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Percutaneous Transluminal Coronary Angioplasty

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Quality of Life After
Percutaneous Transluminal Coronary Angioplasty

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Dedication

I dedicate this thesis to my husband, J. Richard Faris, for his endless patience, support, love and understanding throughout this project.

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Chapter 1: Problem Area

Introduction

Percutaneous transluminal coronary angioplasty (PTCA) is used to treat coronary artery disease; when successful it results in reduction of coronary artery stenosis and relief of symptoms (Gruentzig, 1984; Kent et al., 1984; Rosing, et al., 1984). Objective evidence of improved myocardial perfusion has been reported following PTCA, specifically, improved exercise tolerance as demonstrated with treadmill testing and Thallium-201 imagery, repeat angiography showing patent vessels in the area of previous stenoses, improvement in symptoms as seen with the Canadian Cardiovascular Society Classification for angina pectoris and continued employment (Holmes et al., 1984b). However, subjective data do not exist which describe the effects this procedure has on patients' quality of life. The focus of this study is the self-perceived quality of life of the PTCA patient prior to and after the procedure. Because anxiety and physical status may affect quality of life, they also will be examined.

Problem Statement

PTCA is an important treatment for coronary artery disease; it produces relief of angina, allows increased physical activities including returning to work. Despite the documented objective evidence to support the efficacy of PTCA in improving coronary perfusion, its effects on the patient's perceived quality of life are not known. State anxiety and physical status are affected by the anginal consequences of ischemic heart disease. Their effect on quality of life in the PTCA patient has not been examined.

Significance of the Study

Annually thousands of patients are offered and undergo PTCA as an intervention to relieve the disabling effects of angina (Kent et al., 1984). PTCA has been shown to decrease incidence of anginal episodes, improve exercise tolerance, and allow individuals to return to their previous employment (Holmes et al., 1984b). It is not known whether the patient's perception of quality of life parallels improvements in physiological status.

Human beings live their lives according to a human plan (Cohen, 1982). It is important to know if that life plan and the interrelated purposes of a person are enhanced by certain treatments. Each individual creates a personal world of reality in which he/she assigns significance to what they perceive as important qualities of life. Outcome measures of a specific treatment must be relevant and understandable to the patient, whose perspective is emotional and personal (Schipper, 1983).

To understand the patient's perception of quality of life, questions must focus on important and often sensitive aspects of day to day living. Campbell (1981) contends that subjective indicators assess the experience of life directly, and objective ones merely measure things that influence that life experience.

Researchers recently have found a relationship between anxiety and post-angioplasty complications (Shaw et al., 1986) showing that subjective psychological indicators have an important impact on the outcome for angioplasty patients. Increased tolerance in various physical activities has been related to an improved quality of life (CASS Principal Investigators, 1983; Gutmann et al., 1982; Wilson-Barnett, 1981). Forced inactivity, as the result of coronary artery disease, has been observed to produce depression (Hackett & Cassem, 1984; Roviaro, Holmes & Holmsten, 1984). Improvement in physical status is associated with improved quality of life (CASS Principal Investigators, 1983; Jenkins, Stanton, Savageau, Denlinger & Klein, 1983b; Roviar et al., 1984). Physical status must be examined when studying the subjective effects of angioplasty.

Data on quality of life of these patients will provide physicians, nurses and other health professionals with a basis to help the angioplasty patient adjust after the procedure. This information will add to the present body of knowledge, serve as a basis for patient education and guide further research. In addition, data on the subjective perception of quality of life may provide an additional index of success or failure of therapy.

Purposes of the Study

The purpose of this study is to determine the effect of PTCA on quality of life. Secondary purposes are to determine if there is a significant (1) improvement in a patient's state/trait anxiety prior to and after angioplasty, (2) improvement in physical status prior to and after angioplasty, (3) relationship between quality of life and anxiety prior to and after angioplasty, (4) relationship between quality of life and physical status prior to and after angioplasty, and (5) relationship between physical status and anxiety.

Chapter 2: Theoretical Framework & Review of Related Literature

Quality of life has been studied by many disciplines but there is not a universal definition of quality of life. Each discipline has its own operational definition which reflects the particular interest of that discipline (Gill, 1984).

Social scientists and economists describe the importance of social indicators to assess quality of life; specifically, these areas are educational achievement, demographic, occupational and employment status (Katz, Ford, Moskowitz, Jackson & Jaffe, 1963; Najman & Levine, 1981). Some of these studies define quality of life by adjusting individual health status with longevity and other factors that determine the quality of those days (Hemenway et al., 1985; Plinskin et al., 1981; Weinstein, 1981; Williams, 1985).

Researchers evaluating patients with severe chronic obstructive pulmonary disease define quality of life as it relates to neuropsychological and physical functioning (McSweeney, Grant, Heaton, Adams & Timms, 1982). The central nervous system deficits caused by chronic hypercarbia contribute to a reduced quality of life. Victims of chronic illness, whatever the cause, experience some type of disability that necessitates changes in life style.
Activities associated with a full and productive life are often compromised and the quality of life diminished (Burckhardt, 1985; Laborde & Powers, 1984).

Research evaluating the quality of life in the cardiac patient focuses on objective measures, specifically, physical status, return to work, frequency and intensity of anginal episodes, occurrence of myocardial infarction (MI), frequency of hospitalizations and the necessity of pharmacological control of anginal symptoms (Gutmann et al., 1982, CASS Principal Investigators, 1983). Resumption of activities of daily living and return to work consistently have been examined as outcome criteria for cardiac surgery or angioplasty (Guvendik, Rahan & Yacoub, 1982; Holmes et al., 1984b; Jensen, Clayton & Liddle, 1982). LaMendola and Pelligrini (1980) contend that failure to return to work can no longer be equated with an unsatisfactory quality of life. The patient's employment status may not be the result of a personal desire or ability to work but the result of the physical nature of the work or the family's desire that the patient seek retirement after surgery.

Nursing approaches the definition of quality of life by examining both functional capacity and psychological variables (Burckhardt, 1985; Ferrans & Powers, 1985; Pa[illegible]a et al., 1983; Wilson-Barnett, 1981). Nurse researchers study the quality of life of the CABG patient by examining psychosocial factors, specifically the relationship of life satisfaction and family, occupation, social and sexual life. Their research also examines objective outcome criteria such as frequency of symptoms associated with physical and recreational activity (Flynn & Frantz, 1987; Penckofer & Holm, 1984; Wilson-Barnett, 1981). Nurses in other specialties describe quality of life based on similar variables but add additional criteria specific to their populations. Investigators studied the quality of life in the heart transplant population and examined the relationship between the symptomatic response to immunosuppressive therapy and the perceived distress of that therapy (Lough, Lindsey, Shinn & Stotts, 1987, 1985). Other variables measured in the renal transplant population include improvement in self-esteem, interpersonal relationships, feelings of well-being, and vocational rehabilitation (Simmons, Klein & Simmons, 1977).

The variety of instruments to measure quality of life further contribute to the complexity of defining this concept. The Karnofsky Performance Status Scale, a widely accepted and used instrument completed by physicians, measures the functional performance of chemotherapy patients (Grieco, 1985; Karnofsky & Burchenal, 1949). The scale addresses physical functioning, but does not assess the patient's perceived quality of life.

Oncology nurses, pioneers in the field of quality of life research, stress the importance of measuring subjective variables, specifically aspirations, frustrations, attitudes and perceptions (Young & Longman, 1983). These nurses define quality of life as the degree of satisfaction with perceived present life circumstances as measured by the Quality of Life Questionnaire. Other researchers (Padilla & Grant, 1985; Padilla et al., 1983) stress the importance of combining subjective and objective measures to evaluate quality of life. The three general areas investigated are psychological well-being, physical well-being and symptom control as measured by the Quality of Life Index.

Cantril's Self-Anchoring Striving Scale (1965) provides a simple, widely applicable, and adaptable technique for assessing an individual's perceived position in life as compared to the past five years and projected to the future. This self-defined continuum is plotted on a ten rung ladder and permits a personal comparison of how the individual perceives his life now as compared to a specific point in time. The Self-Anchoring Striving Scale permits comparison of life aspirations of people between different nations.

Initially developed and then revised by Bergner, Bobbitt, Carter and Gilson (1981), the Sickness Impact Profile measures the disruption illness contributes to life activities. This well-accepted and used instrument examines the physical functioning capacity in relation to activities of daily living, psychosocial interaction and behavior, and recreational activities.

The Psychosocial Adjustment to Illness Scale, developed and tested by Derogatis (Morrow, Shiarello & Derogatis, 1978) is a self-administered questionnaire designed to measure psychosocial adjustment to a current medical illness or its residual effects. Seven primary life domains are examined: health care orientation, vocational environment, domestic environment, sexual relationships, extended family relationships, social environment and psychological distress. This instrument has been used with different illness populations including cardiac patients (Folks, Blake, Fleece, Sokol & Freeman, 1986; Raft, McKee, Popio & Haggerty, 19[illegible]).

Ferrans and Powers (1985) designed The Quality of Life Index (QLI) to measure four life domain subscales: health and functioning, socioeconomic, psychological/spiritual, and family. They studied the individual's satisfaction with those domains and the unique importance of each domain to the individual. Quality of life scores are obtained by adjusting the satisfaction scores with the importance scores. This approach corrects for individual value differences and produces a more accurate reflection of the subject's quality of life. These authors define quality of life as the satisfaction of needs.

Because the definitions and approaches to measurement vary considerably from study to study, meaningful comparisons between studies cannot be made. These discrepancies lead to inconsistencies in the interpretation.

Quality of Life After Coronary Artery Bypass Surgery

Improved quality of life following coronary artery bypass surgery (CABG) has been reported extensively in the literature (CASS Principal Investigators, 1983; Flynn & Frantz, 1987; Folks et al., 1986; Jenkins et al., 1983a; Jenkins, Stanton, Savageau, Denlinger & Klein, 1983b; Kornfeld, Heller, Frank & Malm, 1982; Ross et al., 1981; Wortman & Yeaton, 1985). This information is conceptually relevant to the quality of life in the angioplasty population because both PTCA and CABG are means of revascularizing ischemic myocardium.

The Coronary Artery Surgery Study (CASS) (The Principal Investigators, 1981) conducted a prospective, randomized study to compare the results of medical and surgical treatment in a subset of patients with documented coronary artery disease. The patients were divided into three groups according to their past history, present level of anginal symptoms and their ventricular function. All patients received one month of medical therapy and then patients from each group were randomly assigned to either a control group of continued medical therapy or to the surgically treated group. Specific outcome criteria for assessing the response to therapy were incidence of myocardial infarction, mortality and quality of life. The objective indicators used to assess quality of life were: chest pain, heart failure, activity limitation, graded exercise tests, employment status and recreational status (CASS Principal Investigators, 1983). Results indicated equally good five year survival in both subsets of patients. However, their observations indicated that the surgical group had a significantly better quality of life. These investigators did not use self-perceived indices of quality of life.

Wilson-Barnett (1981) assessed the recovery of post-operative cardiac patients. She hypothesized that intervening psychosocial factors, not clearly understood by doctors or nurses, effect the ultimate recovery of the CABG patient from surgery; and that a more global assessment of recovery is necessary. Specifically, this study examines the patient's perspective of recovery as described by psychological and physical problems during recovery, the range of time necessary for complete recovery, teaching needs, and the extent self-concept influenced recovery.

Recovery was defined by both objective and subjective indicators including the resumption of functions and whether the patients felt recovered. The majority of the patients returned to work within three to eight months after surgery, all the patients praised the care they were given and this represented a dramatic contrast to their limited and painful preoperative existences. The author concludes by suggesting that further investigations of personality traits and self-concept could potentially provide guidance for nursing care and help identify those at risk for incomplete recovery.

