores on the Current Health Perception scale of the General Health Perceptions Questionnaire are presented in Table 20. The scores for the subsample of 66 patients for whom complete outcome data were available are indicated in parentheses.

Not all patients completed the health perceptions questionnaire. Eighty-five patients completed the questionnaire prior to surgery. The number completing it at one and six months postimplant were 66 and 60, respectively. Within the subsample of 66 patients for whom complete outcome data were available, 55 patients completed the questionnaire prior to surgery. Fifty of the 66 patients completed it at one month and 57 of the 66 patients completed it at six months. Variations in the number of patients completing the questionnaire at each time are noted in Table 20.

Table 20

## DISTRIBUTION OF CURRENT HEALTH SCALE SCORES OVER TIME

| | Time of Testing | | |
|---|---|---|---|
| | Preoperative | One Month | Six Months |
| Range | 10-44 (10-44)[a] | 14-45 (14-45) | 14-45 (14-45) |
| Mean | 23.67 (24.44) | 28.45 (28.78) | 29.01 (29.16) |
| Median | 23.19 (23.88) | 28.83 (29.17) | 28.33 (28.40) |
| Std. Dev. | 7.8 (8.2) | 7.8 (8.2) | 8.2 (8.2) |
| No. of Patients[b] | 85 (55) | 66 (50) | 60 (57) |

[a] figures in parentheses indicate data for the patients for whom complete outcome data were available

[b] see text for an explanation of the number of patients in each column

Examination of the frequency tables indicated that the distribution of the scores was relatively symmetrical at each of the three times of testing.

The preoperative mean score was significantly lower than the mean score at one month ($t$ (60) = -4.9, $p < .01$). The increase from one month to six months was not statistically significant.

The preoperative Current Health scale score demonstrated correlations of $r = .58$ and $r = .56$ with the one and six months Current Health scale scores, respectively. The correlation between the Current Health scale scores at one month and six months was $r = .68$.

Preoperative health perception was inversely related to the duration of symptoms ($\underline{p} < .01$) and the number of cardiovascular symptoms ($\underline{p} < .01$). At one month, health perception was inversely related to the continuation of cardiac symptoms after implantation ($\underline{p} < .01$), but not related to the patient's general health status. At six months, health perception was inversely correlated to both cardiac symptoms and general health status ($\underline{p} < .01$). Health perception did not demonstrate statistically significant relationships with age, gender or socioeconomic status.

As noted earlier, not all patients completed the Health Perceptions Questionnaire. Preoperatively, 85 patients (63%) completed the questionnaire. The patients who completed the questionnaire were younger ($\chi^2$ (5) = 25.83, $\underline{p} < .01$) than those who did not complete it. There were no statistically significant differences in the gender, age, limiting symptom or duration of symptoms between those who completed the questionnaire and those who did not complete it. At one month, 66 of the 123 patients (54%) completed the General Health Perceptions Questionnaire. Statistically significant differences in age ($\chi^2$ (5) = 15.5, $\underline{p} < .01$) and gender ($\chi^2$ (1) = 5.38, $\underline{p} < .05$) were apparent. Younger men were more likely to complete the questionnaire. There were no differences in the number of cardiac symptoms, incidence of complications or the patient's general health status between those completing the questionnaire and those who did not. At six months, 59 per cent or 60 of the 102 patients interviewed completed the questionnaire and there were no statistically significant differences in the dimensions noted above between those who completed the questionnaire and those who did not complete it.

## RESEARCH QUESTIONS

The ten research questions were answered by analyses of covariance. The analyses were accomplished using a hierarchical multiple regression approach as described by Cohen & Cohen (1975). The clinical variables were entered as the first step in the regression. Therefore, when one of the independent variables of primary research interest, either self perception of health or subjective distress, was entered at Step 2, the increment in $\underline{R}^2$ reflected the variance in the independent variables after partialling out the covariates.

The research questions asked if patient age or gender influenced the relationship between the primary independent variable and outcome. Age and gender were entered at Step 3 and the interactions of age and gender with either current health or subjective distress at Step 4. Step 3 is necessary in order to obtain the correct tests of significance at Step 4, otherwise the tests of signficance at Step 3 were of no specific interest. The tests of significance at Step 4 responded to the research questions about the influence of age or gender on the relationship of the independent variable of primary interest and the outcome. Whenever the overall increment in $\underline{R}^2$ for Steps 3 and 4 was not significant, the tests of significance for the semipartial ($\underline{sr}^2$) correlations for the individual interaction variables were not pursued.

Analysis of covariance requires the assumption of homogeneity of regression of the covariates over the range of values for the independent variables. This assumption of homogeneity of regression was tested in Step 5 in which variables carrying the mutual interactions between the covariates and indpendent variables were entered. When the test of significance at Step 5 is significant, the nature of the interaction(s) must be explored in order to understand the results. Following the traditional practice in analysis of covariance, the tests of significance for the increment in $R^2$ and the semipartial correlations, at Steps 1 through 4, were computed using the residual $(1 - R^2)$ at Step 4, with its associated degrees of freedom, as the error term. The use of this error term removed the covariates, the independent variables and their interactions from the error term, resulting in a "purer" error term (Cohen & Cohen, 1975). The residual $(1 - R^2)$ at Step 5, with its associated degrees of freedom, was used only as the error term in the tests of significance at Step 5. These tests are merely checks on the assumptions of the analysis. Test results were considered significant if $p = .05$ or less.

The tests of significance address the question of the significance of the correlations. However,the partial correlation ($pr^2$) for the primary independent variable is the appropriate measure of the effect size or the proportion of the covariate adjusted outcome variance which is accounted for by the covariate adjusted independent variable. The $pr^2$ for the independent variable of primary interest was computed in the following manner:

$$sr^2_{\text{Step 2}} / 1 - R^2_{\text{Step 1}}$$

where $sr^2_{\text{Step 2}}$ is the variance in outcome accounted for by the primary independent variable from which the covariates have been partialled and $1 - R^2_{\text{Step 1}}$ is the residual variance in the outcome after partialling out the covariates. The $pr^2$ for the primary independent variable will be reported for each of the 10 research questions.

A table of results for the analysis for each of the research questions will be presented and briefly described. These findings will be discussed in the following chapter. The number of subjects in each of the analyses varied because of missing data since patients were dropped from an analysis if they had missing data on any variable.

## QUESTION 1

To what extent does the patient's preoperative health perception explain the variance in the resumption of presymptom activity six months following the implantation of a pacemaker, when controlling for the association with preoperative clinical status? Furthermore, do the age or gender of the patient influence the relationship between preoperative health perception and the resumption of activity?

As seen in Table 21, after controlling for the effect of the preoperative cardiovascular symptoms and general health status prior to implant, the patient's perception of his health prior to implant did not make a statistically significant contribution to the explanation of the variance in resumption of activity six months following pacemaker implantation. The age and gender of the patient did not effect the relationship between health perception and activity resumption.

The $pr^2$ of .0007, computed for preoperative health perception at Step 2, indicated that less than 1 per cent of the variance in the covariate adjusted activity resumption at six months was accounted for by covariate adjusted preoperative health perception.

## Table 21

## ANALYSIS OF COVARIANCE WITH TOTAL ACTIVITY RESUMPTION AT SIX MONTHS AS DEPENDENT VARIABLE, PREOPERATIVE CURRENT HEALTH PERCEPTION, AGE & GENDER AS INDEPENDENT VARIABLES & PREOPERATIVE CLINICAL VARIABLES AS COVARIATES (N=55)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .0837 | 2 | .0837 | | 2.28 |
| | C.V. Symptoms pre-op[a] | | | | | |
| | General Health Status, pre-op | | | | | |
| 2. Primary I.V.[b] | Current Health Preception pre-op. | .0843 | 1 | .0006 | | 0.35 |
| 3. Other I.V.'s | | .1459 | 2 | .0616 | | 1.68 |
| | Age | | 1 | | .0143 | 0.78 |
| | Gender | | 1 | | .0336 | 1.83 |
| 4. Interaction Among I.V.'s | | .1752 | 4 | .0293 | | 0.40 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .8248 | 45 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .3380 | 14 | .1627 | | 0.54 |
| Error Step 5 | | .6620 | 31 | | | |

[a] C.V. Symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] CHP = current health perception

QUESTION 2

To what extent does the patient's preoperative health perception explain the variance in subjective distress at six months, when controlling for the association with preoperative clinical status? Furthermore, do the age or gender of the patient influence the relationship between preoperative health perception and subjective distress at six months?

Table 22 describes the results of this analysis. Preoperative health perception did not make a statistically significant contribution to the explanation in the variance in subjective distress at six months after controlling for the effect of the preoperative clinical variables. The age and gender of the patient did not influence the relationship between the patient's perception of his health before surgery and the extent of subjective distress reported at six months.

The $pr^2$ of .0038, computed for preoperative health perception at Step 2, indicated that less than 1 per cent of the variance in covariate adjusted subjective distress at six months was accounted for by covariate adjusted preoperative health perception.

Table 22

ANALYSIS OF COVARIANCE WITH SUBJECTIVE DISTRESS AT SIX MONTHS AS DEPENDENT VARIABLE, PREOPERATIVE CURRENT HEALTH PERCEPTION, AGE & GENDER AS INDEPENDENT VARIABLES AND PREOPERATIVE CLINICAL VARIABLES AS COVARIATES (N=55)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1759 | 2 | .1759 | | 5.31** |
| | C.V. Symptoms pre-op[a] | | | | | |
| | General Health Status, pre-op | | | | | |
| 2. Primary I.V.[b] | Current Health Perception pre-op. | .1790 | 1 | .0031 | | 0.19 |
| 3. Other I.V.'s | | .2294 | 2 | .0504 | | 1.52 |
| | Age | | 1 | | .0009 | 0.06 |
| | Gender | | 1 | | .0436 | 2.64 |
| 4. Interaction among I.V.'s | | .2386 | 4 | .0091 | | 0.14 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .7611 | 45 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .3777 | 14 | .1391 | | 0.50 |
| Error Step 5 | | .6222 | 31 | | | |

[a] C.V. Symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] CHP = current health perception

** $p < .01$

QUESTION 3

To what extent does the patient's health perception one month after implantation explain the variance in resumption of presymptom activity six months following the implantation of a pacemaker, when controlling for the association with clinical status at one month? Furthermore, do the age or gender of the patient influence the relationship between health perception at one month and the resumption of activity?

As seen in Table 23, the patient's perception of health one month following pacemaker implantation did not make a statistically significant contribution to the explanation in the variance in activity resumption at six months, after controlling for the association with cardiovascular symptoms and/or pacemaker complications and general health status at one month. The age and gender of the patient did not influence the relationship between health perception at one month and activity resumption at six months.

The $\underline{pr}^2$ of .0169 which was computed for preoperative health perception at Step 2, indicated that 2 per cent of the variance in covariate adjusted activity resumption was accounted for by covariate adjusted health perception at one month.

## Table 23

## ANALYSIS OF COVARIANCE WITH TOTAL ACTIVITY RESUMPTION AT SIX MONTHS AS DEPENDENT VARIABLE, CURRENT HEALTH PERCEPTION AT ONE MONTH, AGE & GENDER AS INDEPENDENT VARIABLES AND ONE MONTH CLINICAL STATUS VARIABLES AS COVARIATES (N=50)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1167 | 2 | .1167 | | 2.86 |
| | C.V.Symptoms & Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I.V.[b] | Current Health Perception at 1 month | .1315 | 1 | .0149 | | 0.73 |
| 3. Other I.V.'s | | .1333 | 2 | .0017 | | 0.04 |
| | Age | | 1 | | .0000 | 0.00 |
| | Gender | | 1 | | .0017 | 0.09 |
| 4. Interaction among I.V.'s | | .1840 | 4 | .0506 | | 0.62 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .8160 | 40 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .3975 | 14 | .2135 | | 0.68 |
| Error Step 5 | | .6025 | 26 | | | |

[a] C.V. symptoms = cardiovascular symptoms at one month

[b] I.V. = independent variables

[c] CHP = current health perception

## QUESTION 4

To what extent does the patient's health perception at one month following pacemaker implantation explain the variance in the subjective distress at six months when controlling for the association with clinical status at one month? Furthermore, do the age or gender of the patients influence the relationship between health perception at one month and subjective distress at six months?

Table 24 describes the results of this analysis. The patient's perception of his health at one month following pacemaker implantation made a statistically significant ($p < .05$) contribution to the explanation of the variance in subjective distress reported at six months after controlling for the influence of the patient's clinical status at one month. The age and gender of the patient did not influence the relationship between health perception at one month and subjective distress at six months.

The $pr^2$ of .0950 which was computed for one month health perception at Step 2 indicated that 10 per cent of the variance in covariate adjusted subjective distress at six months was accounted for by covariate adjusted health perception at one month.

Table 24

ANALYSIS OF COVARIANCE WITH SUBJECTIVE DISTRESS AT SIX MONTHS AS DEPENDENT VARIABLE, CURRENT HEALTH PERCEPTION AT ONE MONTH, AGE & GENDER AS INDEPENDENT VARIABLES, ONE MONTH CLINICAL STATUS VARIABLES AS COVARIATES (N=50)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1308 | 2 | .1308 | | 3.69* |
| | C.V.Symptoms & Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I.V.[b] | Current Health Perception at 1 month | .2134 | 1 | .0826 | | 4.67* |
| 3. Other I.V.'s | | .2450 | 2 | .0316 | | 0.89 |
| | Age | | 1 | | .0014 | 0.08 |
| | Gender | | 1 | | .0316 | 1.78 |
| 4. Interaction among I.V.'s | | .2910 | 4 | .0468 | | 0.66 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .7082 | 40 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .3520 | 14 | .0602 | | 0.17 |
| Error Step 5 | | .6480 | 26 | | | |

[a] C.V. symptoms = cardiovascular symptoms at one month

[b] I.V. = independent variables

[c] CHP = current health perception

*$p < .05$

## QUESTION 5

To what extent does the patient's preoperative subjective distress explain the variance in the resumption of presymptom activity at six months, when controlling for the association with the patient's preoperative clinical status? Furthermore, do the age or gender of the patient influence the relationship between preoperative subjective distress and the resumption of activity at six months?

As indicated in Table 25, subjective distress reported by the patient before surgery did not make a statistically significant contribution to the explanation of the variance in activity resumption six months after implantation, after controlling for the association with the patient's clinical status at one month. Furthermore, the patient's age and gender did not influence the relationship between preoperative subjective distress and postoperative activity resumption.

The $\underline{pr}^2$ of .0281 which was computed for preoperative subjective distress at Step 2 indicated that 3 per cent of the variance in covariate adjusted activity resumption was accounted for by covariate adjusted preoperative subjective distress.