Penckofer & Holm (1984) studied two groups of early (less than one year postoperative) CABG patients that were alike in terms of preoperative physical activity, angina level and type of revascularization. Subjective indicators for quality of life were assessed using Cantril's (1965) Self-Anchoring Striving Scale. Compatible with the previously mentioned research, these investigators found a correlation between improved quality of life, a decrease in the level of angina and an increase in the level of physical activity.

This study was replicated by examining the quality of life of early postoperative CABG patients (six to ten weeks). However, the authors did not cite Penckofer & Holm's work (Flynn & Frantz, 1987). In addition to Cantril's Self-Anchoring Striving Scale, these researchers measured exercise tolerance by treadmill testing and social support by Current Social Network Scale. Although patients in early recovery reported numerous complications and physical symptoms, quality of life was enhanced for the majority of patients because of relief of angina.

To evaluate the benefits of CABG (Jenkins et al., 1983b), The Recovery Study assessed the following variables: biomedical, psychoneurological, physical function, role function, occupational, social, family, sexual, emotional and attitudinal behavior. Data were gathered by means of a preoperative interview and self-administered questionnaire and by review of the medical record. Self-report questionnaires included scales from psychological tests to evaluate well-being, self-esteem, hopelessness, dependency, locus of control, willingness to accept help, and other psychological constructs. The investigators examined the relationship between incidence of angina and physical activity pre- and post-surgery. The majority of these patients reported relief of physical and related psychological symptoms, restored physical and social function, return to work and an enhanced quality of life after CABG surgery. A separate report (Jenkins et al., 1983a) describes similar findings in a group of cardiac valve replacement patients.

These researches stress the importance of assessing the patients' psychological state when considering quality of life, stating: "Self-perceptions and emotions contribute more to a general sense of well-being than does the presence of physical symptoms" (Jenkins et al., 1983b, pp. 786). They suggest a certain amount of psychological reactivity may manifest itself in the post-operative period.

Compatible with this observation, Kornfeld and others (1982) traced the postoperative psychological and behavioral courses of patients after CABG. Specifically, these researchers examined quality of life, compliance with medical regimen, and the post-operative stability of the Type A, coronary-prone behavior pattern. The researchers obtained their data by psychiatric interview, questionnaires and medical follow-up. After surgery these patients reported substantial improvement in overall quality of life, improved physical functioning, reduced anxiety and depression, and improved job satisfaction and family relationships.

By reviewing these various studies together, it is possible to compare the time frame of follow-up data assessment. The CASS analysis was performed at six months, one and one-half years and five years after enrollment into the study. For convenience of illustration, only data obtained at one, three and five years after patient entry were described in the report (Principal Investigators, 1981). The patients in The Recovery Study (Jenkins et al., 1983a & 1983b) were interviewed preoperatively and 6 months postoperatively. LaMendola and Pellegrini (1979) retrospectively assessed the quality of life in their sample of CABG patients; the span of time since surgery varied between six and thirty-seven months. Penckofer and Holm (1984) separated the initial assessment of their sample into early (three to five months postoperative) and late (six to eight months). Flynn and Frantz (1987) examined the very early recovery phase of CABG patients (six and ten weeks). Another study conducted a preoperative interview, then assessed their sample by interview nine months after surgery, by questionnaire at forty-two months, and by medical follow-up at four years (Kornfeld et al., 1982).

The National Heart, Lung, and Blood Institute PTCA Registry, established in 1977, reported their follow-up on 2,272 patients at 65 centers and examined the long-term effects of PTCA (Kent et al., 1984). Most of these patients received exercise treadmills at three month intervals for the first year and a repeat angiogram at six months to assess the previous area of stenosis. Once patency was confirmed, follow-up of these patients occurred annually. More recently, physicians and their patients have elected to repeat an exercise treadmill and angiogram if clinically indicated (Willman, 1985). Nitrates, calcium channel blockage therapy and antiplatelet therapy are frequently prescribed for these patients and adjustment of medication regimens typically occurs four to six weeks post-PTCA (Myler, Gruentzig & Stertzer, 1983). Because consistent, objective follow-up data do not exist on all patients experiencing PTCA, this present study will examine patients six weeks after the procedure.

The Role of Anxiety and Physical Functioning in Cardiac Patients

The goal of therapy for most patients with coronary disease is not "cure" but improvement in function as evidenced by improved physical activities, decreased symptoms or limitation of disease progression (Wenger, Mattson, Furberg & Elinson, 1984). Evaluation of new therapies should not be limited to technical success or physiological changes but include outcome criteria that measure function in daily life, productivity and performance of social roles. These authors define quality of life in terms of three major components: functional capacity, perceptions and symptoms and their consequences.

Functional capacity is defined as the ability to carry out activities of daily living, participate in work and recreational activities and be independent. Economic security is related to work and is significantly influenced by physical functioning. Many patients fear the dependency and economic ruin associated with chronic illness; this fear is associated with a reduced quality of life (Hackett & Cassem, 1984).

In contrast to physical functioning, the patient's perceptions are personal and difficult to measure. Cohen (1982) proposed that a significant step is taken in understanding quality of life when the issue is raised how significantly illness hinders the important aspects of an individual's life. Features of human life such as the pursuit of individual pleasure are evidence that the life plan is being actualized.

Only recently have studies examined psychosocial issues as they relate to PTCA. Shaw and others (1986) examined the effect of psychosocial factors on the amount of information gained by PTCA patients and suggested certain coping styles could predict psychosocial and medical outcomes. Patients who were more anxious during hospitalization had poorer social functioning and continued mood disturbance during follow-up.

Several researchers have studied the relationship between psychological adjustment to illness and the level of physical functioning. Despite improved exercise tolerance as demonstrated on the treadmill, typically fewer patients return to work after CABG than were employed before surgery. Several theories have been generated to explain this result. LaMendola & Pellegrini (1979) indicated that post-operative improvement is a function of the patient's perceived physical limits. Other researchers suggest the prolonged period of symptoms and unemployment before surgery may damage self-image (Grundel et al., 1980) or that the reduced employment after CABG is because of a self-imposed activity restriction (Jenkins et al., 1983b).

Exercise has been demonstrated to reduce psychological stress by decreasing employment related stress, more active use and enjoyment of leisure time, and more physical and sexual activity (Brown, Ramirez and Taub, 1978; Eichner, 1983; Roviaro et al., 1984.). Other researchers have emphasized that physical conditioning is the best means of preventing depression in the coronary artery disease patient (Hackett & Cassem, 1984) by improving self-esteem, confidence in performance and subsequent improvement in quality of life. Thus the patient attributes physical performance as an active indicator of health and the recovery process.

Quality of life may be effected by anxiety; specifically, the apprehension and fear of sudden death; the inability to continue employment or perform individual roles as spouse, parent and citizen, and the fear of financial ruin (Hackett & Cassem, 1984). In addition, anxiety and depression may result from symptoms of angina and resulting physical impairment; recurrent hospitalizations for myocardial infarction or ischemia, and the amount of medication required to alleviate symptoms. These situations have been demonstrated to effect quality of life (CASS Principle Investigators, 1983). The ability to actualize life goals assumes importance as an indicator of therapeutic efficacy depending upon the extent the disease is interfering with the individual's life as well as the nature of the intervention (Fletcher, 1984).

PTCA Compared to CABG as a Treatment for Coronary Artery Disease

Coronary angioplasty offers an alternative to coronary artery bypass surgery for many patients with significant atherosclerotic narrowing in their coronary arteries. Many patients have immediate improvement in myocardial blood flow and avoid the expense, risk, and emotional and physical trauma of bypass surgery (Myler, Gruentzig, Stertzer, 1983). As a procedure, PTCA has some practical benefits over CABG. Specifically, the length of hospitalization is typically one to four days and the patient resumes work and other activities of daily living immediately because they are not disabled by a mediastinal incision. Because there are no general contraindications for the application of this technique (Gruentzig, 1984), patients considered high risk for surgery and general anesthesia may be offered PTCA as a treatment for their angina (Moct et al., 1984).

Researchers compared the relative cost of PTCA and CABG in single vessel disease cases. The mean hospital stay for the CABG patients was three times of that of PTCA group and the base charges for hospital and professional components of surgery were three times that of angioplasty. These investigators concluded that PTCA in single vessel coronary artery disease is significantly more cost-effective than CABG (Jang et al., 1984). Because the length of hospitalization and the financial burden accompanying the treatment choice are of considerable concern to the patient, PTCA may effect state anxiety and quality of life.

PTCA was initially developed to treat patients with single vessel, high grade stenosis in the proximal portion of the coronary artery, who are candidates for CABG and have failed medical management. However, left main coronary disease has not been included and these people would probably be better treated with CABG (Myler et al., 1983). Angioplasty is currently applied to successfully treat multivessel disease cases (Dorros, Stertzer, Cowley & Myler, 1984), total occlusion following streptokinase and acute myocardial infarction (Gold et al., 1984; Hartzler, Rutherford & McConahay, 1984; Meyer et al., 1982), tandem stenosis in the same vessel and stenosis in bypass grafts (Ford et al., 1980; Keruakes, George, Stertzer & Myler, 1985).

Review of the CASS registry population undergoing CABG revealed that preoperatively 2.8% of those having initial CABG and 7.1% of those having repeat CABG were candidates for PTCA (Foster et al., 1984). Another report compared the National Heart Lung and Blood Institute PTCA and CASS registries for the role of PTCA in the treatment of unstable angina (Faxon et al., 1984). Although both procedures dramatically reduced symptoms of angina, PTCA is associated with low mortality and morbidity in patients with unstable angina and could be considered an alternative to CABG in these patients.

Raft and others (1985) studied life adaptation after PTCA and CABG. Thirty-two PTCA patients completed the Psychological Adjustment to Illness Scale (PAIS) before the procedure, six months after the procedure and one year after the procedure. Fifteen CABG patients were matched to the PTCA patients in age, sex, work status, duration of symptoms, number of vessels stenosed and comparable pre-operative cardiac function. Six months after the procedure, PTCA patients reported significantly better life adaptation scores in all seven subscales analyzed ($F(1,24)=4.6$, $p=<0.04$). One year after the procedure the PTCA group was still functioning better ($F(1,45)=4.3$, $p=<0.05$), although the difference between the two groups was diminishing; sexual and family life differences had disappeared. However, the PTCA group reported fewer psychiatric symptoms at this time (F=4.5, p<0.05). The authors concluded from these data that patients who undergo PTCA suffer less disability after the procedure than those who undergo CABG.

In another study researchers described the differences in similar samples of PTCA and CABG patients. They stated that PTCA patients had a shorter duration of angina, fewer number of prior myocardial infarctions and were found to have better left ventricular function (Jones, Murphy and Craver, 1984). When these authors compared these findings with 2068 patients, their entire surgical experience, with 777 PTCA patients they found the CABG patients were significantly older, had a higher incidence of hypertension, more multivessel disease and more left ventricular dysfunction.

Although both sets of patients suffer from the effects of angina, it appears that selection criteria are different for CABG and PTCA patients. Some patients with severe angina pectoris and single vessel disease, PTCA is the preferred method of therapy; in some groups of patients with multiple vessel disease, there is an overlap in appropriate therapy; and in some patients the best therapy is CABG.

Employment status was analyzed in a large group of angioplasty patients (Jang et al., 1984). Prior to intervention, 68.3% of all patients were employed full- or part-time. These patients were divided into three groups: patients who had successful PTCA; patients who had unsuccessful PTCA and were treated surgically; and patients who had unsuccessful PTCA and were treated medically. At a mean follow-up of 1.5 years, there was a small decrease in employment in the all groups; but, the successfully treated PTCA patients returned to work significantly sooner than either the surgically treated group or the medically treated group. Because economic security is related to work and returning to work is related to physical functioning, anxiety, a patient's physical status and quality of life may be significantly affected by PTCA.