Table 25

ANALYSIS OF COVARIANCE WITH TOTAL ACTIVITY RESUMPTION AT SIX MONTHS AS DEPENDENT VARIABLE, PREOPERATIVE SUBJECTIVE DISTRESS, AGE & GENDER AS INDEPENDENT VARIABLES, AND PREOPERATIVE CLINICAL STATUS VARIABLES AS COVARIATES (N=61)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .0855 | 2 | .0855 | | 2.96 |
| | C.V. Symptoms pre-op[a] | | | | | |
| | General Health Status, pre-op | | | | | |
| 2. Primary I.V.[b] | Subjective Distress pre-op | .1112 | 1 | .0257 | | 1.78 |
| 3. Other I.V.'s | | .1658 | 2 | .0546 | | 1.89 |
| | Age | | 1 | | .0328 | 2.27 |
| | Gender | | 1 | | .0075 | 0.52 |
| 4. Interaction among I.V.'s | | .2636 | 4 | .0978 | | 1.69 |
| | S.D.[c]*Age | | 1 | | | |
| | S.D.*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | S.D.*Age*Gender | | 1 | | | |
| Error Step 4 | | .7364 | 51 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .2773 | 14 | .0137 | | 0.05 |
| Error Step 5 | | .7227 | 37 | | | |

[a] C.V. symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] S.D. = subjective distress

## QUESTION 6

To what extent does the patient's preoperative subjective distress explain the variance in subjective distress reported at six months, when controlling for the association with the patient's preoperative clinical status? Furthermore, do the age or gender of the patient influence the relationship between preoperative subjective distress and subjective distress at six months?

As indicated in Table 26, the extent of subjective distress reported by the patient preoperatively made a statistically significant contribution ($p < .01$) to the explanation of the variance in subjective distress reported six months following surgery, after controlling for the association of preoperative clinical status. Patient age and gender did not influence the relationship between preoperative subjective distress and subjective distress at six months.

The $pr^2$ of .1372 which was computed for preoperative subjective distress at Step 2, indicated that 14 per cent of the covariate adjusted subjective distress at six months was accounted for by covariate adjusted preoperative subjective distress.

## Table 26

## ANALYSIS OF COVARIANCE WITH SUBJECTIVE DISTRESS AT SIX MONTHS AS DEPENDENT VARIABLE, PREOPERATIVE SUBJECTIVE DISTRESS, AGE & GENDER AS INDEPENDENT VARIABLES AND PREOPERATIVE CLINICAL STATUS VARIABLES AS COVARIATES (N=61)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .2329 | 2 | .2329 | | 11.03** |
| | C.V. Symptoms pre-op[a] | | | | | |
| | General Health Status, pre-op | | | | | |
| 2. Primary I.V.[b] | Subjective Distress pre-op | .3382 | 1 | .1053 | | 9.98** |
| 3. Other I.V.'s | | .4040 | 2 | .0658 | | 3.12 |
| | Age | | 1 | | .0218 | 2.06 |
| | Gender | | 1 | | .0241 | 2.29 |
| 4. Interaction among I.V.'s | | .4618 | 4 | .0578 | | 1.37 |
| | S.D.[c]*Age | | 1 | | | |
| | S.D.*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | S.D.*Age*Gender | | 1 | | | |
| Error Step 4 | | .5382 | 51 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .4978 | 14 | .0360 | | 0.19 |
| Error Step 5 | | .5022 | 37 | | | |

[a] C.V. symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] S.D. = subjective distress

** $p < .01$

QUESTION 7

To what extent does the patient's report of subjective distress one month following the implantation of a pacemaker explain the variance in the resumption of presymptom activities, when controlling for the association with the patient's clinical status at one month? Do the age or gender of the patient influence the relationship between subjective distress at one month and the resumption of activities at six months?

The results of this analysis are described in Table 27. The statistically significant interactions at Step 5 of the covariates with the independent variables (subjective distress, age, gender and their mutual interactions) indicated that the assumption of homogeneity of regression could not be accepted for this analysis. Therefore, the interpretation of the findings as an analysis of covariance was invalid.

Since the increment in $\underline{R}^2$ at Step 5 is statistically significant, one must assess the unique contribution to the explanation in outcome variance of each of the interaction variables. In entering all of the interactions in a single step, as reported in Table 27, the effects of the higher order interactions were partialled out of the two way interactions.

An alternate approach would be to enter the two way, three way and four way interactions in separate steps. The effect of such an approach would be that the variance shared between the two way and higher order interactions would be allocated to the two way interactions, thus increasing their $\underline{sr}^2$'s.

A second approach would be to entirely reorganize the analysis, considering one or both of the covariates as independent variables in their own right. This would include examination of the mutual interactions among all of the independent variables in the analysis. To maintain adequate power and feasibility, one might need to assume that higher order interaction are not present. Since Question 7 is not the major focus of the study, such an elaborate reorganization of the analysis is probably not justified.

In order to clarify the relationship between the covariates and the independent variables which was identified in the original analysis, a secondary analysis of the interactions was done. The interactions primarily involved one of the two covariates, cardiovascular symptoms and complications. The 54 patients were divided into two groups. One group (n = 24) included those patients who reported either cardiac symptoms and/or complications at one month. The second group (n = 30) were patients who were asymptomatic and had had no complications. Examination of scatterplots revealed a different pattern for the relationship between subjective distress and activity resumption in the two groups of patients (Figure 1). The regression slopes of each subgroup of patients were computed. These are presented in Figure 2. The regression slope for the asymptomatic patient group is flat,indicating that those patients generally resumed most of their presymptom activities by six months irrespective of the level of subjective distress reported at one month. For those patients reporting symptoms and/or complications, activity resumption at six months was inversely and significantly ($\underline{p} < .01$) related to subjective distress at one month.

## Table 27

## ANALYSIS OF COVARIANCE WITH TOTAL ACTIVITY RESUMPTION AT SIX MONTHS AS DEPENDENT VARIABLE, SUBJECTIVE DISTRESS AT ONE MONTH, AGE & GENDER AS INDEPENDENT VARIABLES AND ONE MONTH CLINICAL STATUS VARIABLES AS COVARIATES (N=54)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1436 | 2 | .1436 | | 4.75** |
| | C.V. Symptoms and Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I.V.[b] | Subjective Distress 1 Month | .2975 | 1 | .1538 | | 10.19** |
| 3. Other I.V.'s | | .2975 | 2 | .0000 | | 0.01 |
| | Age | | 1 | | .0000 | 0.00 |
| | Gender | | 1 | | .0000 | 0.00 |
| 4. Interaction among I.V.'s | | .3355 | 4 | .0380 | | 0.63 |
| | S.D.[c]*Age | | 1 | | | |
| | S.D.*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | S.D.*Age*Gender | | 1 | | | |
| Error Step 4 | | .6645 | 44 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .7469 | 14 | .4115 | | 3.48** |
| | C.V.Symp[a]*S.D. | | 1 | | .1040 | 12.34** |
| | C.V.Symp*Age | | 1 | | .0612 | 7.26* |
| | C.V.Symp*Gender | | 1 | | .0344 | 4.08* |
| | C.V.Symp*Age* S.D. | | 1 | | .0672 | 7.79** |
| | G.Health[c]*Age* Gender | | 1 | | .0337 | 3.99* |
| | C.V.Symp*S.D.* Gender | | 1 | | .0000 | 0.00 |
| | C.V.Symp*S.D.* Gender*Age | | 1 | | .0000 | 0.00 |

Table 27 (cont'd)

ANALYSIS OF COVARIANCE WITH TOTAL ACTIVITY RESUMPTION AT SIX MONTHS AS DEPENDENT VARIABLE, SUBJECTIVE DISTRESS AT ONE MONTH, AGE & GENDER AS INDEPENDENT VARIABLES AND ONE MONTH CLINICAL STATUS VARIABLES AS COVARIATES (N=54)

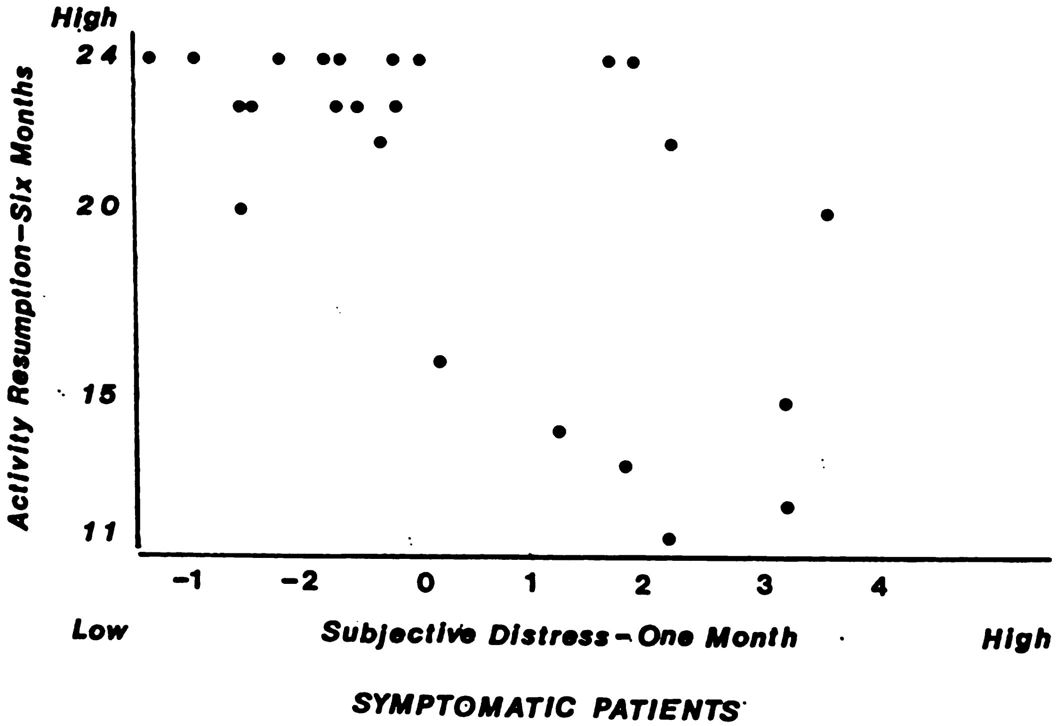
| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| | C.V.Symp*Age*Gender | | 1 | | .0000 | 0.00 |
| | G.Health*Age | | 1 | | .0003 | 0.04 |
| | G.Health*Gender | | 1 | | .0000 | 0.00 |
| | G.Health*S.D. | | 1 | | .0001 | 0.01 |
| | G.Health*S.D.*Age*Gender | | 1 | | .0000 | 0.00 |
| | G.Health*S.D.*Age | | 1 | | .0003 | 0.03 |
| | G.Health*S.D.*Gender | | 1 | | .0000 | 0.00 |
| Error Step 5 | | .2530 | 30 | | | |

[a] C.V. symptoms = cardiovascular symptoms at one month

[b] I.V. = independent variables

[c] S.D. = subjective distress

* $p < .05$ ** $p < .01$



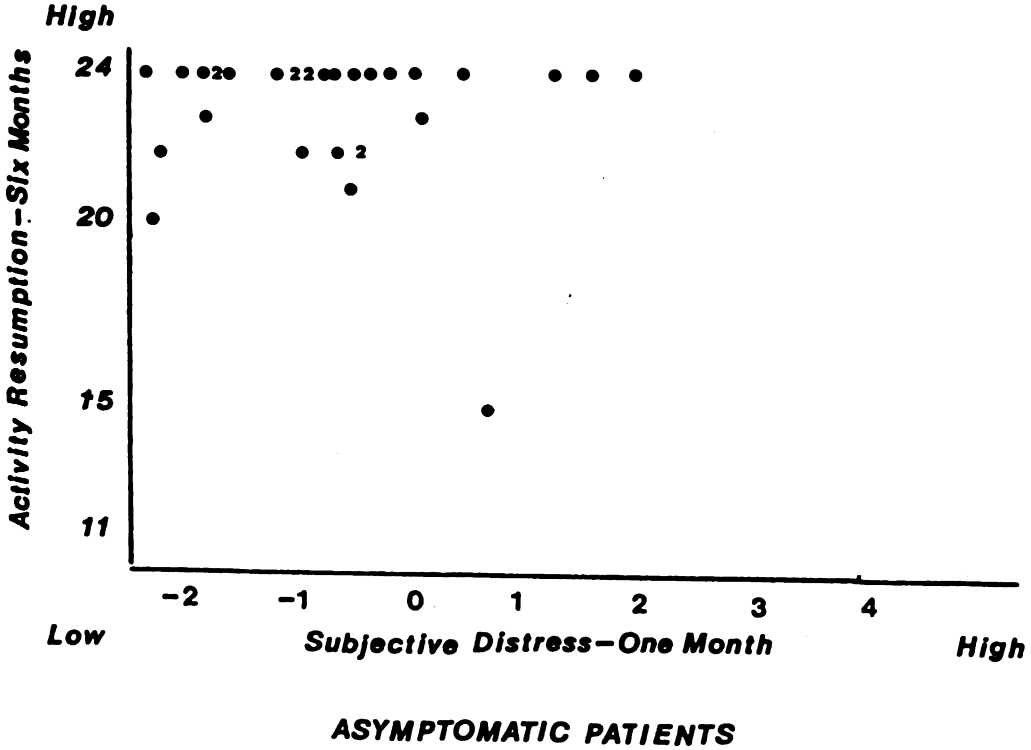


Figure 1. Scattergrams of subjective distress at one month and activity resumption at six months for symptomatic and asymptomatic patients

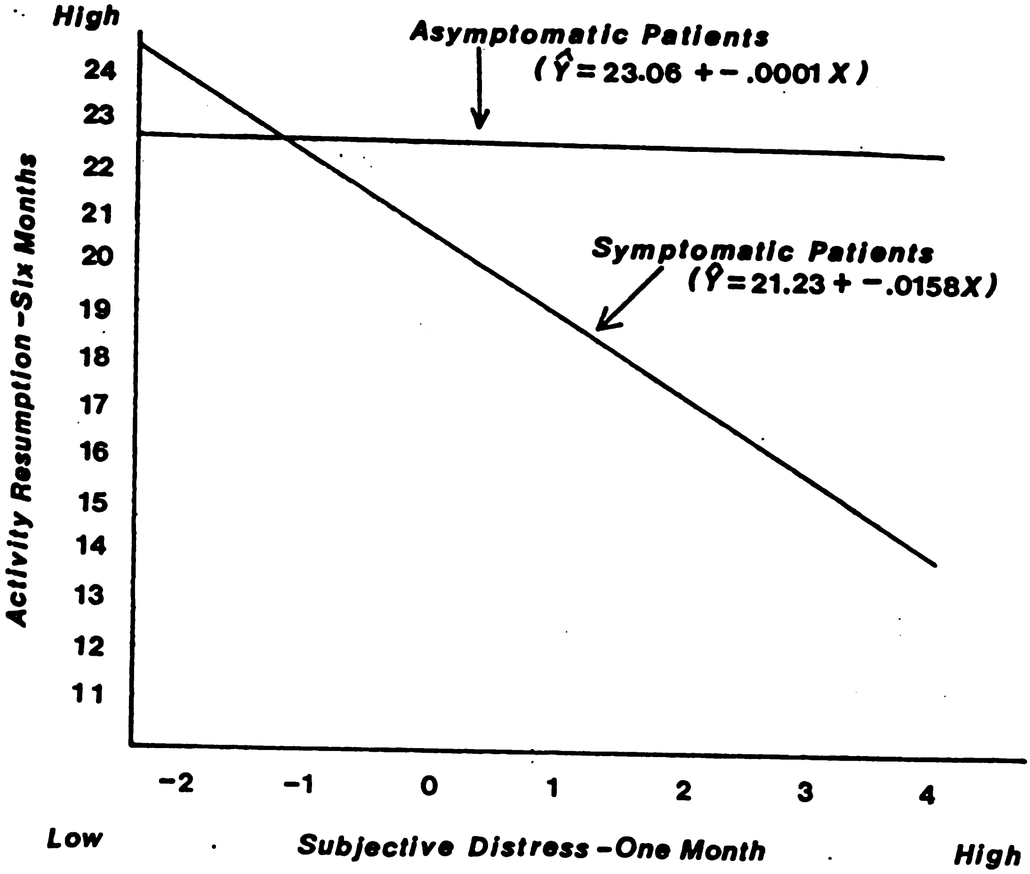


Figure 2. Regression slopes for subjective distress at one month and activity resumption at six months for symptomatic and asymptomatic patients

## QUESTION 8

To what extent does the patient's report of subjective distress at one month explain the variance in subjective distress reported by the patient at six month, when controlling for the association with the patient's clinical status at one month? Do the age or gender of the patient influence the relationship between the subjective distress reported at one month and the subjective distress reported at six months following the implantation of a pacemaker?