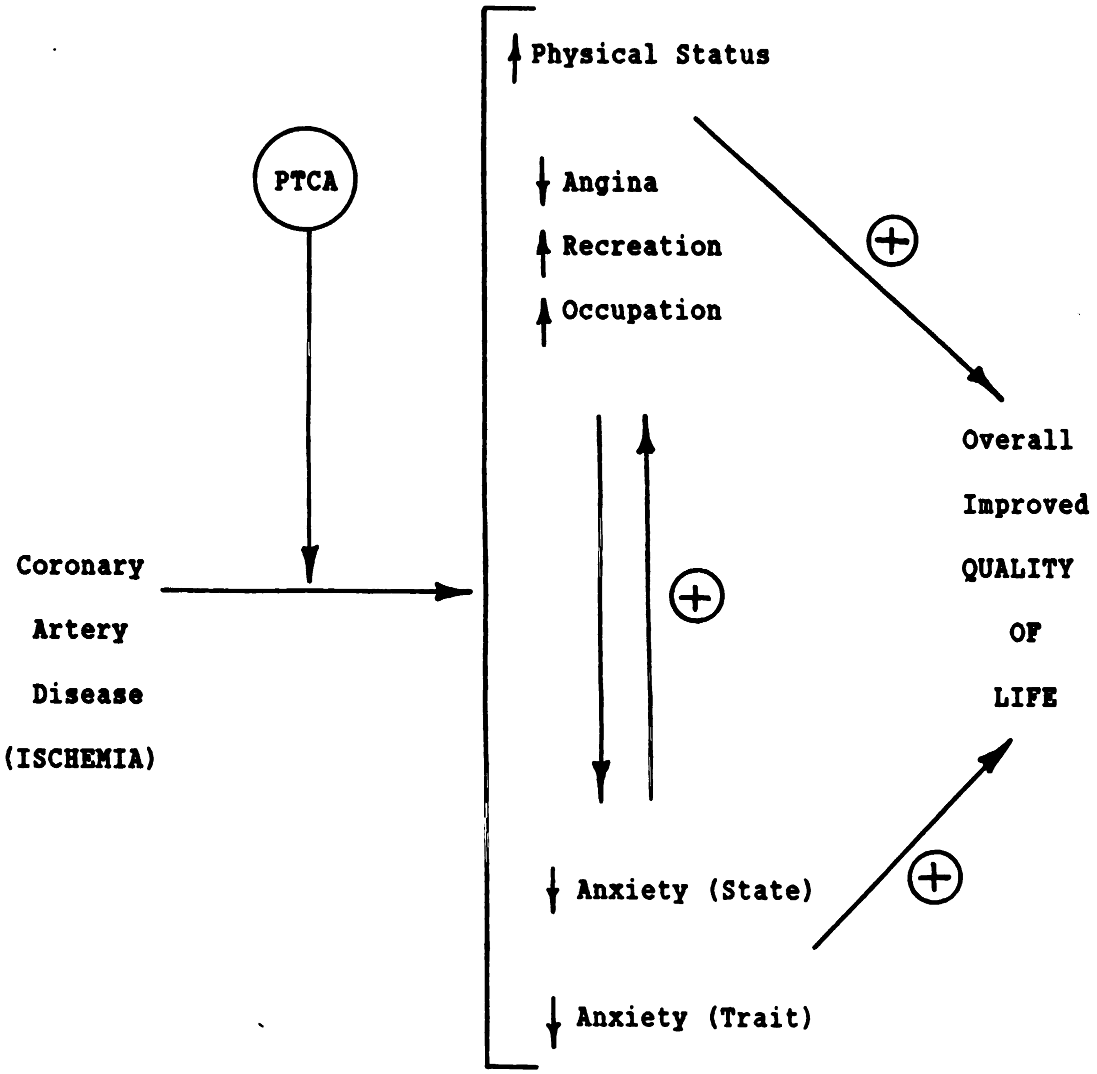
Conceptual Framework

The revascularization of ischemic myocardium and subsequent relief of symptoms that occurs after CABG and PTCA serve as the conceptual framework for this study. Studies documenting improved exercise tolerance (Rosing et al., 1984) after PTCA correlate with the improved functional status observed in the surgery groups. After angioplasty patients report a decrease in episodes of angina; subsequently they are classified with a lower Canadian Cardiovascular Society anginal classification (Kent et al., 1984). Decreased anxiety has been examined after angioplasty and bypass surgery (Jenkins et al., 1983b; Raft et al., 1985; Shaw et al., 1986).

Quality of life has not been examined following PTCA. The patient's self-perceived quality of life and the relationship between physical status, anxiety and quality of life are studied. The conceptual model illustrates how these variables contribute to the individual's perceived quality of life after PTCA. (Figure 1.)

Proposed Conceptual Model for the Relationship Between PTCA and Quality of Life

(Figure 1)



Theoretical and Operational Definition of Terms

Quality of Life is defined by Wenger and others (1984) as: "..a wide range of capabilities, limitations, symptoms and psychosocial characteristics that describe an individual's ability to function and derive satisfaction from a variety of roles" (p. 908). The individual's perception of items of importance in their lives and how satisfied they are with the condition of those items is what makes the items both important and satisfying to them and is measured by the Quality of Life Index (QLI).

Percutaneous Transluminal Coronary Angioplasty is a non-operative technique to compress atheromatous plaque against the wall of the coronary artery and restore adequate blood flow to the ischemic myocardium. The procedure is considered technically successful when there is at least a thirty-five percent decrease of the initial percent diameter of the stenosis angiographically and post-PTCA there is a less than, or equal to, 15mm Hg gradient, with no complications necessitating a coronary surgical procedure or resulting in a myocardial infarction. The procedure is considered clinically successful when there is a technical success in at least one major vessel attempted and there is a decrease in one anginal class as measured by the Canadian Cardiovascular Society Classification, and with no complications necessitating a coronary surgery procedure or resulting in myocardial infarction (Myler et al., in press).

Complex Angioplasty is a procedure that involves multiple lesions, totally occluded vessels, lesions at the bifurcation of vessels or patients who require thrombolysis in conjunction with their PTCA (Myler, 1984).

State Anxiety is an unpleasant emotional reaction to specific stress as measured by the State-Trait Anxiety Inventory (Spielberger, Gorsuch & Lushene, 1983).

Trait Anxiety is an individual's tendency to be anxious as measured by the State-Trait Anxiety Inventory (Spielberger et al., 1983).

Improved Physical Status is the perceived increased exercise capacity as measured by Physical Functioning Questionnaire (Shabetai, 1983) and reflects reduced frequency of anginal episodes, increased social and recreational activities and return to work. In addition, physical status is measured by Canadian Cardiovascular Anginal Classification criteria, used to determine the technical and clinical success of PTCA.

Pre-angioplasty Period is the time period from the day the patient is scheduled for PTCA by the physicians' office to the day of admission to the hospital.

Post-angioplasty Period is defined at the date six weeks immediately after the angioplasty procedure.

Hypothesis

This study is designed to test the following hypotheses as applied to the PTCA patient:

(1) Following PTCA there will be a significant improvement in the overall quality of life when compared with quality of life prior to the intervention.

(2) Following PTCA there will be a significant decrease in the patient's state anxiety when compared to state anxiety before the procedure.

(3) Following PTCA there will be a significant increase in the patient's physical status when compared to physical status before the procedure.

(4) Following PTCA there will be a positive relationship between physical status and quality of life.

(5) Following PTCA there will be an inverse relationship between state anxiety and improved quality of life.

(6) Following PTCA there will be an inverse relationship between state anxiety and improved physical functioning.

(7) Following PTCA there will be an inverse relationship between trait anxiety and quality of life.

Chapter 3: Methods

Research Design

A pre- post-test pre-experimental design was used to measure the self-reported quality of life of patients, with the patients serving as their own controls. Because angioplasty patients are geographically dispersed data were collected using a questionnaire distributed and returned by mail within two weeks preceding the scheduled procedure and six weeks following the procedure. Demographic data were obtained from the patient's medical record.

Consecutive subjects were assigned to the study as they appeared on the angioplasty schedule beginning at the start of data collection period.

Sample

The sample for this study was composed of twenty individuals who were scheduled for elective PTCA under the direction of the following physicians: Richard K. Myler, M. D., Simon H. Stertzer, M. D., and David A. Clark, M. D. This purposeful sample of convenience consisted of literate, English speaking adult patients, without previous history of PTCA or CABG. Permission was obtained for patient participation from the attending physicians (Appendix A).

The Research Setting

Seton Medical Center is a fully accredited, 350-bed not-for-profit medical center, augmented by numerous campus and satellite medical offices and by its 113-bed sister facility, St. Catherine Hospital on Half Moon Bay. Within these half million square feet of facilities, Seton Medical Center offers a full range of primary, general acute and tertiary services. The staff consists of 500 physicians with a broad diversification of specialties, and more than 1500 employees. A variety of continuing education and training programs for physicians and hospital personnel reflect the Center's commitment to keeping abreast of medical advancements. The San Francisco Heart Institute and the Western Hansen's Disease Institute are two important research facilities located at the Medical Center. The locus of the Heart Institute and the participating staff contribute to the reputation of Seton Medical Center as an international referral institution for angioplasty.

Patients are for consideration as possible candidates for PTCA are geographically dispersed throughout the world. Angiographic films are reviewed by Drs. Myler, Stertzer and Clark and once the patient is verified as an acceptable candidate for the procedure, arrangements are made through their office located within The San Francisco Heart Institute.

The patients included in this study were admitted to an adult medical-surgical nursing unit composed primarily of semi-private patient care rooms and predominantly staffed by registered nurses. Primary nursing care is practiced with 3:1 patient/nursing ratio in the transitional care unit and 4-5:1 on the acute care medical units.

Instruments

Permission was obtained from the authors Ferrans and Powers (Appendix B) to use the Quality of Life Index Index (QLI). Consulting Psychologists Press gave permission to use the State-Trait Anxiety Inventory after verification that a psychologist is supervising the study. Permission was obtained by Dr. Shabetai (Appendix B) to use the Physical Functioning Questionnaire/San Diego Questionnaire to assess physical status prior to and after angioplasty.

Quality of Life Index: Ferrans and Powers (1985) developed the QLI to measure objective and subjective aspects of quality of life. Part one of the instrument, Domain Satisfaction, pertains to the different ways people view their lives. Subjects respond to each question on a six-point Likert-Type scale, rating their answer from "very satisfied" to "very dissatisfied". Part two, Domain Importance, refers to the different values people place on these aspects of their lives. Subjects grade importance using a six-point Likert-Type scale from "very important" to "very unimportant" (Appendix C).

Both the satisfaction and importance sections have 32 items that access the following areas: health care, physical health and functioning, marriage, family, friends, stress, standard of living, occupation, education, leisure, future retirement, peace of mind, personal faith, life goals, personal appearance, self-acceptance, general happiness and general satisfaction. By adjusting the satisfaction scores with the importance scores, an overall quality of life score is obtained. This adjusted quality of life score reflects not only satisfaction with an individual's domain but how much that person values that domain. The authors contend that by adjusting satisfaction responses based on importance responses the QLI corrects for individual values and produces a more accurate reflection of the subject's quality of life. The authors state: "The rationale behind this adjustment is that persons who are highly satisfied with important areas of life enjoy a better quality of life that those who are very dissatisfied with important areas of life" (Ferrans & Powers, 1985, p. 18). However, if a patient is greatly dissatisfied with an important area in his or her life, the negative impact of this situation imposes greater significance as compared to being greatly satisfied with an unimportant area of their life.