The results of this analysis are described in Table 28. The extent of subjective distress one month after surgery made a statistically significant contribution ($p < .01$) to the explanation of the variance in subjective distress reported at six months following implantation, after controlling for the influence of the patient's clinical status at one month. Patient age and gender did not influence the relationship between subjective distress at one month and subjective distress at six months.

The $pr^2$ of .1808 computed for subjective distress at one month at Step 2, indicated that 18 per cent of the variance in covariate adjusted subjective distress at six months was accounted for by covariate adjusted subjective distress at one month.

## Table 28

## ANALYSIS OF COVARIANCE WITH SUBJECTIVE DISTRESS AT SIX MONTHS AS DEPENDENT VARIABLE, SUBJECTIVE DISTRESS AT ONE MONTH, AGE & GENDER AS INDEPENDENT VARIABLES AND ONE MONTH CLINICAL STATUS VARIABLES AS COVARIATES (N=54)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1536 | 2 | .1536 | | 5.70** |
| | C.V. Symptoms & Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I.V.[b] | Subjective Distress 1 Month | .3067 | 1 | .1531 | | 11.36** |
| 3. Other I.V.'s | | .3291 | 2 | .0224 | | 0.83 |
| | Age | | 1 | | .0012 | 0.09 |
| | Gender | | 1 | | .0223 | 1.66 |
| 4. Interaction among I.V.'s | | .4073 | 4 | .0783 | | 1.45 |
| | S.D.[c]*Age | | 1 | | | |
| | S.D.*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | S.D.*Age*Gender | | 1 | | | |
| Error Step 4 | | .5927 | 44 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .5058 | 14 | .0985 | | 0.43 |
| Error Step 5 | | .4942 | 30 | | | |

[a] C.V. symptoms = cardiovascular symptoms at one month

[b] I.V. = independent variable

[c] S.D. = subjective distress

** $p < .01$

QUESTION 9

To what extent does the patient's health perception at six months following pacemaker implantation explain the variance in the resumption of presymptom activity at six months, when controlling for the association with the patient's clinical status at six months? Do the age or gender of the patient influence the relationship between health perception and the resumption of activity at six months?

Table 29 describes the results of the analysis for this question. As can be seen in this table, the patient's perception of his own health at six months contributed a statistically significant ($\underline{p} < .05$) portion of the explanation of the variance in activity resumption at six months after controlling for the influence of the patient's clinical status at six months. Patient age and gender did not influence the relationship between health perception and activity resumption.

The $\underline{pr}^2$ of .0974 computed for health perception at six months in Step 2, indicated that 10 per cent of the variance in covariate adjusted activity resumption at six months was accounted for by covariate adjusted health perception at six months.

Table 29

ANALYSIS OF COVARIANCE WITH TOTAL ACTIVITY RESUMPTION AT SIX MONTHS AS DEPENDENT VARIABLE, CURRENT HEALTH PERCEPTION AT SIX MONTHS, AGE & GENDER AS INDEPENDENT VARIABLES AND SIX MONTHS CLINICAL STATUS VARIABLES AS COVARIATES (N=57)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .2234 | 2 | .2234 | | 8.45** |
| | C.V. Symptoms & Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I.V.[b] | Current Health Perception at 6 Months | .2990 | 1 | .0756 | | 5.72* |
| 3. Other I.V.'s | | .3024 | 2 | .0034 | | 0.13 |
| | Age | | 1 | | .0001 | 0.03 |
| | Gender | | 1 | | .0032 | 0.25 |
| 4. Interactions among I.V.'s | | .3786 | 4 | .0762 | | 1.44 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .6214 | 47 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .5924 | 14 | .2138 | | 1.24 |
| Error Step 5 | | .4076 | 33 | | | |

[a] C.V. symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] CHP = current health perception

* $p < .05$ ** $p < .01$

## QUESTION 10

To what extent does the patient's health perception at six months following the implantation of a pacemaker explain the variance in the subjective distress reported at six months, when controlling for the association with the patient's clinical status? Do the age or gender of the patient influence the relationship between health perception and subjective distress at six months?

As described in Table 30, the patient's perception of his health six months following pacemaker implantation contributed a statistically significant ($p < .01$) portion of the explanation for the variance in subjective distress at six months after controlling for the influence of the patient's clinical status. Patient age and gender did not influence the relationship between health perception and subjective distress at six months. The gender of the patient made a statistically significant unique contribution ($p < .01$) to the explanation of the variance in subjective distress after controlling for the association of the clinical variables, health perception and age. Secondary analyses indicated that women were more likely to report higher levels of subjective distress ($r = .36$).

The $pr^2$ of .3076 computed for health perception at six months in Step 2, indicated that covariate adjusted health perception at six months accounted for 31 per cent of the covariate adjusted subjective distress at six months.

Table 30

### ANALYSIS OF COVARIANCE WITH SUBJECTIVE DISTRESS AT SIX MONTHS AS DEPENDENT VARIABLE, CURRENT HEALTH PERCEPTION AT SIX MONTHS, AGE & GENDER AS INDEPENDENT VARIABLES AND SIX MONTHS CLINICAL STATUS VARIABLES AS COVARIATES (N=57)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1612 | 2 | .1612 | | 7.74** |
| | C.V.Symptoms & Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I.V.[b] | Current Health Perception at 6 Months | .4192 | 1 | .2580 | | 24.76** |
| 3. Other I.V.'s | | .4827 | 2 | .0635 | | 3.05* |
| | Age | | 1 | | .009 | 0.83 |
| | Gender | | 1 | | .062 | 5.93** |
| 4. Interactions among I.V.'s | | .5107 | 4 | .0280 | | 0.67 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .4893 | 47 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .5787 | 14 | .0681 | | 0.38 |
| Error Step 5 | | .4213 | 33 | | | |

[a] C.V. symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] CHP = current health perception

* $p < .05$ ** $p < .01$

The underlying sample for the preceding analyses consisted of the 66 patients for whom data on both outcome, activity resumption and subjective distress at six months, were available. This was done in order to achieve a relatively stable sample across all analyses. That meant that not all the available data were used. For example, a patient for whom only the six months subjective distress data were missing would not have been included in any analysis even if he had data for the earlier subjective distress and health perception measures. The analyses were redone using all available data. The findings on the analyses using all data were the same as the findings which have been reported above.

## SUMMARY OF FINDINGS

One hundred and thirty-six patients who underwent initial pacemaker implantation over an 18 month period, were interviewed prior to implant. One hundred and twenty-three of these patients were subsequently interviewed at one month postimplant. At six months, 102 patients were once again interviewed. The attrition from the patient sample resulted primarily from patients receiving follow up care other than through the Pacemaker Center.

There were two outcomes of interest in this study, activity resumption and subjective distress at six months. Even though 102 patients were interviewed at six months regarding their resumption of activities, the investigator was able to obtain completed measures of subjective distress at six months for only 66 patients. Thus, complete outcome data were available for only 66 patients.

This sample of 66 patients was younger than the original sample of 136 patients. They had had symptoms for a longer period of time prior to implantation, but they did not differ from the original sample of 136 on any of the other demographic and clinical status variables. The 66 patients were very similar to the total population of patients undergoing initial pacemaker implantation in Canada between 1977 and 1981 in terms of gender and clinical variables.

Most patients reported between one and three cardiovascular symptoms prior to implant with syncope and presyncope being identified most frequently as the limiting preoperative symptom. The patients had experienced symptoms for varying lengths of time, ranging from those who were asymptomatic to those who had experienced symptoms for greater than two years. More than half of the patients had had symptoms related to the need for a pacemaker for less than one month prior to implant. A vast majority of the patients reported having previously identified cardiovascular illness and approximately one-half of the patients had other chronic health problems.

Postoperatively, most patients (66% at one month and 71% at six months) reported being symptom-free. Complications were infrequent and, if present, tended to occur in the early postoperative period. The incidence of hospitalization for other health problems in the first postoperative month is striking, in that 25 per cent of the patients were hospitalized during this time for nonpacemaker related health problems. In the subsequent five months, 17 per cent of the patients were hospitalized for nonpacemaker related health problems.

These figures are further indications of the multiplicity of health problems in this sample of patients.

By six months following implantation, 51 per cent of the patients reported full resumption of presymptom work, social and leisure activities, with the remaining 49 per cent reporting varying activity resumption. Only 10 per cent of the patients who were employed or actively engaged in housekeeping prior to implantation reported no resumption of these presymptom activities by six months postimplant.

Subjective distress was measured at each of the three interviews. Subjective distress at six months was viewed as one of the two outcome variables. At six months, the level of subjective distress varied across the patient group.

The level of subjective distress reported by the patients prior to surgery and at one month following surgery were considered as independent variables in the analyses. As was found with subjective distress reported at six months, there was variation across the patient sample in terms of the level of distress reported preoperatively and at one month after implantation.

The patients within the sample varied in terms of their perception of their current health at each of the three times that the data were collected. The mean score on the health perception measure was lowest prior to surgery. There was a statistically significant ($\underline{p} < .01$) increase in the mean score on the health perception score, indicating a move toward a more positive view of health at one month. The mean health perception score did not change significantly between one and six months.

The influence of the patient's clinical status on the relationship between the independent and outcome variables was controlled by using analyses of covariance with clinical status as the covariate.

While health perception at six months demonstrated statistically significant association with both activity resumption ($\underline{p} < .05$) and subjective distress ($\underline{p} < .01$) at six months, preoperative health perception was unrelated to either patient outcome at six months. Health perception at one month was significantly associated with subjective distress at six months ($\underline{p} < .05$), but not activity resumption.

Subjective distress prior to implant ($\underline{p} < .01$) and at one month ($\underline{p} < .01$) were significantly associated with subjective distress at six months. Subjective distress prior to surgery was not significantly associated with activity resumption at six months. The relationship between subjective distress at one month and activity resumption varied depending on the incidence of cardiac symptoms and/or complications at one month. Most patients who were asymptomatic and who had had an uncomplicated recovery at one month, reported full resumption of activities at six months, irrespective of the level of subjective distress reported at one month. In those patients who did report cardiac symptoms and/or complications at one month, activity resumption at six months was related to the level of subjective distress reported at one month.

Patient age and gender did not influence the relationship between the independent variables, health perception and subjective distress prior to and one month after implant, and the two outcomes of interest, activity resumption and subjective distress at six months.

# Chapter VII

# DISCUSSION OF THE FINDINGS

This study was focused on the relationships between subjective distress and health perception prior to pacemaker implant and one month following implantation, and patient recovery six months post-implant. Ten research questions were developed to explore these relationships, after controlling for the influence of the patient's clinical status. The influence of age and gender on the relationships was also evaluated. The discussion of the results of the analyses directed by these questions will include comparisons between the findings of this study and the findings reported by previous investigators, along with an interpretation of the findings from an interactionist-role perspective.

Several topics related to the findings of this study will be addressed prior to the discussion of the analyses directed by the ten research questions. The demographic and clinical characteristics of the study sample will be compared to those of other patients undergoing initial pacemaker implantation. The findings on patient recovery, as defined by the extent of activity resumption and subjective distress at six months, will be compared to those reported by other researchers. The extent of subjective distresss and the perceptions of current health reported by the patients in this study will be interpreted on the basis of normative data reported in the literature.

## THE SAMPLE

The final sample of 66 patients for whom complete outcome data were available in this study was slightly younger, had a greater proportion of men, and was more likely to have had a dual chamber pacemaker than the total population of patients undergoing initial pacemaker implantation in Canada in the years 1979 through 1981 as described by Goldman, Duncan & Wilson (submitted for publication). They did not differ from the Canadian population of patients undergoing pacemaker implantation in terms of the electrocardiographic indications for pacing, etiology of the conduction disorder, preoperative symptomatology, or the incidence of postoperative complications. Data on concurrent chronic health problems is not available for the Canadian population, but Furman in 1978 described the patients in his large follow up series as having multiple health problems and frequent hospitalizations for cardiac and nonpacemaker related health problems. The findings of the current study would seem to be similar to Furman's findings in this regard. Thus, it would seem that the sample of patients in this study is representative of the population of patients undergoing pacemaker implantation in Canada.

As noted earlier, all of the patients in this study underwent pacemaker implantation in a large university teaching hospital which had a well developed pre- and postoperative patient teaching program. The patients received their follow up care in a specialized Pacemaker Center. In contrast, approximately 2/3 of the patients in Canada have their pacemaker implantations in local hospitals and most receive follow-up care from their own physicians rather than a specialized clinic

(Goldman, Duncan & Wilson, submitted for publication). The extent to which the health care setting might modify the patient's response and recovery is unknown.

## PATIENT OUTCOMES

### ACTIVITY RESUMPTION

The variety of approaches to the operationalization and measurement of activity resumption in the other studies of patient recovery following pacemaker implantation limit definitive comparisons between the extent of activity resumption reported in this study and that reported in previous research. Given this limitation, it still seems appropriate to attempt to compare the extent of activity resumption reported by the patients in this study with that reported by other researchers.

The findings regarding activity resumption in this study are not quite as favourable as those of Price, Obel & Scott-Millar (1980) who reported that almost all of the patients in their study who had been employed prior to surgery, were employed one year later. Differences in reporting employment resumption and the longer follow up period may explain the discrepancy in the findings. It is not clear from their report whether or not "return to employment" meant full resumption of all presymptom employment activities. The findings regarding return to employment and housekeeping activities in the current study are more favourable than those reported by Becker et al. (1967) and Rossel and Alyn (1977). The patients in both of these studies underwent pacemaker implantation earlier in the history of cardiac pacing.

Most of the patients in this study reported that they had been able to resume their presymptom social and leisure activities without making major changes. This is a very different findings than that reported by Romirowsky (1978), who found that the men with pacemakers tended to restrict social and leisure activity, especially sports activities. The reasons for the discrepancy in the findings of this study and those of Romirowsky is not readily apparent.

The overall impression from the current study is that, while there was individual variation in the resumption of presymptom activities following implantation, most of the patients were able to resume all, or most, presymptom work, social and leisure activities within six months of the pacemaker implantation. The apparent improvement in the extent to which patients were able to resume activities from the earlier research studies (Becker et al., 1967; Rossel & Alyn, 1977) may reflect improvements in pacing technology. There has also been an increase appreciation of the recovery potential following pacemaker implantation, and patients are now encouraged to quickly resume their usual activities.

## SUBJECTIVE DISTRESS AT SIX MONTHS

The other outcome of interest was the extent of subjective distress reported by the patients at six months. There are no normative data for this particular outcome since it was computed specifically for this study from the Anxiety and Depression scales of the Multiple Affect Adjective Check List (Today Form). This combined score was then corrected for an apparent response bias. Some insight into the extent of subjective distress reported by the patients might be gained by comparing the original scores on the Anxiety and Depression scales with the normative data for these two scales given by Zuckerman & Lubin (1965). The developers of the MAACL developed their normative data from a sample of 200 individuals who were selected to represent the age, sex and educational characteristics of the general population. Thus, this normative sample would have been younger and have included a greater proportion of women than the sample population of this study. Normative scores for the MAACL scales are presented as "T scores" with a mean of 50.

The mean score on the Anxiety scale for the patients in the current study at six months converted to a "T score" of 49 and the mean score on the Depression scale converted to a "T score" of 53. These "T scores" indicated that a group of patients in this study did not report elevated levels of anxiety and/or depression at the time of the six months follow-up. There was variation in the individual scores on the two scales with about five per cent of the patients reporting moderately severe anxiety or depression. An additional ten per cent of the scores fell in the range indicating mild anxiety or depression.

The incidence of mild to moderately severe subjective distress in this sample would seem to be less than that reported by Becker et al. (1967) who reported that 30 per cent of the patients in their study exhibited abnormal anxiety, depression, or denial. Crisp & Stonehill (1969) reported that the patient groups were significantly ($p < .01$) more anxious and depressed than the normative samples. Both of these studies were carried out early in the history of pacing. The patients in these studies were among the very first to undergo cardiac pacing when the long range efficacy of pacing was still relatively unknown and the technology was not as well developed. Therefore, it might be expected that these patients would be more likely to report greater subjective distress than the contemporary patients.

The MAACL has not been utilized in other research on patient recovery following pacemaker implantation. Two previous studies (Romirowsky, 1978; Goble et al., 1978b) utilized the IPAT Anxiety Scale (Krug, Scheier & Cattell, 1973) to measure patient anxiety. Although the MAACL (Today Form) was developed as a measure of state affect, in contrast to the IPAT Anxiety Scale which was designed as a measure of anxiety as a personality trait, significant ($\underline{p} < .01$) correlations between the MAACL (Today Form) and the IPAT Anxiety Scale have been reported by Zuckerman & Lubin (1965). Therefore, it seems appropriate to compare the findings of the current study with those of the two previous research reports. While Romirowsky (1978) concluded that the patients with pacemakers were more anxious than patients who had had coronary bypass surgery, the mean scores on the IPAT Anxiety Scale for both patient samples in his study fell within the range of "normal" anxiety according to the normative data reported by Krug, Scheier & Cattell (1973). In another study using the IPAT Anxiety Scale (Goble et al., 1978b), the mean anxiety score for the total sample was also within the range of normal scores at six months. Variation in anxiety within the total group was apparent with the mean score of the 20 per cent of patients who were judged to have a "disappointing" recovery being higher than the mean score for those with either a "satisfactory" or "outstanding" recovery.

Thus, it can be concluded from the findings of the current study that, generally, the patients did not report elevated levels of distress at the time of follow up. This finding is congruent with the work of Romirowsky (1978) and Goble et al. (1978). The finding of low distress at six months is further verified by the study completed by Price, Obel & Scott-Millar (1980), who report that the majority of the patients in their follow up series did not demonstrate elevated levels of depression at follow up.

In summary, at the time of the six months follow up, the patient sample, as a whole, did not report elevated levels of subjective distress, although a small proportion (approximately 15%) reported mild to moderate distress. Research early in the history of pacing found a greater incidence of emotional distress than had been reported in studies undertaken in the last ten years. The finding of this current study related to subjective distress at six months is congruent with the more contemporary studies.

## RELATIONSHIP BETWEEN OUTCOMES

Resumption of activity and subjective distress were significantly ($\underline{r} = -.43$, $\underline{p} < .01$), but not highly correlated. A scatterplot of the scores revealed that generally those patients who reported lower levels of subjective distress at six months, reported complete or almost complete resumption of activities. Those patients who reported higher levels of subjective distress (the top 25%) reported the full range of activity resumption. Thus, there were some, albeit not a large number, of the sample who reported full or almost full activity resumption in the face of fairly high levels of subjective distress. It is beyond the scope of the current study to attempt to explain this observation, but the observation does highlight the multifaceted nature of patient recovery and supports the findings of previous research that the determinants of different facets of recovery may vary depending on the outcome of interest (see Appendix G).

One might speculate that the patients may have felt that they had to resume their presymptom activities (especially employment or housekeeping and social activities) even though they continued to experience subjective distress. It is even possible that these patients had some concern about the possible adverse effect of increased activity on their health.

## INDEPENDENT VARIABLES

### SUBJECTIVE DISTRESS PRIOR TO SURGERY AND AT ONE MONTH

If the same approach to the interpretation of the meaning of the preoperative and one month Subjective Distress scale scores is used as was used for the score at six months (i.e., comparison of the underlying MAACL Anxiety and Depression scale scores with the population norms), one finds that the mean scores for the sample prior to surgery and at one month are within the range of normal affect. Therefore, it appears that the patients did not report elevated levels of subjective distress at either time.

The distribution of Subjective Distress scores and the underlying MAACL Anxiety and Depression scale scores prior to surgery and at one month following implantation was similar to that seen at six months, indicating that there was individual variation in the level of distress reported across the patient group.

Surgery is usually assumed to be an anxiety provoking experience and consequently, one would have expected to see an elevation in the level of subjective distress reported prior to surgery, if the MAACL were truly tapping state versus trait affect. There are several possible explanations for this finding. It is possible for the mean score to be within the normal range, while a number of the patients had high scores indicative of increased anxiety and/or depression. The distribution of the individual scores was similar to that seen in the six months scores. Only about five per cent of the scores were indicative of moderate anxiety and/or depression and ten per cent were indicative of mild anxiety and/or depression.

Another possible explanation for finding the mean score within the normal range of scores would be that those patients who were most distressed did not complete the questionnaire. There is no way of knowing whether this was true or not. Those who completed the questionnaire tended to be younger, but they did not differ in terms of other demographic and clinical factors. It was the investigator's clinical impression during the process of data collection that the patients who did not complete the MAACL did not differ from those who did complete the questionnaire, in terms of the degree of emotional distress expressed during the pre- and postoperative interview.

The MAACL could have been tapping more stable trait affect instead of state affect. This possibility is somewhat countered by the observation of the correlations between the Anxiety and Depression scale scores over time. The correlations of r = .46 to .54 are not as high as would be expected if trait affect over time were measured on the same instrument.

Another possible explanation for the lack of elevation in the mean score prior to surgery might be that the patients as a group, were not generally distressed by the experience of hospitalization and pacemaker implantation. The majority of the patients had other health problems and many had been hospitalized previously. In the interviews, most of the patients expressed relief that something could be done to relieve their symptoms. Some of the patients had temporary pacemakers in place and had already experienced the abatement of their symptoms. While there were often questions about exactly what would be done or how the pacemaker worked, most patients had had some explanation by the physicians and/or the nurses on the unit. Implantation had frequently been described to the patient as a "minor procedure" which did not require general anesthesia and the patients did not express a lot of concern about the procedure itself. Thus, it seems entirely possible that the patients were not particularly distressed by the impending surgery. This seems to be the most likely explanation for the finding.

## HEALTH PERCEPTION

Since the General Health Perceptions Questionnaire is a relatively new research instrument, there is limited comparative data available except for the data reported by Ware, Davies-Avery & Donold (1978). They reported the distribution of scores on the six scales of the

General Health Perceptions Questionnaire for four cross-sectional community based samples. It is possible to compare: a) the distribution of scores in the current study sample to those reported by Ware and his colleagues, b) the distribution of scores of this sample over time, and c) individual scores within the sample. It is not possible to give a substantive interpretation for specific mean or individual scores. For example, one can say that those who have a score of 20 have a less positive perception of their health than those who have a score of 40, but it is not possible to say that those who score below a certain score perceive their health to be "poor".

As a group, the patients tended to perceive themselves to be less healthy prior to surgery as reflected by the lower mean score on the Current Health scale at that time. Perception of health improved over time with the statistically significant improvement occurring in the first postoperative month.

The four samples described by Ware and his colleagues (1978) were cross-sectional samples from four different communities. Therefore, they might be considered as normative samples, and it is useful to compare the scores of the patient group to those reported by Ware et al. Based on the mean scores, the patient sample had a less positive perception of their health than the normative groups prior to surgery, but by one month following implantation, their perception of their health status was similar to that of normative groups. It is somewhat surprising that this group of individuals who tended to have multiple health problems as well as a permanent pacemaker, would have such a positive perception of their current health status.

It could be that the patients did not perceive the need for a pacemaker as indicative of continuing poor health since for most of the patients the symptoms had been controlled. Another possible explanation was advanced by Stonehill (1970) who noted a tendency for the patients with pacemakers in his study to deny worry about getting an incurable illness. Stonehill suggested that the denial of concern about health was one means by which the patients with a pacemaker coped with this potentially anxiety provoking health problem. Brown & Rawlinson (1975) noted a similar tendency for patients who had had cardiac surgery to distance themselves from the sick role.

The distribution of scores on the Current Health scale indicated that there were individual differences in the patients' perceptions about their health. While the health perceptions scores demonstrated statistically significant relationships with the clinical status indicators such as symptomatology, examination of the plots of residual health perception scores after partialling out the clinical status variables, revealed that there was still considerable variation across the sample.

## SUMMARY OF FINDINGS FOR PATIENT OUTCOMES, HEALTH PERCEPTION AND SUBJECTIVE DISTRESS

In summary, while there was individual variation within the patient sample, the patients, as a whole, had a good recovery following pacemaker implantation. Most were able to resume their presymptom work, social and leisure activities. They generally did not report elevated levels of subjective distress. Even though many had multiple chronic health problems and all had a permanent pacemaker which required lifelong medical supervision, within one month of the pacemaker implantation, they tended to perceive themselves to be as healthy as normative samples drawn from the general population.

## ASSOCIATION BETWEEN THE INDEPENDENT VARIABLES AND RECOVERY OUTCOMES

### HEALTH PERCEPTION AND RECOVERY OUTCOMES

Health perception at six months. The finding of statistically significant correlations between the patient's perception of his own health at six months following pacemaker implantation and the extent of resumption of activity and reported subjective distress, after controlling for the possible influence of the patient's clinical status, is congruent with previous findings reported by Garrity (1973a, 1973b) and Brown & Rawlinson (1976, 1977). The latter researchers did note that the relative significance of the correlation between health perception and patient morale, in relationship to other psychological and clinical variables, differed for men and women. In this study, neither patient age or gender influenced the relationship between health perception and patient outcome.

As noted earlier, there was a statistically significant inverse correlation between activity resumption and subjective distress at six months. Those with lower subjective distress usually resumed their presymptom activities. Patients with more positive health perception tended to resume more activities and report less subjective distress.

There are several possible interpretations for these findings. The decision to return to presymptom activities and the subjective distress reported by the patient could have been effected by the patient's perception of his health as postulated by Garrity (1973a, 1973b). The person who perceives that he is not healthy, may feel unable to resume some previous activities. The lack of resumption of these activities might interfere with his ability to enact some of his previous roles, such as family provider, homemaker, or friend. Feelings of discomfort, as indicated by increased subjective distress in this study, could result either from the actual and the anticipated inability to fulfill previously established roles.

On the other hand, it is possible that factors other than perception of health, such as an employer's refusal to allow the patient to return to work, or the patient's family physician counselling retirement or reduction in activity, might limit the resumption of presymptom activity. This activity limitation, in turn, might influence the patient's perception of his health. Reif (1976) has described this phenomena in her study of postinfarction recovery. The restriction of activities could lead to feelings of inadequate role enactment, resulting in the patient's reporting increased subjective distress. Similarly, feelings of subjective distress related to other facets of the individual's life might modify health perceptions.

Because all variables were measured at the same time, and there is no strong theoretical support for a unidirectional cause and effect interpretation, the most tenable interpretation is that there is a reciprocal relationship among the independent and dependent variables as represented in Figure 3.

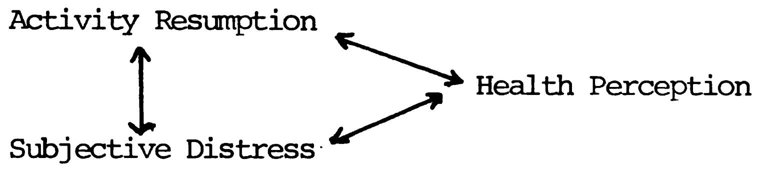


Figure 3. Multidirectional relationship between health perception at six months and the two recovery outcomes

Health perception over time. The primary purpose of this study was to identify one or more variables which, if assessed early in the patient's course of recovery, might be predictive of ultimate recovery. Thus, while health perception at six months was found to be related to recovery outcomes, this finding does not answer the primary questions asked in this study, unless health perception is found to be unchanging over time.

Both Garrity (1973a, 1973b) and Brown & Rawlinson (1975) concluded that health perception was relatively stable over time. In other words, those individuals who had a positive perception of their health prior to myocardial infarction and/or cardiac surgery, tended to have a more positive perception of their health at the time of follow up. Since health perception at six months is related to the recovery outcomes, one might conclude, as Garrity did (1973a, 1973b), that health perception might be predictive of patient recovery.

In an attempt to follow the line of reasoning presented by Garrity, the investigator decided to examine the relationship between health perception at six months and health perception prior to and one month following implantation. The analyses were developed in the same manner as the primary analyses in this study (p. 122-123), with the two patient clinical status variables as covariates. The tables of the findings are presented in Appendix H. The analyses indicated that 1) health perception at one month accounted for a statistically significant portion of the explanation of the variance (41%) in health perception at six months, after controlling for the clinical status of the patient at one month; 2) preoperative health perception similarly demonstrated a lesser, but still statistically significant correlation with health perception at six months after controlling for the patient's preoperative clinical status; 3) the above relationships were not influenced by the patient's age or gender. Therefore, health perception in this sample of patients undergoing pacemaker implantation demonstrated relative stability over a six months period. Those patients who were most positive about their health either prior to implantation or one month following implantation, were more likely to be the most positive about their health at six months.

Preoperative and one month health perception and recovery outcomes. Since health perception demonstrated relative stability over time, and health perception at six months was significantly related to the recovery outcomes, one might anticipate that the patient's health perception earlier in the course of recovery might be significantly related to the recovery outcomes. This did not prove to be the finding.

After controlling for the influence of the patient's clinical status, health perception at one month was predictive of the level of subjective distress reported at six months, but it was not predictive of the extent of activity resumption. The health perception immediately prior to implantation was not predictive of either subjective distress or activity resumption at six months.

As noted in chapter III, some roles may be viewed by the individual as only temporary and not really reflective of his "self", while other roles are merged within the individual's self concept. Among the factors facilitating role-self merger is the individual's perception of the extent to which significant others identify him in the particular role. Role-self merger can be said to occur when the individual continues to enact the role when it no longer applies or when one does not relinquish the role even though there are advantageous or viable alternatives available.

The extent of merger of the sick role into the patient's self concept varied across the sample in this study as indicated by the range of scores on the Current Health scale of the General Health Perception Questionnaire. This variation was evident at each of the three times of testing and was apparent even after controlling for the patient's clinical status.