The instrument was tested for reliability and validity with a sample of graduate students (n=88) and later with a convenience sample of dialysis patients (n=37). Criterion related validity was established by comparing the overall satisfaction with life question as measured by Campbell, Converse and Rogers (1976). Although the authors reported an acceptable correlation of 0.61, they acknowledged some instability in the instrument. After they adjusted the upper parameter for the correlations from 1.0 to the square root of the product of the reliabilities of the instrument and criterion, they compared this adjusted value with the scores of the two groups. A correlation of 0.75 for the graduate students and 0.65 for the dialysis patients supports the validity of the QLI.

Test-retest reliability of the QLI was supported in both groups with correlations of 0.87 with the graduate students and 0.81 with the dialysis patients. The instrument demonstrated a Cronbach alpha of 0.93 for the graduate students and 0.90 for the dialysis patients. Studies evaluating construct validity are currently in process and not available for comparison.

<u>State-Trait Anxiety Inventory:</u> One of the most widely used instruments to measure anxiety is the State-Trait Anxiety Inventory (STAI) developed by Spielberger and Gorsuch in 1966. This instrument yields a measure of both state and trait anxiety and has been utilized in previous angioplasty research (Shaw et al., 1986).

Reliability studies using the STAI have been reported using college and high school students (Spielberger, Gorsuch, Lushene, Vagg & Jacobs, 1983). Test-retest reliability correlations for STAI ranged from 0.73 to 0.86 in the college students and 0.65 to 0.75 in the high school population. The researchers hypothesized the low score could be explained by the influence of situational factors present over the three month span of time. The alpha coefficient was high for both state (0.93) and trait (0.90) anxiety indicating internal consistency. Concurrent, convergent, divergent and construct validity of both STAI scales were established in studies comparing the STAI to the Minnesota Multipurpose Inventory (MMPI), Cornell test for anxiety and The Profile of Mood States (Spielberger et al., 1983). The STAI is included as Appendix D.

The Physical Functioning Questionnaire: This questionnaire was developed by Ralph Shabetai, M. D. and used to assess quality of life of cardiomyopathy patients. The questions contained in this instrument were based on Dr. Shabetai's years of experience with these patients. The Physical Functioning questionnaire was adapted from the original instrument by substituting "angina, chest pain or chest discomfort" for questions that specifically ask "shortness of breath". Information assessing reliability and validity of this instrument is not currently available. Data collected were used to assess physical status as related to activities associated with angina and frequency of symptoms; the characteristics of normal daily activities and if the activity was limited, the possible perceived cause; the level of perceived physical status; and occupational and recreational status (Appendix E).

Anginal symptoms are classified according to their severity as defined by the Canadian Cardiovascular Society (Campeau, 1976). These classifications are listed in Appendix E.

Demographic Data and Medical History: Demographic data including age, sex, gender, marital and employment status, and ethnic background were obtained from the patient's medical record. In addition, information concerning duration of symptoms, predominent symptom, history of heart attack and number of arteries involved were gathered.

Pilot Study

A pilot study of five patients was conducted to assess the comprehension of the self-administered questionnaires and for unanticipated problems with methodology. All pilot study subjects were recovering in the hospital after PTCA and were not included in the main study.

Complex angioplasty was performed on three of these patients. They were monitored for twenty-four hours in the intensive care/coronary care (ICU/CCU) unit, with arterial and venous sheaths still in place, and on heparin or nitroglycerine intravenous infusions. None of these patients suffered an acute MI or required emergency CABG. The pilot study participants response was very positive, all of the questionnaires were completed and respondents stated that the instructions were clear.

Administrative scheduling difficulties necessitated shortening the period of time from when the study packet was mailed and patients were admitted to the hospital. Patients were allowed two weeks before coming to the hospital to complete the questionnaires or refuse to participate. Although a small number of patients were scheduled more than a week in advance, a large proportion of potential subjects were not contacted because of the two-week minimum time frame.

The revised proposal stated patients would be contacted one week in advance and opportunities for declining to participate were provided. All changes in methodology were submitted and approved by the Committee on Human Research from the University of California, San Francisco and Seton Medical Center.

Procedure

An introductory letter identifying the researcher (Appendix G) and a self-administered questionnaire consisting of the three instruments were mailed to all potential subjects who met the sampling criteria. A description of the purpose of the study included a statement assuring anonymity and that voluntary participation in the study was not related to patient care. A signed consent form (Appendix H) was obtained and returned with the completed questionnaires in a stamped, addressed envelop provided. Privacy was assured by assigning code numbers rather than names, and by locking the response forms in the investigator's home.

If the questionnaire was not received by the investigator prior to the patient's admission, and time permited, the investigator telephoned the patient, answered any questions the patient had about the study and ask him to bring the completed questionnaire with them to the hospital. To control for bias, any patient who had not completed the questionnaires prior to admission was dropped from the study. Study results, especially the state anxiety, could be skewed because of the timing of collection or the hospital environment.

A letter was sent to each referring physician notifying him/her that their patient had been invited to participate in this study (Appendix I). Baseline medical characteristics and demographic data were obtained from the patient's medical record the evening after the procedure. Each patient was greeted informally by the investigator prior to discharge to answer any questions about the study and to aid in securing compliance with follow-up data collection.

Questionnaires assessing post-PTCA quality of life, physical status and state-trait anxiety were mailed six weeks after successful completion of the procedure. Two weeks after this mailing, a follow-up reminder was mailed to each participant whose questionnaire had not been received (Appendix J). All of the subjects who complete the study received a letter from the researcher thanking them for their participation and offering to send them a study summary when available.

Data analysis

Descriptive statistics were used to analyze the demographic data and correlation statistics were used to test the hypothesis. Ordinal/interval data were collected; for statistical purposes the data were converted to interval to analyze mean scores. The Pearson Product Moment Correlation was used to analyze the relationship between the variables with a significance pre-set at ≤ 0.05.

Chapter 4: Results

Introduction

In this study self-perceived quality of life, physical functioning and state-trait anxiety were examined. Because the Canadian Cardiovascular Society Angina Classification is a determinant of the clinical success of PTCA, this information also was examined. A study packet containing the three questionnaires was distributed by mail to 70 patients scheduled for PTCA between October 1986 and June 1987. Thirty-four patients met the study criteria, received the study materials pre-admission, had a successful procedure, and were entered into the study for follow-up. Table 1 is a summary of the subjects contacted to participate in the study.

Table 1: Summary of subjects contacted:

Complete pre- post-test data available and analyzed	20
Post-PTCA data pending	14*
Pre-PTCA data returned; unable to complete study because did not meet study criteria	14
Declined to participate	14
Did not receive study packet pre-admission	6
Did not speak or read English	2
Total Subjects approached to participate in study	70

* Data not to be included in thesis due to time constraints.

Fourteen patients returned completed questionnaires pre-PTCA, however, they were told they would not be contacted further because they did not meet study criteria. Data from these patients will be presented after the results from the study group have been reported.

Demographic Data

A sample of twenty patients was studied, 17 males and 3 females; the mean age was 60 years, range between 39 and 76. The majority of the patients were caucasian, married and employed.

The medical history revealed the following information. Chest pain was the predominant complaint in thirteen patients; sixteen patients had complained of symptoms less than three months. Two patients were asymptomatic, seven had Class II angina, seven had Class III angina, and four had Class IV angina. Eight of these twenty patients had a previous history of MI, five within the last six months.

Seven patients had single vessel disease (35%). The majority of the patients had multivessel disease; thirteen had double vessel disease, four had three vessels treated, and three patients had four or more arteries dilated.

Thirteen patients had complex angioplasty and were observed in the ICU/CCU after the procedure. Six had total occlusions attempted and dilated; fourteen had tandem lesions; six had bifurcation lesions requiring more than one access site; and eight patients had a staged procedure. All of these patients were considered clinically stable pre- and post-PTCA. However, one patient had abrupt re-closure less than twenty-four hours after the initially successful procedure, received streptokinase in the catheterization laboratory and was successfully redilated. Although no "Q" waves were appreciated on serial electrocardiograms, an acute MI was suspected to have occurred and this patient's data was analyzed separately. Demographic data and medical history profiles are listed below in Table 2.

Study Hypothesis: Quality of Life

It was hypothesized that following PTCA there would be a significant improvement in the individual's perceived quality of life as measured by the Quality of Life Index. There was an improvement in mean

Table 2: Demographic data and medical history

Demographic Data

Age
Range: 39-76
(mean age, 60)

Marital	
Married	16
Divorced	2
Widowed	1
Separated	1

Sex	
male	17
female	3

Race	
Caucasian	17
Other	3

Employment	
Employed	15
Retired	5

Medical History

Canadian Cardiovascular Society Angina Classification	
Asymptomatic	2
II	7
III	7
IV	4

Predominant Symptom	
Asymptomatic	2
Chest pain	13
Dyspnea	3
Other	2

Symptom Duration	
Asymptomatic	2
> one year	2
6-12 months	1
1-3 months	7
< one month	8

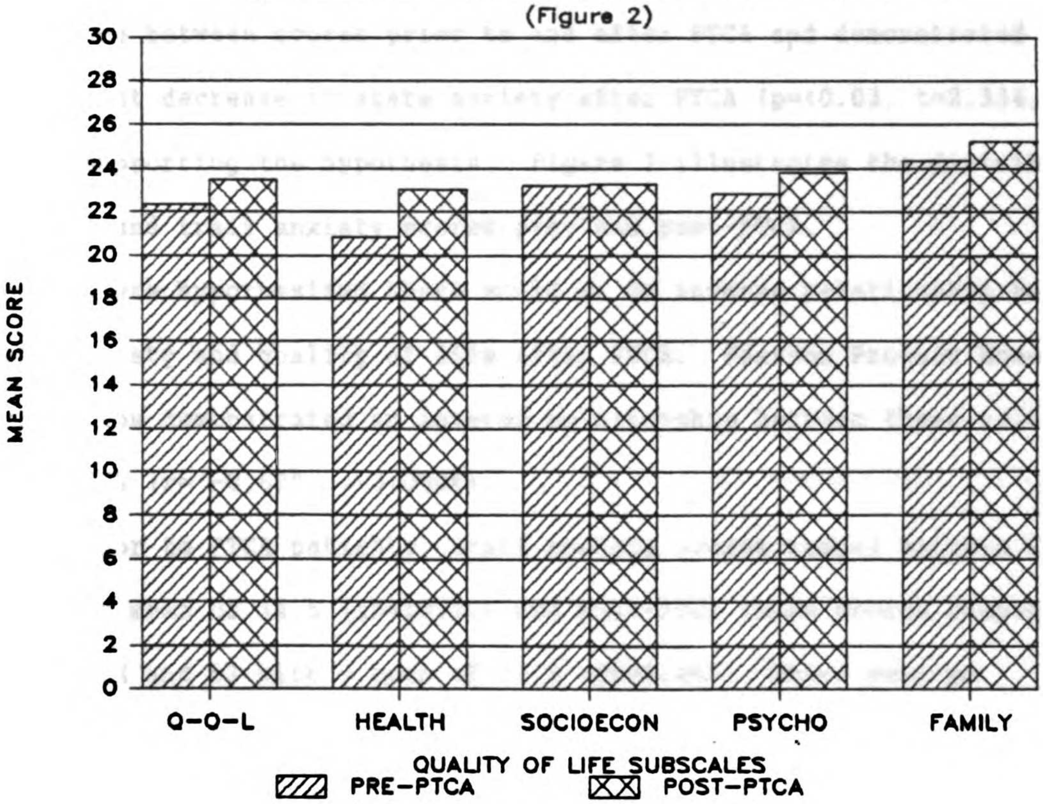
Infarction (8 patients)	
1971-1984	3
*1986	2
*1987	3

*Recent history of MI in prior six weeks quality of life scores (22.35 before PTCA, SD= 4.036; 23.48 after .092). However, there was no significant change in quality of life when prior to and after PTCA measures were compared (p=0.113, t=1.658, df=19). Data do not support the hypothesis that there will perceived improvement in quality of life after PTCA.