If roles emerge from interaction, it is not surprising that, even though health perception or the extent of role-self merger demonstrated some degree of stability over time, the patient's perception of his health prior to implantation and early in the recovery process was not necessarily predictive of recovery outcome. Health perception at six months was certainly influenced by previous merger of the sick role with the self, but it was more responsive to more contemporary factors such as interactions with significant others and environmental stimuli. The period of hospitalization and implantation presented a unique experience for all patients. They were presented with multiple stimuli and interactive cues from caregivers, family and others which might have led them to perceive the sick role as an appropriate one for them. By one month following implantation, with the return to the home environment and relief of symptoms (for the majority of patients), most of the patients reported that they perceived their health to be improved, indicating that the sick role was probably seen as less appropriate.

One might assume that the environment stimuli and interactional cues at one month were more like those to which the patient was responding at six months than those of the hospitalization period. Consequently, the patient's health perception at one month was more closely related to health perception at six months than the patient's perception of his health prior to implantation had been. Health perception at one month was predictive of only one of the two recovery outcomes, subjective distress. It is not clear exactly why health perception at one month was predictive of one outcome, but not the other. It could be that health perception and subjective distress are more closely related since they are both subjective feeling states. The skewed distribution for activity resumption would have attenuated all of the correlations found for this variable, including those with health perception.

## SUBJECTIVE DISTRESS PRIOR TO AND ONE MONTH FOLLOWING IMPLANT AND RECOVERY OUTCOMES

Different approaches were used in defining and measuring emotional distress and recovery outcomes in this study and previous research. Nonetheless, the findings in the current study of statistically significant relationships between subjective distress prior to and at one month following implantation and subjective distress reported by the patient at six months, after controlling for the patient's clinical status are congruent with the findings of previous researchers (Greene & Moss, 1968; Goble et al., 1978a, 1978b; Price, Obel & Scott-Millar, 1980, in studies with patients undergoing pacemaker implantation and Brown & Rawlinson, 1976; Croog & Levine, 1977; Gundle et al., 1980; Stern et al., 1977 in studies with individuals with myocardial infarctions or undergoing cardiac surgery).

The findings of this study lend less support to the previous findings of significant relationship between prior subjective distress and activity resumption at six months (Greene & Moss, 1968; Goble et al., 1978a, 1978b; Price, Obel & Scott-Millar, 1980; Croog & Levine, 1977; Stern et al., 1977). The level of subjective distress prior to implantation did not demonstrate a statistically significant association with the extent of presymptom activity resumption at six months, after controlling for the patient's preoperative clinical status. The relationship between the level of subjective distress at one month and activity resumption at six months varied depending upon the patient's clinical status at one month. Those patients who had no cardiovascular symptoms or complications at one month generally reported full or almost full resumption of activities at six months irrespective of the level of subjective distress reported at one month. On the other hand, for those patients who reported symptoms and/or complications at one month, the extent of activity resumption at six months was related to the level of subjective distress reported at one month. Thus, while the extent of subjective distress prior to implantation and early in the recovery period was predictive of the level of subjective distress reported by the patient at six months, it was not a good predictor of the extent of presymptom activity resumption at six months.

In the previous discussion of findings related to health perception, subjective distress was viewed as a reflection of some perceived difficulty in role enactment by the patient. When subjective distress is viewed from this perspective, the findings are difficult to explain. It is not clear why prior perceived difficulty in role enactment should be predictive of continued perception of difficulties in role enactment, but not predictive of activity resumption at six months. The Subjective Distress score in this study was developed from the Anxiety and Depression scales of the MAACL. These concepts, anxiety and depression, are more directly addressed by the more personality oriented theories, such as those of H.S. Sullivan or S. Freud. It is possible that the exploration of one of the personality oriented theoretical perspectives might offer an explanation for the findings.

The secondary analyses of the interactions between the clinical status covariates and subjective distress in the analysis of the relationship between subjective distress at one month and activity resumption at six months clearly pointed out the ceiling effect on the correlations resulting from the skewed distribution of activity resumption at six months. While this effect was most apparent in this one analysis, it is likely that the skewing attenuated the correlations with activity outcome in the other analyses as well.

## INFLUENCE OF DEMOGRAPHIC VARIABLES

The age and gender of the patient did not influence the relationships found between health perception and subjective distress prior to and one month following implantation, and recovery outcomes at six months.

Age contributed very little to the explanation of the variance in outcome over and above that contributed by the clinical status and health perception or prior subjective distress. Similarly, gender, generally, made little unique contribution. In the one instance in which gender did demonstrate a statistically significant unique contribution to the explanation of the variance in the level of subjective distress at six months, women tended to report more subjective distress. Brown & Rawlinson (1976) reported a similar finding in their study of patients who had undergone cardiac surgery. It is not clear whether women are more distressed or whether they are just more likely to identify and report their emotional distress.

# Chapter VIII

# SUMMARY AND CONCLUSIONS

## SUMMARY OF THE STUDY

The purpose of this study was to identify one or more patient variables which would suggest interventions to promote recovery following pacemaker implantation.

One hundred and two patients were interviewed prior to and at one and six months following pacemaker implantation to determine cardiac symptoms and general health status, along with changes in work, social and leisure activities. Written questionnaires to assess subjective distress and self perception of health were administered at each interview. Demographic and selected clinical data were retrieved from a computerized database maintained in the Pacemaker Center. Since not all patients completed the written questionnaires, complete follow up data were available for 66 patients. These 66 patients were very similar to the general population of patients undergoing initial pacemaker implantation in Canada between January 1, 1979 and December 31, 1981.

The extent of resumption of presymptom work, social and leisure activity and subjective distress at six months were considered the patient outcome of interest. Analyses were carried out to determine the extent to which subjective distress and perception of health prior to implantation and at one month explained the variance in activity resumption and subjective distress at six months, after controlling for the influence of the patient's clinical status. The possible interactive influence of patient age or gender on the relationship between the independent and outcome variables was also evaluated.

The patients, as a group, had a good recovery following implantation. By the time of the six months follow up, half of the patients were able to resume all of their presymptom work, social and leisure activities. Only 10 per cent of the patients who were employed or actively engaged in housekeeping prior to implantation, reported no resumption of these activities at six months postimplant. Most patients did not report elevated levels of subjective distress. Even though many of the patients had multiple chronic health problems and all had a permanent pacemaker,which required life long medical supervision, within one month of implantation, the patient group perceived themselves to be as healthy as normative samples drawn from the general population.

Patients who had a more positive perception of their health at six months were likely to report greater resumption of activity and less subjective distress at six months. Those patients who had a more positive perception of their health prior to implant and at one month, tended to have a more positive perception of their health at six months, after controlling for the patient's clinical status. Nonetheless, health perception prior to implant was not predictive of either patient outcome after controlling for the influence of the patient's preoperative clinical status. Health perception at one month was predictive of subjective distress at six months, but not of the extent of activity resumption after controlling for the patient's clinical status at one month.

Subjective distress prior to implant was predictive of subjective distress at six months, but not of activity resumption. Subjective distress at one month was predictive to subjective distress at six months after controlling for the patient's clinical status. The relationship between subjective distress at one month and activity resumption at six months varied depending on the patient's clinical status. Those patients who had no cardiovascular symptoms or complications generally reported full, or almost full, resumption of activities irrespective of the level of subjective distress at one month. For those patients who were symptomatic or who had experienced postimplant complications, the extent of activity resumption was significantly related to the level of subjective distress at one month.

## LIMITATIONS OF THE STUDY

### THE DESIGN

A longitudinal follow up design was chosen for this study because it enabled the investigator to actually measure the independent variables, health perception and subjective distress, prior to implant and at one month rather than being dependent on patient recall. The design did have some limitations. Over the two years of data collection, there were changes in the physical facilities and personnel in the Pacemaker Center, as well as in the pacing technology and follow up procedures. Although examination of the data did not reveal any differences between those patients who were seen early in the study and those who were entered later, the possibility always exists in a study in which patients are entered and followed over an extended period that changes beyond the investigator's control will modify the patient responses.

During the data collection period, there were no manufacturer's recalls or alerts for any of the pacemakers implanted in the patients in this study. There have been times in the past when a substantial proportion of the patients required frequent (often weekly) monitoring because of concerns about unpredicted pacemaker failure (MacGregor, Noble, Morrow, Scully, Covvey & Goldman, 1977). Had the data been collected during a recall period, it is possible that the findings regarding patient subjective distress could have been quite different.

The investigator conducted all of the interviews and it became apparent that, for some of the patients, she gave a sense of continuity between the hospital and the follow up clinic. Many of the patients shared additional comments about their feelings and questions regarding the pacemaker and their health in general, beyond the specific data needed for this study. It is entirely possible that the patient's participation in the study, with the opportunity to discuss his or her questions or concerns at three different times, might have decreased the patient's anxiety about the pacemaker and his or her health in general. The investigator's interest in the patient's resumption of activities possibly was seen by the patients as encouraging activity.

## MISSING DATA

The major limitation of the study was the incomplete data available from the two written questionnaires. There is no way of knowing whether or not those patients who completed the questionnaires were truly representative of the patient group, as a whole, in terms of the two variables measured. Completion of the written questionnaires was more frequently a problem with the older patients who were less familiar with filling out written forms. Once the investigator became aware of the reluctance of some of the patients to complete the written questionnaire, she did offer to read the questions and record the patient's responses in order to not lose the data. Even then, some of the patients declined to complete the questionnaires.

## THE INTERVIEW

The data on activity resumption had a skewed distribution. It may well be that this distribution is truly representative of the extent of activity resumption or it may be that the questions asked in the interview did not capture more subtle differences in activity resumption. The patients may have reported full resumption although they had made some changes in the kind or amount of presymptom activity.

An additional problem was the poor fit between the questions asked in the interview and the interactionist-role theoretical perspective. Resumption of presymptom activity was theoretically viewed as the resumption of presymptom roles, but the questions in the interview were specifically directed toward behaviours or activities rather than the patient's perception of his resumption of presymptom roles. It is entirely possible that even if activities had changed to some extent, the individual might have perceived that he or she was still able to fulfill a presymptom role adequately.

The final limitation is related to the use of patient reported symptoms as a measure of the patient's clinical status at follow-up rather than some more objective measure of patient clinical status. Patient report of symptoms could have been affected by the patient's subjective emotional state as well as by his perception of his health. Thus, in using clinical status as a covariate, some of the variance in the independent variables might have been removed. Other, more objective measures of cardiovascular status, such as treadmill testing or complete physical assessment by a physician, were not available to the investigator. A noninvasive measure of cardiac output could give a more objective evaluation of the efficacy of the pacemaker. Such a measure was not available to this investigator.

## IMPLICATIONS FOR PRACTICE

Preoperative health perception was not predictive of either patient outcome. Preoperative subjective distress was predictive of only subjective distress at six months. At one month, health perception was predictive of subjective distress at six months and subjective distress was predictive of subjective distress at six months as well as activity resumption in those patients who were symptomatic or who had had complications. Consequently, it seems that it is difficult to predict ultimate recovery on the basis of preoperative psychological data, but assessment of the patient's level of subjective distress and perception of health at one month following implant should enable health care personnel to identify patients who are "at risk" for less than optimal recovery. Unfortunately, at least in this investigator's experience, the follow up clinics are often very busy and there is little opportunity to adequately assess the patient's emotional response to the pacemaker. The findings of this study suggest that, even though most patients are achieving a good recovery, additional efforts should be made to more adequately assess patient responses at one month post-implant in order to identify the remaining patients who are "at risk" for less than optimal recovery.

It was hoped that the patient variables identified in this study would be helpful in pointing toward interventions which would facilitate recovery. From the findings it seems that interventions which promote a positive perception of health and/or reduce the patient's sense of subjective distress might promote recovery.

The in-hospital teaching program and the counselling given by the nurses and physicians in this Center encourage the patients to resume activities. Very few, if any, limitations are put on activity specifically "because of the pacemaker". While this positive approach to the recovery of patients who have had a pacemaker is becoming increasingly prevalent in North America, one still encounters patients who have been told that they cannot do certain things "because of the pacemaker". This is particularly distressing if the individual experiences unnecessary discrimination in the job market.

Patient groups such as the Pacemaker Club in this Center, and educational newsletters and publications from the manufacturers are good approaches to continuing patient education and support. Since the attitudes of the general public impact upon the perceptions of the patients and their families, the general public needs to be aware of the potential for full recovery for patients who have pacemakers. Continued positive publicity in the popular print and broadcast media of the achievements of individuals who have pacemakers is one way of encouraging a positive attitude within the general public.

Health care economics were not the primary focus of this study, but the findings of this study do provide data which could be useful in the current discussions on the cost/benefit analysis of cardiac pacing. Almost all of the patients, many of whom were quite disabled with potentially life threatening conduction disorders prior to implant, were able to resume presymptom activities without increased emotional distress. Thus, the use of the pacemaker was not only lifesaving but it enabled the patient to maintain his quality of life. The findings of this study would seem to indicate that the cost of pacemaker implantation and follow up is a good investment of health care dollars.

## SUGGESTIONS FOR FURTHER RESEARCH

The suggestions for further research resulting from this investigator's experience with this study are varied and touch on a number of areas, including: 1) some considerations in conducting clinical research with older individuals; 2) the need for the development of a valid and reliable measure of activity resumption; 3) the need for the development of a noninvasive, easily administered, objective measure of clinical cardiovascular status; 4) future directions for research on patient recovery following pacemaker implantation; 5) future directions for research on self perception of health; 6) the potential of interactionist-role theory in future research on patient response to illness and recovery.

Some of the traditionally used research instruments are not appropriate for research with older individuals. As noted earlier, many of the older patients in this sample were reluctant to complete the written questionnaires. Data might be more easily and completely gathered using an interview. If written material is used, it needs to be printed with large type which is easily read. (The print on the MAACL is quite small and difficult to read.) Attention needs to be given to the total length of time of the interview and/or other data collection procedures since older individuals may tire easily.

Research efforts need to be directed toward the development of a standardized instrument to quantitatively measure activity resumption as an aspect of recovery. It is difficult to compare the findings from various studies on resumption of activity because of the multiple operational definitions and approaches to measurement of this aspect of recovery being used in the literature. The activity scales which the investigator reviewed prior to developing the interview guide, tended to focus on gross activity limitations and would not appear to be sensitive to subtle differences in a basically ambulatory population.

The frequently used "return to work" criteria is an incomplete reflection of total activity and is inappropriate for many patients, particularly those who are retired.

Another area for instrument development is the need for a noninvasive valid measure of cardiac status. Most studies currently rely on either patient report of symptom or the physician classification of cardiac function according to the New York Heart Association classification. Both of these approaches are less than optimal. Patient report of symptom depends on the subjective perception of the symptom by the patient as well as his willingness to report the symptom. The New York Heart Association classification offers only four levels and thus is not sensitive to subtle differences. It is also, to a great extent, based upon the physician's interpretation of the patient's report of activity tolerance. A noninvasive measure of cardiac output used in conjunction with patient report of symptoms and activity tolerance would give greater objectivity to clinical cardiovascular status data.

This study focused on patient response during the first and six months following implant. Longterm follow up is needed to assess whether or not the extent of activity resumption and low incidence of emotional distress is maintained. This study included only adult patients. The impact of pacemaker implantation in the child needs to be explored. As pacing technology continues to develop, research and evaluation should include not only the assessment of physiological and clinical outcomes, but also patient recovery outcomes, especially activity resumption and emotional responses.

The patient's perception of his current health demonstrated little ability to predict ultimate recovery in this study although it was highly correlated to recovery when measured at the time of the six months follow up. Ware (1976) identified three higher order factors within general health perception: current and prior health; future health; and sick role propensity. It is possible that these other factors may have greater predictive ability than perception of current health. Future research should attempt to further delineate the various facets of health perception and test the relationship of these facets to ultimate recovery outcomes. If health perception does demonstrate a relationship to ultimate recovery, clinical trials of interventions, designed to change health perception, will need to be undertaken.

The interactionist-role theoretical perspective proved helpful in explaining some of the findings of this study on patient recovery. The use of this theoretical perspective should be explored in studying patient recovery in other settings and with other groups of patients. It may prove to be particularly helpful in assessing resumption of roles, and the impact of significant others on recovery outcome.

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# APPENDICES

## Appendix A

### Patient Data

### A. Preoperative:

Code number ______________ 1-4______

Card Number 1 5 1

blank 6-7______

Birthdate ______________ Age in years ____________ 8-9______

Age group:

_____1)under 45 years _____4)65 to 74 years
_____2)45 to 54 years _____5)75 to 84 years
_____3)55 to 64 years _____6)above 84 years 10______

Sex:

_____1) Male _____2)Female 11______

Marital Status:

_____1)married _____3)widowed
_____2)divorced _____4)single 12______

Occupation:___________________________________

_____own current _____husband's former
_____own former _____no answer
_____husband's current
Blishen Class__________________ 13______

blank 14-15______

Symptomatology (all):

_____asymptomatic _____angina
_____syncope _____chest pain (other)
_____presyncope _____palpitations
_____fatigue _____decreased mental acuity
_____dyspnea
Total number of cardiac symptoms 16______

Limiting symptom:

_____1)asymptomatic
_____2)syncope
_____3)presyncope
_____4)fatigue
_____5)dyspnea
_____6)angina
_____7)chest pain (other)
_____8)palpitations
_____9)decreased mental acuity

17______

Duration of symptoms_______________

_____1)asymptomatic
_____2)less than 1 week (7 days)
_____3)one week to one month
_____4)one through 3 months
_____5)four through 6 months
_____6)seven through 12 months
_____7)more than 12 months, but less than 24 months
_____8)twenty four months or more 18______

Chronic cardiovascular disease, pre-op:

_____1)no
_____2)yes, but did not require treatment
_____3)yes, required treatment 19______

Other chronic illness, pre-op:

_____1)no
_____2)yes, but did not require treatment
_____3)yes, required treatment 20______

Chronic illness (cardiovascular and/or other) pre-op (combination of 19 and 20):

_____1)no
_____2)yes, but did not require treatment
_____3)yes, required treatment 21______

EKG Indications (major):

| | Cont. | Intermit. |
|---|---|---|
| Sinus bradycardia | _____01 | _____02 |
| Sinus arrest | _____03 | _____04 |
| Brady/tachycardia | _____05 | _____06 |
| Sino-atrial exit block | _____07 | _____08 |
| Intra-atrial block | _____09 | _____10 |
| $1^0$AV block | _____11 | _____12 |
| $2^0$AV block, Mobitz I | _____13 | _____14 |
| $2^0$AV block, Mobitz II | _____15 | _____16 |
| Complete heart block | _____17 | _____18 |

| | Cont. | Intermit. | |
|---|---|---|---|
| Atrial Fib/Flutter with Slow Ventricular Response | _____19 | _____20 | 22-23_____ |
| Right Bundle Branch Block | _____21 | _____22 | |
| Left Bundle Branch Block | _____23 | _____24 | |
| Left Anterior Hemiblock | _____25 | _____26 | |
| Left Posterior Hemiblock | _____27 | _____28 | |
| Anomalous AV Conduction | _____29 | _____30 | |
| Bradycardia relating to drug therapy | _____31 | _____32 | |

Conversion of Tachyarrhythias:

_____33)atrial _____34)ventricular

Suppression of Tachyarrhythmias:

_____35)atrial _____36)ventricular

Most Likely Etiology:

_____1)Idiopathic (unknown)
_____2)Degenerative (conduction system fibrosis)
_____3)Chronic Ischemic Heart Disease
_____4)Acute Myocardial Infarct (recent)
_____5)Cardiomyopathy
_____6)Chagas' disease 24-25_____
_____7)Congenital
_____8)Surgical (remote)
_____9)Surgical (recent)
_____10)Other
_____11)Myocarditis (including rheumatic)

blank 26-27_____

MAACL-Anxiety pre-op (00 to 21) 28-29_____

MAACL-Depression pre-op (00 to 40) 30-31_____

blank 32-33_____

General Health Perceptions Scales:

- Current Health - pre-op (09 to 45) 34-35_____
- Prior Health - pre-op (03 to 15) 36-37_____
- Resistance/susceptibility - pre-op (04 to 20) 38-39_____
- Health Outlook - pre-op (04 to 20) 40-41_____
- Health Worry - pre-op (04 to 20) 42-43_____
- Sickness Orientation - pre-op (02 to 10) 44-45_____
- Rejection of Sick Role - pre-op (04 to 20) 46-47_____
- Attitude toward going to the doctor - pre-op (02 to 10) 48-49_____

blank 50-51_____

Major Presymptom Activity (from interview):

_____1)work
_____2)housekeeping 52______
_____3)school
_____4)organizational or group work
_____5)other

Change in the kind or type of activity since
symptoms began: 53______

_____1)yes, increase or additional
_____2)yes, decrease or deletion
_____3)no change

Change in the amount of activity since symptoms began:

_____1)yes, increase or additional 54______
_____2)yes, decrease or deletion
_____3)no change

Social Activity prior to symptoms:

_____1)yes _____2)no 55______

Change in kind or type of social activity since
symptoms began:

_____1)yes, increase or additional 56______
_____2)yes, decrease or deletion
_____3)no change

Change in the amount of social activity since
symptoms began:

_____1)yes, increase or additional 57______
_____2)yes, decrease or deletion
_____3)no change

Leisure activities prior to symptoms:

_____1)yes 58______
_____2)no

Change in kind or type of leisure activities
since symptoms began:

_____1)yes, increase or additional 59______
_____2)yes, decrease or deletion
_____3)no change

Change in amount of leisure activity since
symptoms began:

_____1)yes, increase or additional 60______
_____2)yes, decrease or deletion
_____3)no change

## B. Postoperative - one month

Code number 1-4______

Card Number ____2____ 5__2___

blank 6-7______

Pacing Mode:

_____1)VOO
_____2)VVI
_____3)VVT
_____4)VAT
_____5)AAI
_____6)AAT
_____7)external convertion
_____8)other

8______

Symptoms at one month post-op:

_____1)none
_____2)limiting symptom identified pre-op* not present, but one or more other symptoms are present
_____3)limiting symptom identified* pre-op present
_____4)limiting symptom* and others present

9______

* Limiting symptom pre-op (from Card 1 #17)

______________________________________

Complications between time of surgery and one month baseline visit:

_____1)none
_____2)yes, required MD office visit, <u>only</u>
_____3)yes, required extention of original hospitalization
_____4)yes, required rehospitalization

10______

Pacemaker function at one month:

_____1)normal
_____2)abnormal
_____3)questionable

11______

Pacemaker related complications to one-month visit:

_____01)none
_____02)neuromuscular stimulation (pack-related)
_____03)neuromuscular stimulation (lead-related)
_____04)wound hematoma
_____05)lead fracture
_____06)other lead problem (includes dislodgement, malposition, penetration, perforation, "exit block", etc.)
_____07)phlebitis/thrombosis/embolism
_____08)infection/erosion (pack related)
_____09)infection/erosion (lead-related)
_____10)pulse-generator migration
_____11)electrical/myopotential interference
_____12)pacemaker induced arrhythmias
_____13)psychological problems

12-13______

Other health problems during first month post-op:

_____1)has not seen MD for health problem other than pacemaker
_____2)has seen MD in last month for "routine" follow up care 14______
_____3)has seen MD in last month because of continuing symptoms
_____4)has seen MD in last month for increase or change in symptoms
_____5)has seen MD for a new symptom
_____6)has been hospitalized during last month for a health problem other than the one being treated by the pacemaker

blank 15-16______

MAACL-Anxiety - one month (00 to 21) 17-18______

MAACL-Depression - one month (00 to 40) 19-20______

blank 21-22______

General Health Perception Scales:

- Current Health - one month (09 to 45) 23-24______
- Prior Health - one month (03 to 15) 25-26______
- Resistance/susceptibility (04 to 20) 27-28______
- Health Outlook - one month (04 to 20) 29-30______
- Health Worry - one month (04 to 20) 31-32______
- Sickness Orientation - one month (02 to 10) 33-34______
- Rejection of Sick Role - one month (04 to 20) 35-36______
- Attitude toward going to the doctor (02 to 10) 37-38______

blank 39-40______

"Work" activity at one month post-op (from interview):

_____1)has not resumed any work, housekeeping, school or organizational activity, and has not made plans
_____2)has not resumed work, housekeeping, school or organizational activity, but has plans to do so 41______
_____3)has resumed some activities, but less than half of presymptom level, and can not state plans for additional resumption
_____4)has resumed some, but less than half of presymptom activities, but has plans for additional resumption
_____5)has resumed at least half of presymptom activity, but has no further plans to resume additional activities

_____6) has resumed at least half of presymptom activity, and has plans for further resumption of activity
_____7) has returned to presymptom level of activity
_____8) was not involved in "work" activity presymptom

Social activities at one month post-op:

_____1) has not resumed social activities and has not made plans to return
_____2) has not resumed social activities <u>but</u> has plans to return to activity
_____3) has resumed some, but less than half of presymptom social activities and cannot state plans for additional activities 42______
_____4) has resumed some, but less than half of presymptom activity, <u>but</u> does have plans for additional activity
_____5) has resumed at least half of presymptom social activity, but has no further plan for resumption
_____6) has resumed at least half of presymptom social activity and has plans for additional activity
_____7) has returned to presymptom social activities
_____8) was not involved in social activity presymptom

Leisure activity - one month post-op:

_____1) has not resumed any leisure activity and has not made plans to return
_____2) has not resumed any leisure activity, <u>but</u> has made plans to resume activity
_____3) has resumed some, but less than half of presymptom leisure activity and does not have plans to resume 43______
_____4) has resumed some, but less than half of presymptom leisure activity, <u>but</u> has plans to resume further activity
_____5) has resumed at least half of presymptom leisure activity, but has no further plans to resume activity
_____6) has resumed at least half of presymptom activity and has plans for further resumption
_____7) has resumed presymptom leisure activity
_____8) was not involved in leisure activities presymptom

## C. Post-operative - six months

Code number ______________ 1-4______

Card Number 3 5 3

blank 6-7______

Symptoms at six months post-op:

_____1) none
_____2) limiting symptom identified pre-op* not present, but one or more other symptoms are present
_____3) limiting symptom identified pre-op* present
_____4) limiting symptom identified pre-op* and others present

*Limiting symptom (from Card 1 #17) 8______

________________________________________

Complications between one and six months:

_____1) none
_____2) yes, required MD office visit, only
_____3) yes, required rehospitalization 9______

Pacemaker function at six months:

_____1) normal
_____2) abnormal
_____3) questionable 10______

Pacemaker related complication at six month visit:

_____01) none
_____02) neuromuscular stimulation (pack-related)
_____03) neuromuscular stimulation (lead-related)
_____04) wound hematoma
_____05) lead fracture
_____06) other lead problem (includes dislodgement, malposition, penetration, perforation, "exit block", etc.)
_____07) phlebitis/thrombosis/embolism
_____08) infection/erosion (pack-related)
_____09) infection/erosion (lead-related)
_____10) pulse-generator migration
_____11) electrical/myopotential interference
_____12) pacemaker induced arrhythmias
_____13) psychological problems 11-12______

Other health problems during the one month to six months period:

_____1) has not seen MD for health problem other than pacemaker
_____2) has seen MD during time for "routine" follow up care
_____3) has seen MD during time because of continuing symptoms
_____4) has seen MD during time for increase or change in symptoms
_____5) has seen MD for a new symptom 13______
_____6) has been hospitalized during time for a health problem other than the one being treated by the pacemaker

blank 14-15______

MAACL Anxiety, six months (00 to 21) 16-17______

MAACL, Depression, six months (00 to 40) 18-19______

blank 20-21______

General Health Perception Scales:

- Current Health - six months (09 to 45) 22-23______
- Prior Health - six months (03 to 15) 24-25______
- Resistance/susceptability - six months (04 to 20) 26-27______
- Health Outlook - six months (04 to 20) 28-29______
- Health Worry - six months (04 to 20) 30-31______
- Sickness Orientation - six months (02 to 10) 32-33______
- Rejection of Sick Role - six months (04 to 20) 34-35______
- Attitude toward going to the doctor - six months (02 to 10) 36-37______

blank 38-39______

"Work" activity level at six months (from interview):

A. Kind:

_____1) has not resumed any of presymptom "work", housekeeping, school or organizational activity
_____2) has made major changes in kind of presymptom activity
_____3) has made minor changes in kind of presymptom activity
_____4) has resumed all of presymptom "work", housekeeping, school or organizational activities, or if uninvolved in such activity, presymptom, remains uninvolved

B. Amount:

_____1) has not resumed any presymptom "work", housekeeping, school or organizational activities

_____2) now spends less than half of presymptom time in "work", housekeeping, school or organizational activity

_____3) now spends at least half or more than half of presymptom time on such activities

_____4) has resumed presymptom level (time) of work, housekeeping, school, or organizational activity

Score: Kind__________+Amount__________=__________ (2 to 8) 40_____

Social activity at six months (from interview)

A. Kind:

_____1) has not resumed any of presymptom social activities

_____2) has made major changes in kind of activity

_____3) has made minor changes in kind of activity

_____4) has resumed all of presymptom social activity or has increased activity or if uninvolved in social activity presymptom, remains uninvolved

B. Amount:

_____1) has not resumed any presymptom social activities

_____2) now spends less than half of presymptom time in social activity

_____3) now spends half or more than half of presymptom time in social activity

_____4) has resumed presymptom level (time) of social activity, or has increased activity or if uninvolved in social activity presymptom, remains uninvolved

Score: Kind__________+Amount__________=__________ (2 to 8) 41_____

Leisure Activity at six months (from interview)

A. Kind:

_____1)has not resumed any presymptom leisure activities

_____2)has made major changes in kind of leisure activities

_____3)has made minor changes in kind of leisure activities

_____4)has resumed presymptom leisure activity or has increased activity or if uninvolved presymptom, remains uninvolved

B. Amount:

_____1)has not resumed any of presymptom leisure activity

_____2)now spends less than half of presymptom time on leisure activity

_____3)now spends at least half or more than half of presymptom time on leisure activity

_____4)has resumed presymptom level (time) of leisure or has increased time in leisure activity, or if uninvolved in leisure activity, presymptom, remains uninvolved

Score: Kind____________+Amount____________=____________ (2 to 8) 42______

Total activity score at six months

Score: "Work"_________+Social_________+Leisure_________=_______________ (06 to 24)

43-44_______

## Appendix B

## HEALTH PERCEPTION QUESTIONNAIRE #1

The purpose of this questionnaire is to find out how you feel about your health. THERE ARE NO RIGHT OR WRONG ANSWERS. We just want to know how true each health statement is for you.