Four subscales were studied: health and functioning, occupational/socioeconomic and community, family and sexual functioning, and psychosocial/spiritual. Adjusted scores were obtained by comparing thirty-three satisfaction responses of certain life domains with thirty-three importance responses. Subjects were asked to rate their responses on a scale of 1 (very dissatisfied or very unimportant) to 6 (very satisfied or very important). Figure 2 illustrates the distribution of total scores pre- and post-PTCA for each of these subscales.

QUALITY OF LIFE AFTER PTCA

(Figure 2)



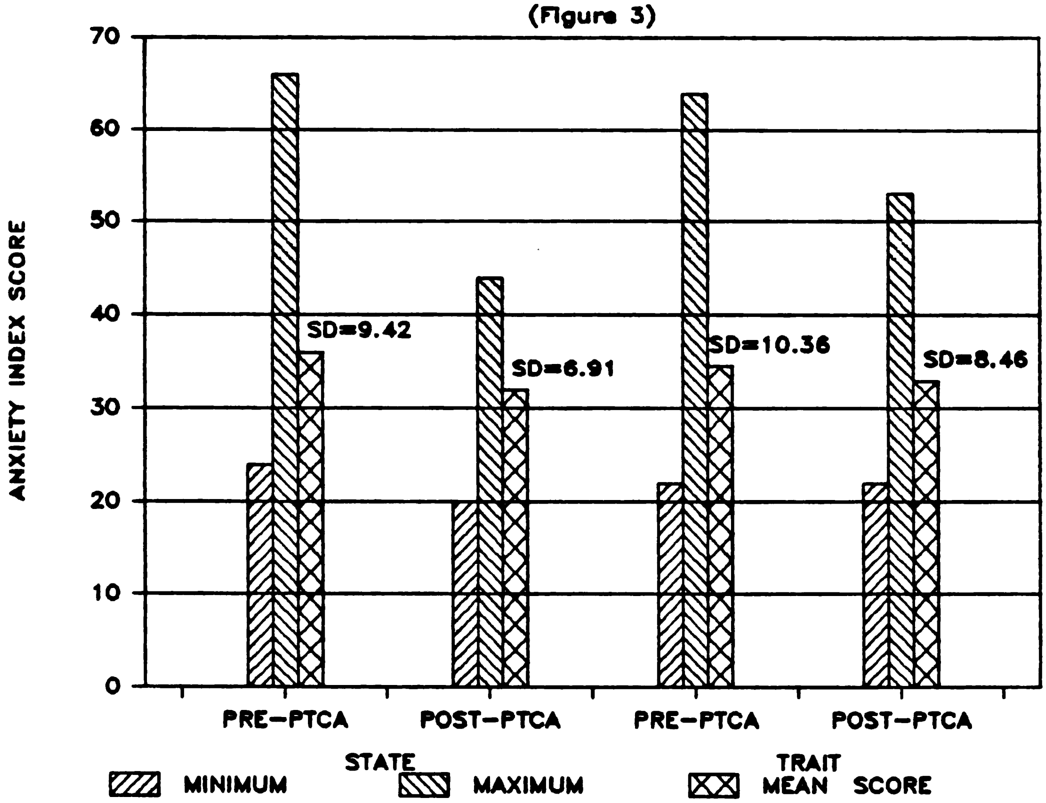
Significant correlations were present between quality of life and each of the subscales: health and physical functioning (r=0.852, p=0.0001), socioeconomic (r=0.902, p=0.0001), psychological/spiritual (r=0.864, p=0.0001) and family relationships (r=0.771, p=0.0001). In addition, paired t-tests demonstrated a significant improvement in the subscale health and functioning (p=<0.0434, t=2.164, df=18). The other subscales did not reach significance between the two measurements (socioeconomic p=0.886, t=1.145, df=19); psychological/spiritual (p=0.239, t=1.21, df=19); family (p=0.365, t=0.930, df=18).

Study Hypothesis: State-Trait Anxiety

It was hypothesized that there would be a significant decrease in the patient's state anxiety after PTCA. Prior to PTCA patients' state anxiety scores ranged between 24 and 62 with a mean of 36.6 (SD=9.42) and post-PTCA these scores ranged between 20 and 44 with a mean of 31.9 (SD=6.91). A paired t-test was performed to determine if there was a difference between scores prior to and after PTCA and demonstrated a significant decrease in state anxiety after PTCA (p=<0.03, t=2.334, df=19) supporting the hypothesis. Figure 3 illustrates the distribution of state and trait anxiety scores pre- and post-PTCA.

It was hypothesized there would be an inverse relationship between state anxiety and quality of life after PTCA. Pearson Product Moment Correlation demonstrated an inverse relationship between these values after PTCA (r= -0.688, p=0.0008).

Prior to PTCA patients' trait anxiety scores ranged between 22 and 64 with a mean of 34.5 (SD=10.36) and post-PTCA these scores ranged between 22 and 53 with a mean of 32.9 (SD=8.46). There were no significant differences in trait anxiety scores prior to and after PTCA (p=0.367, t= -0.923, df=19). It was hypothesized there would be a



STATE-TRAIT ANXIETY AFTER PTCA
(Figure 3)

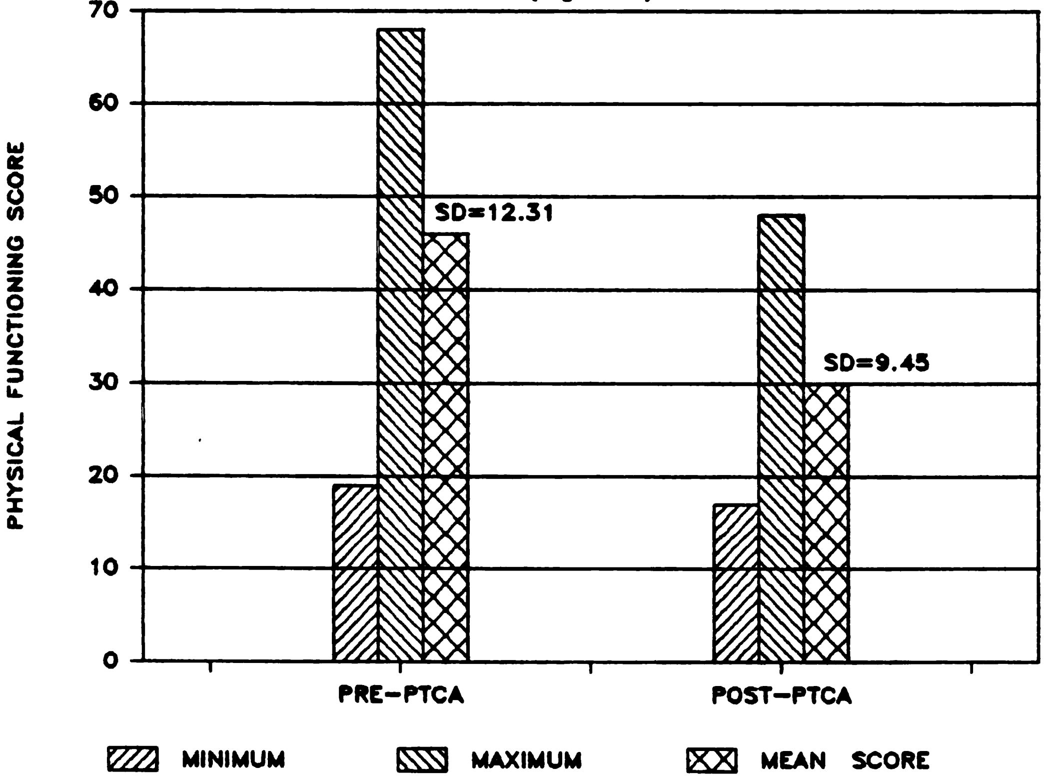
inverse relationship between trait anxiety and quality of life after PTCA. Student t-test was performed and demonstrated a significant relationship between trait anxiety and quality of life (r= -0.685, p=0.001) after PTCA supporting the hypothesis. However, no significant change was observed in quality of life and trait anxiety between time 1 measurement and time 2 measurement.

Study Hypothesis: Physical Functioning

It was hypothesized there would be a significant increase in the patients' physical status after PTCA when compared to before the procedure. Total scores measuring perceived physical functioning before angioplasty ranged between 19 and 68 with a mean of 46.5 (SD= 12.31). Post-PTCA these scores ranged between 17 and 48 with a mean 29.9 (SD=9.45). A paired t-test indicated a significant increase in physical functioning after PTCA (p=<0.0000, t=5.50, df=19) supporting the hypothesis. Figure 4 illustrates the distribution of physical functioning scores prior to and after angioplasty.

PHYSICAL FUNCTIONING AFTER PTCA

(Figure 4)



A Canadian Cardiovascular Society Angina Classification was determined for each patient from the individual's responses on the Physical Functioning Questionnaire. Fourteen patients experiencing Class II-IV before PTCA were asymptomatic after the procedure. Two patients stated they did not have any angina symptoms before PTCA remained asymptomatic after the procedure. Five patients continued to have Class I: two of these patients were listed as Class III-IV before angioplasty (Table 3).

Table 3: Canadian Cardiovascular Society Angina Classification

ID#	Pre-PTCA	Post-PTCA
3	III	Asymptomatic
4	III	Asymptomatic
6	II	II
9	II	III
17	IV	Asymptomatic
18	III	Asymptomatic
19	II	Asymptomatic
20	IV	II
24	Asymptomatic	Asymptomatic
25	II	I
28	Asymptomatic	Asymptomatic
33	IV	Asymptomatic
38	III	II
40	III	Asymptomatic
45	II	Asymptomatic
49	II	Asymptomatic
50	III	Asymptomatic
51	II	I
52	III	Asymptomatic
58	IV	I

A separate analysis demonstrates differences between the eight patients (group 1) that still reported symptoms of angina and those who were asymptomatic (group 2, n=12). Independent groups t-tests were conducted for these two groups and for the following variables: Total Quality of Life, pre- and post-PTCA; the four subscales of the Quality of Life Index, pre- and post-PTCA; state-trait anxiety pre- and post-PTCA; and physical functioning scores, pre- and post-PTCA. Asymptomatic patients demonstrated a significant improvement in physical functioning compared to Group I (p=<0.001, t=4.72, df=10.09) after PTCA. No significant difference was demonstrated between these groups of patients and the other variables (Table 4).

Table 4: Independent groups t-tests, comparing symptomatic and asymptomatic patients with quality of life variables.

Variable	t	df	p
Pre-PTCA			
Total Quality of Life	1.15	17.73	0.267
Health/Functioning	1.20	17.99	0.245
Socioeconomic	0.81	16.30	0.430
Psychological	1.15	17.49	0.266
Family	0.43	17.75	0.671
State Anxiety	0.70	18.00	0.500
Trait Anxiety	0.32	18.00	0.754*
Physical Functioning	0.58	18.00	0.567*
Post-PTCA			
Total Quality of Life	-0.63	18.00	0.536*
Health/Functioning	-1.69	16.17	0.110
Socioeconomic	-0.12	17.39	0.901
Psychological	0.16	17.49	0.873
Family	0.27	16.67	0.789
State Anxiety	0.71	17.87	0.490
Trait Anxiety	-0.05	17.51	0.963
Physical Functioning	5.25	18.00	0.0001*

* F test of equal variances rejected at alpha of 0.05; pooled variances reported.