Please keep in mind that while some statements may appear similar to others, each statement is different from all others and should be rated by itself.

Please read all of the statements and then take a moment to circle the number under the phrase which best describes how much you believe the statement.

For example, if you believe the statement: "People today are healthier than people used to be" is mostly true, then you would circle the 2 under "mostly true" in the example below.

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| People today are healthier than they used to be | 1 | 2 | 3 | 4 | 5 |

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| 1. According to the doctors I've seen, my health is now excellent. | 1 | 2 | 3 | 4 | 5 |
| 2. I try to avoid letting illness interfere with my life. | 1 | 2 | 3 | 4 | 5 |
| 3. I seem to get sick a little easier than other people. | 1 | 2 | 3 | 4 | 5 |
| 4. I feel better now than I ever have before. | 1 | 2 | 3 | 4 | 5 |
| 5. I will probably be sick a lot in the future. | 1 | 2 | 3 | 4 | 5 |
| 6. I never worry about my health. | 1 | 2 | 3 | 4 | 5 |
| 7. Most people get sick a little easier than I do. | 1 | 2 | 3 | 4 | 5 |
| 8. I don't like to go to the doctor. | 1 | 2 | 3 | 4 | 5 |
| 9. I am somewhat ill. | 1 | 2 | 3 | 4 | 5 |
| 10. In the future, I expect to have better health than other people I know. | 1 | 2 | 3 | 4 | 5 |
| 11. I was so sick once I thought I might die. | 1 | 2 | 3 | 4 | 5 |

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| 12. I'm not as healthy now as I used to be. | 1 | 2 | 3 | 4 | 5 |
| 13. I worry about my health more than other people worry about their health. | 1 | 2 | 3 | 4 | 5 |
| 14. When I'm sick I try to just keep going as usual. | 1 | 2 | 3 | 4 | 5 |
| 15. My body seems to resist illness very well. | 1 | 2 | 3 | 4 | 5 |
| 16. Getting sick once in a while is part of my life. | 1 | 2 | 3 | 4 | 5 |
| 17. I'm as healthy as anybody I know. | 1 | 2 | 3 | 4 | 5 |
| 18. I think my health will be worse in the future than it is now. | 1 | 2 | 3 | 4 | 5 |
| 19. I've never had an illness that lasted a long period of time. | 1 | 2 | 3 | 4 | 5 |
| 20. Others seem more concerned about their health than I am about mine. | 1 | 2 | 3 | 4 | 5 |
| 21. When I'm sick I try to keep it to myself. | 1 | 2 | 3 | 4 | 5 |
| 22. My health is excellent. | 1 | 2 | 3 | 4 | 5 |

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| 23. I expect to have a healthy life. | 1 | 2 | 3 | 4 | 5 |
| 24. My health is a concern in my life. | 1 | 2 | 3 | 4 | 5 |
| 25. I accept that sometimes I'm going to be sick. | 1 | 2 | 3 | 4 | 5 |
| 26. I have been feeling bad lately. | 1 | 2 | 3 | 4 | 5 |
| 27. It doesn't bother me to go to a doctor. | 1 | 2 | 3 | 4 | 5 |
| 28. I have never been seriously ill. | 1 | 2 | 3 | 4 | 5 |
| 29. When there is something going around I usually catch it. | 1 | 2 | 3 | 4 | 5 |
| 30. Doctors say that I am now in poor health. | 1 | 2 | 3 | 4 | 5 |
| 31. When I think I am getting sick I fight it. | 1 | 2 | 3 | 4 | 5 |
| 32. I feel about as good now as I ever have. | 1 | 2 | 3 | 4 | 5 |

Health Perception Questionnaire Form II from Ware, John E., "Measuring General Health Perceptions", Health Services Research, Winter, 1976, p. 396-415.

## Appendix C

## HEALTH PERCEPTIONS QUESTIONNAIRE #2

Each of us have family or friends who are important to us and who influence our lives. Please select one of those people who is the most important to you now.

Who is that person?______________________(husband, wife, friend or child (name))

The purpose of this questionnaire is to find out how you think the person whom you just named feels about your health. THERE ARE NO RIGHT OR WRONG ANSWERS. We just want to know how true you think he or she would think each statement is.

Please keep in mind that while some statements may appear similar to others, each statement is different from all others and should be rated by itself.

Please read all of the statements and then take a moment to circle the number under the phrase which best describes how much you believe the person you have selected would agree with the statement.

For example, if you believe that he or she believes that the statement "People today are healthier than people used to be" is mostly true, then you would circle the 2 under "mostly true" in the example below.

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| People today are healthier than they used to be. | 1 | 2 | 3 | 4 | 5 |

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| 1. According to the doctors you have seen, your health is now excellent. | 1 | 2 | 3 | 4 | 5 |
| 2. You feel better now than you ever have before. | 1 | 2 | 3 | 4 | 5 |
| 3. You seem to get sick a little easier than other people. | 1 | 2 | 3 | 4 | 5 |
| 4. You will probably be sick a lot in the future. | 1 | 2 | 3 | 4 | 5 |
| 5. You never worry about your health. | 1 | 2 | 3 | 4 | 5 |
| 6. Most people get sick a little easier than you do. | 1 | 2 | 3 | 4 | 5 |
| 7. You are somewhat ill. | 1 | 2 | 3 | 4 | 5 |
| 8. In the future he (she) expects you to have better health than other people he (she) knows. | 1 | 2 | 3 | 4 | 5 |
| 9. You were so sick once he (she) thought you might die. | 1 | 2 | 3 | 4 | 5 |
| 10. You are not as healthy now as you used to be. | 1 | 2 | 3 | 4 | 5 |

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| 11. You worry about your health more than other people worry about their health. | 1 | 2 | 3 | 4 | 5 |
| 12. Your body seems to resist illness very well. | 1 | 2 | 3 | 4 | 5 |
| 13. Getting sick once in a while is part of your life. | 1 | 2 | 3 | 4 | 5 |
| 14. You are as healthy as anybody you know. | 1 | 2 | 3 | 4 | 5 |
| 15. He (she) thinks your health will be worse in the future. | 1 | 2 | 3 | 4 | 5 |
| 16. You have never had an illness that lasted a long time. | 1 | 2 | 3 | 4 | 5 |
| 17. Others seem more concerned about their health than you are about your health. | 1 | 2 | 3 | 4 | 5 |
| 18. Your health is excellent. | 1 | 2 | 3 | 4 | 5 |
| 19. You expect to have a healthy life. | 1 | 2 | 3 | 4 | 5 |
| 20. Your health is a concern in your life. | 1 | 2 | 3 | 4 | 5 |

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False |
|---|---|---|---|---|---|
| 21. You accept that sometimes you are going to be sick. | 1 | 2 | 3 | 4 | 5 |
| 22. You have been feeling bad lately. | 1 | 2 | 3 | 4 | 5 |
| 23. You have never been seriously ill. | 1 | 2 | 3 | 4 | 5 |
| 24. When there is something going around you usually catch it. | 1 | 2 | 3 | 4 | 5 |
| 25. Doctors say that you are now in poor health. | 1 | 2 | 3 | 4 | 5 |
| 26. You feel about as good now as you ever have. | 1 | 2 | 3 | 4 | 5 |

This questionnaire is a modification of the Health Perception Questionnaire Form II, Ware, J.E., "Scales for Measuring General Health Perceptions", Health Services Research, Winter, 1976, p. 396-415.

## Appendix D

## PATIENT INTERVIEW GUIDE

Patient Code:______________________

Date of Preoperative Interview:___________________

Date of Surgery:___________________

Date of Postoperative Interview #1:__________________

Date of Postoperative Interview #2:__________________

If no follow-up, Reason:_____________________________

# PATIENT INTERVIEW - PREOPERATIVE

1. What symptoms have you been having that made you come to see a doctor at this time?

______________________________________________

______________________________________________

______________________________________________

2. How long have you been aware of this (these) symptoms?***

______________________________________________

3. Before you began to have these symptoms, had you ever been told that you had a heart problem?______________
Were you taking any medicine, following a special diet, or had you ever been in the hospital for a heart problem?

______________________________________________

4. Do you have any other health problems for which you need to see a doctor?____________________________
Are you currently taking any medicine, following a special diet or other kind of treatment for this problem?

______________________________________________

5. A. Men, single, divorced or separated women,: Are you currently working?

_____ yes, GO TO ITEM 5A.1
_____ no, GO TO ITEM 5A.2

5A.1 What is your occupation?____________________
5A.2 What was your former occupation?______________

B. Married or widowed women,: What is your husband's occupation?_______________. (If he is retired or deceased) What was his occupation?_______________

6. I would like to get an idea of how you spend your time now, as well as how this compares to how you spent your time before you began to have the current symptoms. What activities took the major portion of your time before you began to have symptoms: work, housework, being a student, organizational or group work or other?

_____work, GO TO ITEM 7
_____housework, GO TO ITEM 8

_____student, GO TO ITEM 9
_____organizational or group work, GO TO ITEM 10
_____other, GO TO ITEM 11

7. Working:

7.1 What do you do in your job?____________________

__________________________________________________

7.2 Have you changed the type of work that you do since you began to have your current symptoms?

______No
______Yes

If yes, how has your work changed?_____________

__________________________________________________

7.3 Have you changed the amount of work (amount of time that you work) since you began having the current symptoms?

______No
______Yes

How many hours a week do you work?_____________

How many hours a week did you work before you began having your current symptoms?____________

8. Housekeeping:

8.1 What household activities are you involved in?

__________________________________________________

8.2 Have you changed the kinds of things that you do in taking care of your home since you began to have your current symptoms?

______No
______Yes

If yes, what changes have you made?____________

__________________________________________________

8.3 Have you changed the amount of time that you can spend doing housework? Are you doing less around the house than you did before the symptoms began?

______No
______Yes

9. <u>Student</u>:

9.1 What kind of a study program are you taking?_____

__________________________________________________

______Full-time
______Part-time

9.2 Have you changed the kinds of classes that you take since you began to have <u>your current symptoms</u>?

______No
______Yes

If yes, how have you changed?____________________

__________________________________________________

9.3 Have you limited the number of classes that you are taking since you began to have the <u>current symptoms</u>?

______No
______Yes

10. <u>Organizational or Group Work</u>:

10.1 What kinds of activity are you involved in, in the groups or organizations?____________________

__________________________________________________

10.2 Have you changed the kinds of activities that you do since you began to have your <u>current symptoms</u>?

______No
______Yes

If yes, how has that changed?____________________

__________________________________________________

10.3 Have you changed the amount of time that you spend working with the groups or organization?

______No
______Yes

How many hours a week do you spend working with this group?______________________________

How many hours a week did you spend working with this group before you began to have your current symptoms?______________________________

11. Other:

11.1 When did you stop working (or taking the major responsibility for the housekeeping?)__________

______________________________________________

11.2 Did you stop because of your health?

______NO
______Yes

12. Before your symptoms began, in an average week were you involved in social activities such as:

a) attending church or church related activities
b) community or social groups such as the Horticultural Society, cultural groups, Senior Citizens groups. etc.
c) visiting with family, neighbors and friends
d) playing cards with friends or family
e) going out to eat, to concerts and plays, etc. with friends or family
f) talking with family and friends on the phone

______No
______Yes

12.1 Have you changed the kinds of social activities that you do since you began to have your current symptoms?

______No
______Yes

If yes, how have these activities changed?______

______________________________________________

12.2 Have you had to limit the amount of such activities that you do since you began to have the current symptoms?

______No
______Yes

13. How did you spend your leisure time before you began to have your current symptoms, for example, doing such things as:

a) hobbies such as needlework, reading, caring for indoor plants
b) yard work and gardening
c) watching TV
d) taking continuing education or interest courses at a Sr. Citizen Center, CAAT's etc.
e) walks
f) sports
g) travel

______No leisure activities
______Involved in leisure activities

13.1 Have you changed the kinds of leisure activities that you do since you began to have your current symptoms?

______No
______Yes

If yes, how have they changed?________________

______________________________________________

13.2 Have you had to limit the amount of these activities since you began having the current symptoms?

______No
______Yes

14. Overall, how would you say the symptoms have affected your activities and life?__________________________

______________________________________________

______________________________________________

****** Throughout interview the symptoms named by the patient are inserted in place of the word "symptoms", "current symptoms".

# PATIENT INTERVIEW - POSTOPERATIVE #1

1. Are you having any of the symptoms that you had before your pacemaker was put in?

   ______No ______Yes

   If yes, what symptoms are you having?_______________

   ______________________________________________________

2. Have you had any problems with your pacemaker?

   ______No ______Yes

   If yes, did you call your doctor about this?

   ______No ______Yes

   Did you go to see your doctor in his office about this?

   ______No ______Yes

   Were you hospitalized for this problem?

   ______No ______Yes

3. Have you seen a doctor for any health problems, other than your pacemaker, since it was put in?

   ______No ______Yes

   If yes, what was the reason for seeing your doctor?____

   ______________________________________________________

4. What kinds of "work" activity are you doing now? (refer to pre-op interview for category of major activity)

   Work:_________________________________________________

   ______________________________________________________

   Household:____________________________________________

   ______________________________________________________

   Student:______________________________________________

   ______________________________________________________

   Organizational or group:______________________________

   ______________________________________________________

4.1 How does this compare with what you were doing before you began to have (limiting symptom)?

_____the same _____less than half

_____half or more than half _____have not resumed

4.2 Have you made any plans for returning to work, school or organizational activities or resuming your household jobs? (select category according to major presymptom activity)__________________

What are your plans?___________________________

5. What social activities are you doing now?

a) attending church or church related activities
b) community or social groups such as the Horticultural Society, cultural groups, Senior Citizens groups, etc.
c) visiting with family, neighbors and friends
d) playing cards with friends or family
e) going out to eat, for a drink, or to concerts and plays
f) talking with family and friends on the phone

______No social activities

______Yes, involved in_________________________

5.1 How does this compare to what you did before you began to have (limiting symptoms)?

_____the same _____less than half

_____half or more than half _____have not resumed

5.2 Have you made any plans to return to your previous social activities?_____________________________

What are your plans?___________________________

6. What leisure activities are you doing now?

a) hobbies such as needlework, reading, caring for indoor plants
b) yard work and gardening
c) watching TV
d) taking continuing education or interest classes
e) taking walks
f) sports activities
g) travel

______No leisure activities

______Yes, involved in_________________________

6.1 How does this compare to what you did before you began to have (limiting symptom)?

______the same ______less than half

______half or more than half ______have not resumed

6.2 Have you made any plans to return to your previous leisure activities?___________________________

What are your plans?___________________________

7. What instructions have you received from your doctor about resuming activities?

PATIENT INTERVIEW - POSTOPERATIVE #2

1. Are you having any of the symptoms that you had before your pacemaker was put in?

   ______No ______Yes

   If yes, what symptoms are you having?______________

   ____________________________________________________

2. Have you had any problems with your pacemaker?

   ______No ______Yes

   If yes, did you call your doctor about this?

   ______No ______Yes

   Did you go to see your doctor in his office about this?

   ______No ______Yes

   Were you hospitalized for this problem?

   ______No ______Yes

3. Have you seen a doctor for any health problems, other than your pacemaker, since it was put in?

   ______No ______Yes

   If yes, what was the reason for seeing your doctor?