It was hypothesized there would be a positive relationship between physical status and quality of life after PTCA. On the Physical Functioning Questionnaire a lower score indicates better functioning and a higher score indicates poorer functioning. Also the QLI score increases with improved quality of life. Although a negative correlation was seen between physical functioning and quality of life after angioplasty ($r= -0.209$, $p=0.376$) this relationship did not reach significance and the hypothesis was not supported.

In addition, it was hypothesized there would be an inverse relationship between state anxiety and physical functioning after angioplasty. Statistical analysis demonstrated no significant relationship ($p=<0.393$, $r=0.203$) between these two variables.

Comparison of patients not completing the study and the study group

Fourteen patients completed and returned the first study questionnaires; ten patients were male and four female. These patients ultimately did not meet study criteria and were not contacted further. Data from these patients were compared with the pre-PTCA data obtained from the study group ($n=20$). The groups were similar for age, number of vessels occluded, symptom duration, predominant symptoms and angina classification. However, twenty-nine percent were women in this group; only fifteen percent of the study group were women. Although paired differences t-test indicated no significant differences between the two groups perceived quality of life and anxiety, these fourteen patients reported significantly better physical functioning before their anticipated PTCA ($p=<0.02$, $t=-2.510$, df 19) than the study group.

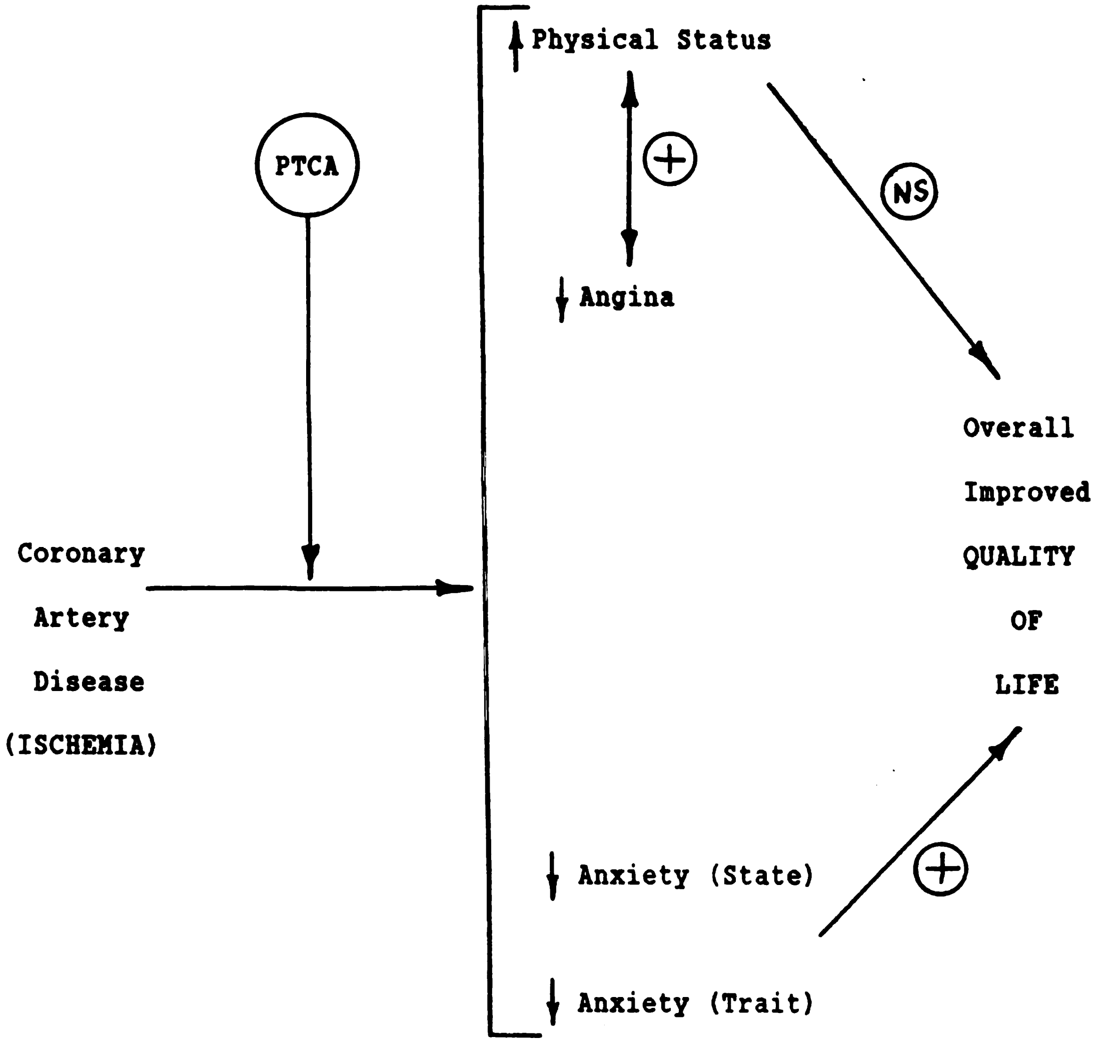
Five of these patients had previous CABG and this difference may have reflected an effective life style adaptation or effective coping. Shaw and others (1986) describe effective copers as those who "..react to situations in a balanced way, able to use the information they have to cope effectively with the circumstances presented by the situation" (p. 593).

The remaining nine patients in this group were not included in the study for the following reasons: Three patients had unattempted or unsuccessful angioplasty; one patient restenosed three weeks after successful PTCA and had elective CABG, two had emergency CABG, two declined to participate in follow-up and one early death occurred. There were no late deaths in either group.

A revised conceptual model was made to illustrate the relationship between PTCA and quality of life. This model is presented in Figure 5.

Conceptual Model for the Relationship Between PTCA and Quality of Life

(Figure 5)



Chapter 5: Discussion

Introduction

These results indicated that the majority of PTCA patients report a high level of life satisfaction with most aspects of their life domain, an improved level of physical functioning, and diminished state anxiety. The results from this study do not correlate with the improvements in quality of life experienced by CABG patients (CASS Principal Investigators, 1983; Flynn & Frantz, 1987; Folks et al., 1986; Jenkins et al., 1983a; Ross et al., 1981; Westaby et al., 1979; Wilson-Barnett, 1981). In addition, a significant relationship was not demonstrated in this study between quality of life or anxiety and physical functioning. However, these data and data from previous quality of life studies in the CABG population have consistently shown improved physical and psychological functioning and reduced symptoms.

To date the majority of studies have focused on objective indicators of improved functioning after PTCA and have paid little attention to the effect this procedure has on the subjective indicators of quality of life. Although relief of symptoms after PTCA were associated with improved physical functioning, thirty percent of the patients continued to experience angina with excessive exertion. However, activity restriction did not effect the overall quality of life scores.

Early restenosis occurs within six months in twenty to thirty percent of PTCA patients (Holmes et al., 1984a). One patient was unable to complete the study because he restenosed three weeks after successful PTCA and had elective CABG. Another patient completed the study but his physician told the author he had elective bypass surgery three months later for recurrent stenosis. It is unknown how many of the patients from this study may ultimately have restenoses and how these events will effect their quality of life.

Quality of Life

Although overall quality of life scores and subscales scores improved after PTCA, a statistically significant difference was only observed in the health and functioning subscale. Significant improvements were observed between quality of life and state anxiety after PTCA and between physical functioning and quality of life.

Raft and others (1985) compared life adaptation data prior to and six months (time 1) and one year (time 2) after CABG (n=15) and PTCA (n=32). Time 1 measurement indicated that the PTCA group functioned significantly better at work, at home and psychologically when compared to the CABG group (F (1,45)=4.6, p<0.04). At time 2 measurement, the PTCA group was still functioning better although the difference between the scores of the two groups was diminishing (F(1,45)=4.3, p=<0.05). In addition, at time 2 patients in the PTCA group reported better health (F=11.84, p<0.002) and greater ability to work (F=4.5, p<0.04) and fewer psychiatric symptoms (F=4.5, p<0.05).

Other researchers have reported improved quality of life after CABG (CASS Principal Investigators, 1983; Flynn & Frantz, 1987; Folks et al., 1986; Jenkins et al., 1983a; Kornfeld et al., 1982; Ross et al., 1981; Westaby et al., 1979; Wilson-Barnett, 1981). Quality of life was measured by different criteria in each study and during different phases of recovery. These inconsistencies make comparison between studies tenuous. The onset of symptoms, symptom duration and angina classification is not reported in each study.

Regardless of what criteria was used and how it was measured, a consistent relationship was found between the absence of angina and improved quality of life, reduced psychological symptoms and increased physical functioning after CABG. These studies confirm the results observed in the present study (Flynn & Frantz, 1987; Jenkins et al., 1983a; Ross et al., 1981)

Jones and others (1984) compared the demographics and medical histories of 339 PTCA patients and 338 CABG patients. The PTCA patients had a shorter duration of angina, fewer number of prior myocardial infarctions and better left ventricular function ($p<0.01$). In addition, the surgical population was significantly older, had a higher incidence of hypertension and more multivessel disease. PTCA patients typically experience less chest pain for a shorter period of time before their intervention, have fewer chronic diseases than CABG patients and may not perceive themselves as sick. People with greater than eight months of symptoms have poorer adaptation to their illness (Raft et al., 1985). Seventy-five percent of the patients in this sample had a symptom duration of less than six months.

Researchers examined expected and realized benefits from bypass surgery in relation to severity of illness (Gortner, Gilliss, Moran, Sparacino & Kenneth, 1985). Sixty-six subjects were interviewed and data were grouped in categories of expected benefits such as: freedom from pain; increased activity and exercise; relaxation; travel; improved quality of life; prevention of further myocardial damage, particularly MI. Symptom relief was realized for 92% of these patients and contributed to the perceived improved quality of life. However, an unusually large percentage of these patients (33%) suffered from left main disease and this difference could have effected the results of this study. No mean age is given for the study population, however the age range is slightly older than this study (40-78). The alternative of surgery represented the last option for most surgical patients.

Demographic data from these two studies (Gortner et al., 1985; Jones et al., 1984) are similar to other research studying quality of life after CABG. Thus the CABG patient may be more disabled by his/her illness and a more significant change is demonstrated in quality of life after surgery.

The small sample size and a six week reassessment interval may have influenced the results. In addition, PTCA patients may not perceive themselves as severely disabled by their disease because of the recent onset of symptoms and their quality of life may not be significantly effected. This knowledge could explain the lack of statistical significance between the two measurements.

State-Trait Anxiety

Patients report significantly reduced state anxiety after angioplasty. There was an inverse relationship between state anxiety and quality of life after angioplasty; however, no statistically significant difference was observed between state anxiety and physical functioning after PTCA. Although mean trait anxiety scores were lower after angioplasty, the difference did not reach statistically significance, which was as anticipated.

State-trait anxiety has been used to study quality of life in CABG patients (Jenkins et al., 1983a, 1983b) and as a predictor of psychosocial and medical outcomes after PTCA (Shaw et al., 1986). Patients in all three studies completed the questionnaire the night before the procedure. Therefore, the patients' responses may have been influenced by hospital environmental factors and results may be biased.

State anxiety scores before bypass surgery (mean=42.62, SD=12.29) and before PTCA (mean=37.9, SD 12.8) were higher when compared to the pre-PTCA scores in the present study (mean=36.55, SD=9.42). Postoperative data collected six months after bypass surgery (mean= 34.55, SD 12.05) continues to be higher when compared to post-PTCA data collected six weeks after the procedure in this study (mean=31.90, SD=8.46). Patients in the present study appear to be less anxious than patients in these other studies (Jenkins et al., 1983a, 1983b; Shaw et al., 1986).

Jenkins and others (1983a) measured state-trait anxiety prior to and six months after valve surgery (n=89). A significant decrease was observed in state anxiety (p=<.0001) after surgery, however no significant change was noted in trait anxiety. In another study, these researchers studied a group of patients (n=318) prior to and six months after CABG surgery. They observed a significant decrease in state anxiety score after surgery (p=<.0001, t=5.81). Statistical results on trait anxiety scores were not reported.

Ninty-seven PTCA patients answered the STAI the night before PTCA (Shaw et al., 1986). State anxiety was the only study variable that significantly related to the level of social functioning at six months after the procedure (F=5.61; p=<0.03), suggesting that the patient's high anxiety measured the night before PTCA negatively influenced social functioning six months later. In addition, multiple regression indicated the state anxiety score and the number of arteries narrowed were significantly related to the level of mood disturbance (F=7.64, p=<0.01) and for anxiety (F=8.77, p=<0.01). These researchers suggest that patients with multivessel disease and with more anxiety the night prior to PTCA tended to have more mood disturbance 6 months after their angioplasty. State-trait anxiety was not measured after PTCA. Trait anxiety was used in all logistic regression analyses, but it did not reach significance in any analysis. The authors state that trait anxiety alone is not a crucial element in predicting outcome after PTCA.

The results of the current study concur with these studies; state anxiety was significantly decreased after the procedure and no significant change was observed in trait anxiety. The study design controlled for threats to external validity by asking patients to complete this questionnaire before coming to the hospital.

Jenkins and others (1983a, 1983b) asked patients to evaluate their physical status before and six months after bypass and valve replacement surgery. Although no data are reported, these authors state there was a general improvement in physical functioning six months after surgery. However, the increase in functional capacity postoperatively did not lead to substantial increases in feelings of positive well-being, self-esteem, and hope or decreases in helplessness and dependency. No statistical data is reported comparing anxiety with physical functioning after surgery.

In the present study, pre-PTCA mean anxiety scores of 34.55 and post-PTCA mean of 31.90 are slightly lower than Spielberger's reference population of general medical and surgical patients (mean 39.0), and far below the average of 56.5 reported for neuropsychiatric clinic patients (Speilberger et al., 1983). In addition, the majority of PTCA patients reported significantly improved physical status after the procedure. Because the patients were not anxious after their PTCA and their physical functioning had substantially improved, a significant inverse relationship was not detected between these two variables.

Physical Functioning

Patients reported significant improvement in physical functioning after angioplasty. The majority of patients were free of any anginal symptoms. Although improved physical functioning was positively correlated with quality of life after PTCA, this relationship was not significant.

Flynn and Frantz (1987) studied the quality of life of bypass patients ($n=29$) during early convalescence, six and ten weeks postoperatively. An exercise treadmill test was used to measure improvements in physical endurance. Criteria for evaluation were based on stages completed or achievement of predicted heart rate (PHR). However, only fourteen subjects performed a treadmill test; one achieved PHR, eight achieved at least 85% PHR, and five did not achieve 85% PHR. The patients receiving the lowest score stopped exercise because of fatigue, dyspnea, weakness, or leg and joint pain not because of angina or electrocardiographic changes. This data must be interpreted cautiously because a large proportion of the sample was not tested. In addition, current medication therapy is unknown. The authors state that none of the patients were currently enrolled in structured cardiac rehabilitation programs.

No significant differences were found between present life satisfaction and any of the health indicators. However, there was a significant difference between health perception and angina ($t=-429$, $p<0.05$) and dyspnea ($t=-2.27$, $p<0.05$). The symptomatic subjects reported their health status lower than those without symptoms.

Although, a number of physical complications occurred in recovery, the majority of patients reported an improved quality of life secondary to the relief of angina. During early recovery data results may reflect a "halo" effect because the patients have just survived heart surgery and have a sense of perceived cure.

Physical endurance was not measured in the present study; patients were asked to respond to questions pertaining to activities of daily living. In addition, patients still symptomatic after PTCA did not report a significantly lower quality of life in this study. The small sample size may have effected these results.

Penckofer and Holm (1984) examined the quality of life of bypass patients (n=34) and found a significantly higher level of activity three to eight months after surgery (X=4.91, SD=51) than before (X=3.07, SD=1.52) (F(1.32)=38.37, p<.001). Although the authors do not describe a relationship between this finding and the quality of life variables, they contend the lowered incidence of angina after bypass surgery contributed to the improvement in physical functioning.

Quality of life and postoperative physical functioning were examined in a group of 95 CABG patients (LaMendola & Pellegrini, 1979). Quality of life is studied through measures of social situation, physical limits, and work status. The authors suggest that the type of experience following surgery influences the person's perceptions of their physical limits. The majority of the patients were employed (n=45); seventeen patients were retired; sixty percent of the total sample perceived they had no physical limitations (n=57) after bypass surgery. The authors contend that this information reflects a high satisfaction with the surgical outcome.

These studies confirm the results of the present study. Although improved physical functioning and relief of angina were related to an improved quality of life after bypass surgery, resuming physical activities and returning to work were delayed because of the surgical event.

The majority of PTCA patients are told they may resume normal activities, including work, within a week after the procedure. Some physicians prefer to have post-PTCA treadmill results before permitting their patients to return to strenuous activity (Myler et al., 1983). The different lengths of recovery makes comparison between these two groups difficult.

Symptomatology may not be an accurate indicator of the physical limitations imposed by coronary artery disease. Many patients indicated on the questionnaire they were advised by their physicians to severely limit their activities until after their PTCA. Typically, the patients were told to avoid stairs, sex, recreational activities, and work. Prior to PTCA many patients were relatively asymptomatic, but exertional angina was difficult to assess because of the activity limitations.

Return to work has consistently been used to measure improved physical functioning and quality of life after CABG (Morton & Tolan, 1982; Sergeant, Lesaffre, Flameng & Suy, 1986; Westaby et al., 1979) and after PTCA (Holmes et al., 1984b). The question concerning employment needs to be more personal and specific. The higher the total score on the physical status questionnaire, the more physically limited the individual. Those under retirement age answered they were working prior to PTCA. However, they also indicated on the questionnaire they were awaiting clearance from their physicians to return to work after their angioplasty and were not physically working at the time of data collection. All patients who were employed prior to PTCA had returned to work after PTCA.

Retired patients were dissatisfied by the association with disability. Although retired from the occupation they practiced throughout the largest sector of their lives, many of these patients stated on the returned questionnaire they were more active in retirement. Specifically, one 72 year old man worked as a volunteer more than forty hours per week; a 73 year old woman raises 5000 orchids in her home; a 95 year old is a novelist and playwright, currently working on two books; another 76 year old supervises bridge games on cruise ships; and a fifty-nine year old ophthalmologist recently limited his practice to teaching so he would have more time for tournament tennis. His goal is to beat his granddaughter at tennis when she is twenty; she is currently one year old.

In summary, we need to redefine physical functioning and productivity. If the study population consists of people previously retired, assessing employment status after a procedure may not be a valid indicator of physical functioning. It is important to know if the reason for retirement was secondary to symptoms or because of age. A more precise and sensitive measurement of physical functioning would be preferred, specifically the double-rate pressure product obtained on treadmill testing. However, not every patient has a treadmill before and after angioplasty.

Limitations of the study

Polit and Hungler (1983, p.157) describe this design as "pre-experimental" because it fails to control for a number of threats to internal validity. History may be a study threat because any event between discharge and data collection could have effected the individual's perceived quality of life. In addition, not every patient received the study materials precisely the same number of days pre-admission and the inconsistent time span could have effected results.

Ferrans and Powers (1985) piloted the QLI with graduate students and dialysis patients. The graduate students were studied two weeks apart and the dialysis patients were studied one month apart. Stability reliability of the instrument was supported by correlations of 0.87 for the graduate students and 0.81 for the dialysis patients.

Testing may have influenced the study results because patients may be sensitized to the study questions and have increased awareness of the content areas. Ferrans & Powers (1985) acknowledged testing threats could have influenced the internal validity of their instrument; however, they state a large number of ratings are difficult to remember and can make testings virtually independent of each other. PTCA patients were tested six weeks apart.

The QLI instrument used in this study has not been used in any published studies with cardiac patients, although several studies are in progress. Normative values have not been established for this instrument. All of the scales in this study demonstrate a high degree of internal consistency, but this may be a significant limitation of this study.

The Physical Functioning Questionnaire was originally designed for cardiomyopathy patients. Permission was obtained from the author to change the wording to reflect terminology understandable to angioplasty patients (Appendix B). Although this instrument has been used in studying the quality of life of cardiomyopathy patients, reliability and validity have not been established for the questionnaire in the current form.

The study design does not control for threats due to maturation. As individual's return to their homes, families and activities of daily living after PTCA, some physical and psychological adjustment occurs during this recovery period. Improvement in physical functioning, anxiety and quality of life may be a reflection of life adaptation and improved coping (Raft et al., 1985; Wilson-Barnett, 1981).

Selection criteria limit generalizing the results to all PTCA patients. Eighteen patients either did not receive the study materials in time or declined to participate. Although these patients were similar to those who completed the study in terms of demographics, symptoms and medical conditions, they may have had significant differences in other aspects of their life experience.

Seton Medical Center (SMC) population of PTCA patients may differ significantly from those treated at other medical centers for several reasons: The physicians performing angioplasty at SMC have been performing this procedure the longest and have the most experience. Patients are referred from all over the World; typically these are cases too complicated for other physicians with less experience to attempt. Because most patients are aware the seriousness of their condition warrants a trip to a different facility, and may involve considerable travel, this knowledge could effect the results of the study. Asking patients to evaluate their quality of life before PTCA has greater reliability than asking them to consider this concept retrospectively.

The researcher attempted to control for threats to both internal and external validity by asking the patients to complete the questionnaires at home. Any patient who had not completed the study materials before coming to the hospital was excluded from the study.

Implications for further research

This study examined the effects of PTCA on the patient's perceived quality of life, anxiety and physical functioning prior to and after PTCA. Data are available and analyzed for twenty patients. A larger, randomly selected sample would maximize the possibility that the data are true estimates of the population. The chance of error goes down in direct proportion to the increased size of the sample. Practical considerations limited this study sample to twenty. In addition, a multicenter, collaborative study would provide a more global picture of the PTCA patient's quality of life.

The majority of the patients were married. Although the QLI questionnaire asked questions specific to social support, additional information may be helpful especially spouse/family stress. Little has been reported on behavioral and social sequelae of PTCA, particularly with regard to family and marital well-being, self-efficacy and the rehabilitative process. Families recovering from CABG experience a disorganizing and stressful period after the surgery (Gilliss, 1984). This information has not been studied in the PTCA population. Several patients experienced tragic events in their families during the six weeks after PTCA. Specifically, these patients indicated on their return questionnaires the following information: One patient's son was in a near-fatal auto accident; another man's wife had a nervous breakdown and was hospitalized; and one female patient's husband was in an inpatient alcohol recovery program.

Low self-efficacy and self-esteem have been suggested by some authors to negatively influence the resumption of physical and recreational activities including returning to work after CABG (LaMendola & Pellegrini, 1979). However, self-efficacy has not been studied in the PTCA population. The relationship between quality of life, anxiety, physical functioning and self-efficacy needs to be studied.

Nurses are very involved in helping patients obtain optimum level of functioning after illness. This study did not formally ask what plans or goals the patient had made before the procedure. By eliciting expected benefits prior to PTCA, recovery goals are made specific to the individual case and patient/family involvement can begin early.

Typically, PTCA patients do not consider themselves severely ill or disabled by their disease. After angioplasty, the patients may think they are cured or "normal" and may not make the necessary life style changes to prevent the recurrence of coronary artery disease. In addition, the brief hospitalization period prevents nurses from providing complete risk factor information to the patient. The patient's anxiety level during hospitalization may prevent absorption of information. This population of patients needs to be targeted for reinforced patient education and rehabilitation after discharge. Simple tools assessing health motivation and baseline knowledge level could be administered after admission and before discharge. This data could provide additional information to the knowledge base about the PTCA patient, establish a framework for patient education during the hospitalization, and target educational needs in the community.