   ____________________________________________________

4. I would like to get an idea of how you spend your time now as well as how that compares to how you spent your time before the pacemaker was put in and before you began to have the <u>symptoms</u> (see preoperative interview)

   What is the activity that takes the major portion of your time these days - your occupation, being a housewife, a student, working with a group or organization or other activities?

   ______work, GO TO ITEM 5
   ______housework, GO TO ITEM 6
   ______student, GO TO ITEM 7
   ______group or organization, GO TO ITEM 8
   ______other, GO TO ITEM 9

5. Working:

5.1 What do you do in your job?____________________

__________________________________________________

5.2 Have you changed the type of work that you do since you had the pacemaker put in?

______No
______Yes

If yes, do you consider these changes to be major or minor changes?______________________________

What changes have you made?____________________

__________________________________________________

5.3 Have you changed the amount of work (amount of time that you work) since you had the pacemaker put in?

______No
______Yes

How does the amount of time that you work each week compare to the amount that you were working before you began to have the symptoms?

______the same ______less than half

______half or more than half ______have not resumed

6. Housekeeping:

6.1 What household activities are you now involved in?

__________________________________________________

6.2 Have you changed the kinds of things that you do in taking care of your home since you had the pacemaker put in?

______No
______Yes

If yes, do you consider these changes to be major or minor changes?______________________________

What changes have you made?______________________

__________________________________________________

6.3 Have you changed the amount of housework that you do since you have had the pacemaker put in?

______No
______Yes

How does the amount of time that you spend on housework each week compare to the amount that you were doing before you began to have the symptoms?

______the same　　　　_____less than half

______half or more than half　　　　_____have not resumed

7. Student:

7.1 What kind of a study program are you now taking?

______________________________________________

______Full-time
______Part-time

7.2 Have you changed the kinds of classes that you take since you had your pacemaker put in?

______No
______Yes

If yes, do you consider these changes to be major or minor changes?______________________________

What changes have you made?____________________

______________________________________________

7.3 Have you changed the number of classes that you are taking since you had the pacemaker put in?

______No
______Yes

How does this compare to the number of classes that you were taking before you began to have symptoms

______the same　　　　______less than half

______half or more than half　　　　______have not resumed

8. Organizational or Group Work:

8.1 What kinds of activity are you involved in, in the groups or organizations?______________

8.2 Have you changed the kinds of activities that you do since you had the pacemaker put in?

______No
______Yes

Do you consider these changes to be major or minor changes?______________________________

What changes have you made?__________________

______________________________________________

8.3 Have you changed the amount of time that you spend working with the groups or organization since your pacemaker was put in?

______No
______Yes

How does this compare to the amount of time that you spent before you began to have the symptoms?

______the same ______less than half

______half or more than half ______have not resumed

9. Other:

9.1 When did you stop working (or taking the major responsibility for the housekeeping)?

______before the pacemaker was put in
______after the pacemaker was put in

10. In an average week are you currently involved in any of the following kinds of social actitivies?

a) attending church or church related activities
b) community or social groups such as the Horticultural Society, cultural groups, Senior Citizens groups, etc.
c) visiting with family, neighbors and friends
d) playing cards with friends or family
e) going out to eat, for a drink, concerts, or plays etc. with friends or family
f) talking with family and friends on the phone

______No
______Yes

10.1 Have you changed the kinds of social activities that you do since your pacemaker was put in?

______No
______Yes

If yes, do you consider these changes to be major or minor changes?________________________________

What changes have you made?______________________

__________________________________________________

10.2 Have you changed the amount of social activity that you do since your pacemaker was put in?

______No
______Yes

How does this compare to the amount of activity that you did before you began to have <u>symptoms</u>?

______the same ______less than half

______half or more than half ______have not resumed

11. How do you spend your leisure time now, for example, doing such things as:

a) hobbies such as needlework, reading, caring for indoor plants
b) yard work and gardening
c) watching TV
d) taking continuing education or interest courses at a Sr. Citizens Center, CAAT's etc.
e) walks
f) sports
g) travel

______No leisure activities
______Involved in leisure activities

11.1 Have you changed the kinds of leisure activities that you do since you had your pacemaker put in?

______No
______Yes

If yes, do you consider these changes to be major or minor changes________________________________

What changes have you made?____________________

__________________________________________________

11.2 Have you changed the amount of time you spend in leisure time activity since you had your pacemaker put in?

______No
______Yes

How has this changed?_________________________

How does this compare to your leisure time activity before you began to have symptoms?

______the same ______less than half

______half or more than half ______have not resumed

12. Overall, how would you say having the pacemaker has affected your activities and your life?______________

_____________________________________________________

_____________________________________________________

13. Have there been any major changes in your life since your pacemaker was put in such as children getting married or moving away, friends moving or family or friends becoming ill?

______No
______Yes

If yes, what has happened?___________________________

_____________________________________________________

## Appendix E

## VERBAL INTRODUCTION TO THE STUDY

Hello, __________, I am Jane Wilson. I am a teacher on the Faculty of Nursing at the University of Toronto, and I am conducting a study of patients' reactions to having a pacemaker put in. This study is being done to meet part of the requirements for a doctoral degree in Nursing at the University of California, San Francisco.

I am asking patients who are having pacemakers if they would be willing to talk with me and fill in two written questionnaires three different times - today and when you come back to the Pacemaker Clinic to see the doctor, one month and six months from now. The questions are about your symptoms and their effect on your life, the changes that occur after you have your pacemaker, and your feelings about your health and life in general. The interview will take 15 to 20 minutes and it should take you about 15 to 20 minutes to fill out the questionnaires. That is a total time of 30 to 40 minutes for each of three times.

I will be taking notes during the interview, but I will not include your name on the record form. When I publish the findings of this study, necessary precautions will be taken to protect the identity of any one who participated.

While there are no direct benefits to you, it is hoped that by learning more about various things that affect patients reactions to a pacemaker the nurses and doctors who work with pacemaker patients will be able to be more helpful to patients in the future.

Your involvement or non-involvement in this study will not affect the care that you receive from your doctors or nurses in any way.

I will also have to get some information from your medical record such as information about your electrocardiogram and the type of pacemaker that you will have.

Your doctor knows about this study and has agreed to my asking you to participate.

If you get tired during the interview or the questionnaires or if you do not want to answer a question, you may decline to do so. You may also decide to withdraw from the study at any time.

I need to have you sign a written consent form indicating that you are willing to participate and that you understand what will be involved.

We can then arrange for a convenient time this afternoon or early this evening to talk and fill in forms.

# Appendix F

## Consent Form

### A STUDY OF PATIENT RESPONSES TO PACEMAKERS

Jane Wilson has explained to me that she is doing a study of factors affecting patient reaction to the insertion of a pacemaker.

My participation in this study will involve an interview with Miss Wilson and the completion of two questionnaires today and an interview and the completion of two questionnaires when I return to the clinic for my regularly scheduled appointment one month and six months from now. Completion of the interview and questionnaires will take about 30 to 40 minutes each time.

My participation in this study is voluntary. If I get tired during the interview or during the completion of the questionnaires or if I do not want to talk about any of the questions, I can decline to answer. I may also decide to withdraw from the study at any time.

My participation in this study will not affect the care given to me by the doctors or nurses. While there are no direct benefits to me for participating in this study, it is hoped that the information gained will be helpful to the doctors and nurses and to patients with pacemakers, in the future.

Miss Wilson has explained to me that she will be taking notes during the interview and that my name will not appear on any of the records. When results of the study are published my identity will be protected. She has also explained that she will be reviewing my medical record to obtain information regarding my medical progress.

If I have any questions about this study or my participation, I can call Miss Wilson at 978-2865 in Toronto.

Dated at Toronto this________day of _______________, 19____

________________________ ____________________

Witness Signature

University of California, San Francisco

Study Number: 932107-01

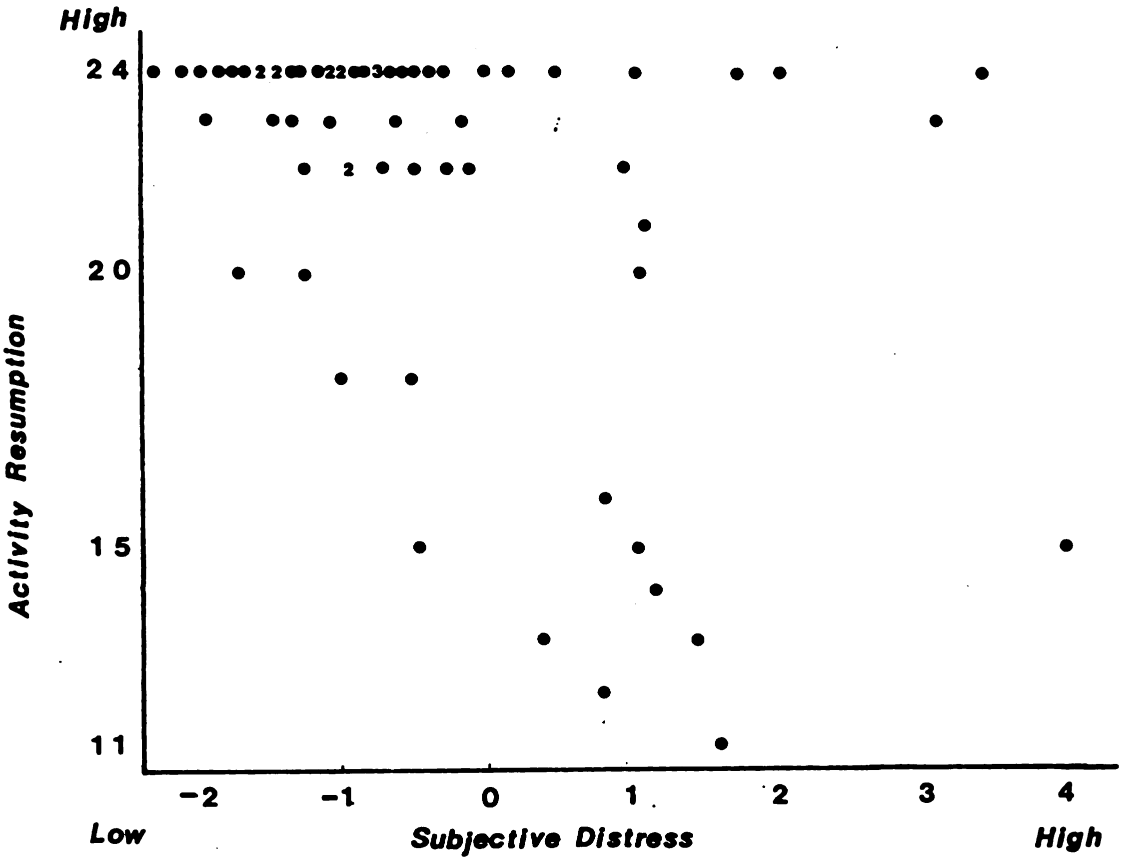

Figure 3. Scattergram of subjective distress and activity resumption at six months (n = 66)

# Appendix H

# ANALYSIS OF THE RELATIONSHIP OF PREOPERATIVE AND ONE MONTH HEALTH PERCEPTION WITH SIX MONTHS HEALTH PERCEPTION

_To what extent does the patient's preoperative health perception explain the variance in the patient's health perception at six months, after controlling for the patient's preoperative clinical status? Furthermore, does the patient's age or gender influence the relationship between preoperative and six months health perception?_

As can be seen in Table 31, the patient's preoperative health perception contributes a statistically significant ($p < .01$) portion of the explanation for the variance in six months health perception, after controlling for the patient's preoperative clinical status. Patient age and gender do not influence this relationship.

The $pr^2$ of .1764 which was calculated for preoperative health perception at Step 2, indicates that 18 per cent of the covariate adjusted six months health perception is accounted for by covariate adjusted preoperative health perception.

Table 31

ANALYSIS OF COVARIANCE WITH CURRENT HEALTH PERCEPTION AT SIX MONTHS AS DEPENDENT VARIABLE, PREOPERATIVE CURRENT HEALTH, AGE & GENDER AS INDEPENDENT VARIABLES AND PREOPERATIVE CLINICAL STATUS VARIABLES AS COVARIATES (N=52)

| Variable Set | Variable(s) | $R^2$ | df | Inc. in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1940 | 2 | .1940 | | 8.26** |
| | C.V. Symptoms pre-op[a] | | | | | |
| | General Health Status, pre-op | | | | | |
| 2. Primary I.V.[b] | Current Health Perception pre-op | .3402 | 1 | .1462 | | 12.44** |
| 3. Other I.V.'s | | .3985 | 2 | .0583 | | 2.48 |
| | Age | | 1 | | .5169 | 4.40* |
| | Gender | | 1 | | .0008 | 0.07 |
| 4. Interaction among I.V.'s | | .5064 | 4 | .1079 | | 2.29 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .4936 | 42 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .6378 | 14 | .1313 | | 0.73 |
| Error Step 5 | | .3622 | 28 | | | |

[a] C.V. symptoms = cardiovascular symptoms

[b] I.V. = independent variables

[c] CHP = current health perception

* $p < .05$ ** $p < .01$

To what extent does the patient's health perception at one month explain the variance in health perception at six months, after controlling for the patient's clinical status at one month? Furthermore, does the patient's age or gender influence the relationship between health perception at one month and health perception at six months?

As can be seen in Table 32, the patient's health perception at one month contributes a statistically significant ($p < .01$) portion of the explanation for the variance in health perception at six months, after controlling for the patient's clinical status at one month. Patient age and gender do not influence this relationship.

The $pr^2$ of .4096 computed for one month health perception at Step 2 indicates that 41 per cent of the vocariate adjusted six months health perception is accounted for by the covariate adjusted one month health perception.

## Table 32

### ANALYSIS OF COVARIANCE WITH CURRENT HEALTH PERCEPTION AT SIX MONTHS AS DEPENDENT VARIABLE, CURRENT HEALTH PERCEPTION AT ONE MONTH, AGE & GENDER AS INDEPENDENT VARIABLES AND ONE MONTH CLINICAL STATUS VARIABLES AS COVARIATES (N=50)

| Variable Set | Variable(s) | $R^2$ | df | Inc, in $R^2$ | $sr^2$ | F |
|---|---|---|---|---|---|---|
| 1. Covariates | | .1001 | 2 | .1001 | | 4.30* |
| | C.V.Symptoms & Complications[a] | | | | | |
| | General Health Status | | | | | |
| 2. Primary I. .[b] | Current Health Perception one Month | .4734 | 1 | .3733 | | 32.03** |
| 3. Other I.V.'s | | .5005 | 2 | .0270 | | 1.16 |
| | Age | | 1 | | .0269 | 2.30 |
| | Gender | | 1 | | .0025 | 0.22 |
| 4. Interaction among I.V.'s | | .5339 | 4 | .0335 | | 0.72 |
| | CHP[c]*Age | | 1 | | | |
| | CHP*Gender | | 1 | | | |
| | Age*Gender | | 1 | | | |
| | CHP*Age*Gender | | 1 | | | |
| Error Step 4 | | .4661 | 40 | | | |
| 5. Interactions: | | | | | | |
| Covariates and I.V.'s | | .5832 | 14 | .0493 | | 0.02 |
| Error Step 5 | | .4168 | 26 | | | |

[a] C.V. symptoms = cardiovascular symptoms

[b] I.V. = independent variable

[c] CHP = current health perception

* $p < .05$ ** $p < .01$