In addition, a longer follow-up period might provide data not evident in this study. The six week follow-up period was chosen because most patients have returned to normal activities for several weeks and many patients have had an exercise test with their physician. However, repeated measures every six months for two years would provide a more comprehensive assessment of recovery and would help evaluate rehabilitative outcomes, incidences of restenoses and long-term recovery.

Conclusion

PTCA patients report improved health and functioning after their procedure, reduced state anxiety, almost no angina, and improved physical status. Although not statistically significant, improvements were noted in the subscales: psychosocial/spiritual, socioeconomic/occupation, and family and sexual functioning.

Improving quality of life and restoring the individual to optimum level of functioning are the goals of recovery from ischemic heart disease. The goal is not cure, but helping the person toward healthy adaptation with their illness. It is important to know what aspects of an individual's life make life satisfying and worthwhile. Data on quality of life after PTCA will help the nurse identify realistic goals with the patient, develop a strategy for life-style changes, assist with the psychosocial needs of the patient and family members and provide a basis for patient education.

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APPENDIX A

PERMISSION FOR PATIENT ACCESS

SAN FRANCISCO HEART INSTITUTE
1900 SULLIVAN AVENUE • DALY CITY, CA 94015 • (415) 991-6712 • TELEX 176737

April 18, 1986

Nancy A. Stotts, R.N., Ed.D.
Associate Professor, Department of Physiological Nursing
University of California, San Francisco
500 Parnassus Ave.
San Francisco, CA 94143

Dear Dr. Stotts;

I have been asked by Judi Faris to write to you in support of her proposal, "Self-perceived Quality of Life After Successful Percutaneous Transluminal Coronary Angioplasty".

The San Francisco Heart Institute, located within Seton Medical Center, is an internationally recognized center for research and the treatment of coronary artery disease. Annually, over 75 thousand patients are offered angioplasty in the U. S. as an intervention to relieve the disabling effects of angina; more than a thousand at Seton Medical Center. Although many technological and therapeutic advances have been made since the first angioplasty patient was treated almost nine years ago in San Francisco, we still have alot to learn.

As scientists, our concern is to improve the therapeutic results so that the implications of our research have far reaching advantages. But as physicians, our ultimate concern is for the patient and what these therapeutic advances mean to them. Data on quality of life after angioplasty will add an additional dimension to the success or failure of therapy.

I have known Mrs. Faris for over seven years and of her enthusiastic participation in previous angioplasty research. I fully support the proposed research as well as the participation of our patients.

Sincerely yours;

Richard K. Myler, M. D.
Medical Director, San Francisco Heart Institute
Clinical Professor
University of California, San Francisco

cc Judi Faris

A subsidiary of Mission Services Corporation, in affiliation with Seton Medical Center
Sponsored and operated by the Daughters of Charity of Saint Vincent de Paul

APPENDIX B

PERMISSION TO USE
QUALITY OF LIFE INDEX &
PHYSICAL FUNCTIONING QUESTIONNAIRE

THE
UNIVERSITY
OF
ILLINOIS
COLLEGE
OF NURSING

University of Illinois at Chicago
Department of Medical-Surgical Nursing
845 South Damen Avenue, 7th Floor
Box 6998, Chicago, Illinois 60680
(312) 996-7900

February 28, 1986

Ms. Judy Faris
128 Halladay Ave.
San Francisco, CA
94110

Dear Ms. Faris:

Thank you for your interest in the Quality of Life Index (QLI). I have enclosed the cardiac version of the QLI and the computer program for calculating scores. I have also included a list of the weighted items that are used for each of four subscales: health and functioning, socioeconomic, psychological/spiritual, and family, as well as the computer commands used to calculate the subscale scores. The same steps are used to calculate subscales scores as overall scores.

If you do decide to use the QLI, I would appreciate it if you would send me the raw data from the QLI and sociodemographic information for psychometric purposes.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Carol Ferrans

Carol Estwing Ferrans, PhD, RN
Research Associate

CEF:es

UNIVERSITY OF CALIFORNIA, SAN DIEGO

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE

PLEASE REPLY TO:
CARDIOLOGY SECTION (111A)
VETERANS ADMINISTRATION HOSPITAL
3350 LA JOLLA VILLAGE DRIVE
SAN DIEGO, CALIFORNIA 92161
(619) 453-7500, EXT. 3817

June 2, 1986

Judi A. Faris, R.N.
128 Holladay Avenue
San Francisco, CA 94110

Dear Mrs. Faris:

Thank you for your letter of May 20, 1986. Your project certainly sounds worthwhile as it would certainly be desireable to know how much angina can be relieved by anioplasty and what effect on the patient's life in general results.

We developed the questionaire to which you refer, out of dissatisfaction with the New York Heart Association classification of cardiac symptomatology, which we find too subjective.

References: Shabetai,JACC 1:252-263, 1983 and Am J Cardiol 49(8):1832-1837, 1981.

I see no reason why you could not adapt this type of questionaire to angina. You would want to know what sort of tasks brought on angina before and after angioplasty. You would then have something far more valuable than a bold statement that a given number of patients moved from one NYAH classification to another.

Of course you will run into difficulties. You have to deal with changes in the nature of the angina, in severity and how it is appreciated, and you will need to take into consideration the speed and energy with which the patients tackled every-day tasks before and after the operation. In the early post-operative period it will be important to distinguish between angina and post-operative chest pain. Thus, while an instrument of this sort is an improvement over a simple 1-4 numerical classification, it still has its short-comings. There are more elaborate quality of life questionaires that are increasingly being used, particularly in assessing the results of drug treatment for heart failure.

I see our questionaire occasionally refer to in the literature as the San Diego questionaire, but unfortunately, I don't have the citations to give you.

It certainly is my pleasure to have you use the questionaire adapted from dyspnea and fatigue as the principle symptom to dyspnea. If you want to look at some of the more detailed questionaires we use in our drug studies, you should telephone to Rosemary Cremo or Catherine Nielsen at 619-453-7500, ext. 3848.

Good luck with your thesis and thank you for your inquiry.

Yours sincerely,

RALPH SHABETAI, M.D.
Professor of Medicine
University of California San Diego
Chief, Cardiology Section
San Diego VA Medical Center

RS/amg

APPENDIX C

QUALITY OF LIFE INDEX

QUALITY OF LIFE INDEX (CARDIAC) - PART I*
(DOMAIN SATISFACTION)

ople differ in how they look at their lives. The things that are satisfying to one person may not be satisfying to some-
e else.

r each of the following, please choose the answer that best describes how satisfied you are with that area of your life.
none of the answers fit exactly, pick the answer that comes closest to how satisfied you are. Please mark your answer by
rcling the number.

some questions do not apply to you, please leave them blank. For example, one question asks about your job. If you are
employed, leave the question blank. Please try to answer all the questions that apply to you.

ere are no right or wrong answers.

	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
. How satisfied are you with your health?	1	2	3	4	5	6
. How satisfied are you with the health care you are receiving?	1	2	3	4	5	6
. How satisfied are you with the amount of chest pain you still have?	1	2	3	4	5	6
. How satisfied are you with your physical independence (ability to do things for yourself, get around)?	1	2	3	4	5	6
. How satisfied are you with your potential to live a long time?	1	2	3	4	5	6
. How satisfied are you with your family's health?	1	2	3	4	5	6
. How satisfied are you with your children?	1	2	3	4	5	6

	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
8. How satisfied are you with your family's happiness?	1	2	3	4	5	6
9. How satisfied are you with your relationship with your spouse/ significant other?	1	2	3	4	5	6
10. How satisfied are you with your sex life?	1	2	3	4	5	6
11. How satisfied are you with your friends?	1	2	3	4	5	6
12. How satisfied are you with the emotional support you get from others?	1	2	3	4	5	6
13. How satisfied are you with your ability to meet family responsibilities(things you have to do for your family)?	1	2	3	4	5	6
14. How satisfied are you with your usefulness to others?	1	2	3	4	5	6
15. How satisfied are you with the amount of stress or worries in your life?	1	2	3	4	5	6
16. How satisfied are you with your home (furniture, house or apartment)?	1	2	3	4	5	6
17. How satisfied are you with your neighborhood?	1	2	3	4	5	6
18. How satisfied are you with your standard of living?	1	2	3	4	5	6
19. How satisfied are you with the overall conditions in the United States?	1	2	3	4	5	6

QUALITY OF LIFE INDEX (CARDIAC) - PART 2
(DOMAIN IMPORTANCE)

People differ in how they look at their lives. What is important to one person may not be important to another.

For each of the following, please choose the answer that best describes how important that area of your life is to you.
If none of the answers fit exactly, pick the answer that comes closest to how you feel. Please mark your answer by circling the number.

If some questions do not apply to you, please leave them blank. For example, one question asks about your job. If you are unemployed, leave the question blank. Please try to answer all the questions that apply to you.

There are no right or wrong answers.

	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
1. How important is your health to you?	1	2	3	4	5	6
2. How important is health care to you?	1	2	3	4	5	6
3. How important is it to you to be completely free of chest pain?	1	2	3	4	5	6
4. How important is your physical independence (ability to do things for yourself, get around) to you?	1	2	3	4	5	6
5. How important is living a long time to you?	1	2	3	4	5	6
6. How important is your family's health to you?	1	2	3	4	5	6
7. How important are your children to you?	1	2	3	4	5	6
8. How important is your family's happiness to you?	1	2	3	4	5	6
9. How important is your relationship with your spouse/significant other to you?	1	2	3	4	5	6

	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
10. How important is your sex life to you?	1	2	3	4	5	6
11. How important are your friends to you?	1	2	3	4	5	6
12. How important is emotional support to you?	1	2	3	4	5	6
13. How important is meeting family responsibilities to you (things you have to do for your family)?	1	2	3	4	5	6
14. How important is being useful to others to you?	1	2	3	4	5	6
15. How important is it to you to have a reasonable amount of stress or worries?	1	2	3	4	5	6
16. How important is your home to you (furniture, house or apartment)?	1	2	3	4	5	6
17. How important is your neighborhood to you?	1	2	3	4	5	6
18. How important is a good standard of living to you?	1	2	3	4	5	6
19. How important are the overall conditions in the United States to you?	1	2	3	4	5	6
20. (If employed) how important is your job (or working) to you?	1	2	3	4	5	6

	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
21. (If unemployed, retired, or disabled) how important would it be to you to have a a job?	1	2	3	4	5	6
22. How important is your education to you?	1	2	3	4	5	6
23. How important is your financial independence to you?	1	2	3	4	5	6
24. How important are leisure time activities to you?	1	2	3	4	5	6
25. How important is the ability to travel on vacations to you?	1	2	3	4	5	6
26. How important is having a happy old age/retirement to you?	1	2	3	4	5	6
27. How important is peace of mind to you?	1	2	3	4	5	6
28. How important is your personal faith in God to you?	1	2	3	4	5	6
29. How important is achieving your personal goals to you?	1	2	3	4	5	6
30. How important is happiness to you?	1	2	3	4	5	6
31. How important is it to you to be satisfied with life?	1	2	3	4	5	6
32. How important is your personal appearance to you?	1	2	3	4	5	6
33. How important are you to yourself?	1	2	3	4	5	6

APPENDIX D

STATE-TRAIT ANXIETY INVENTORY

SELF-EVALUATION QUESTIONNAIRE

Developed by Charles D. Spielberger
in collaboration with
R. L. Gorsuch, R. Lushene, P. R. Vagg, and G. A. Jacobs

STAI Form Y-1

Name ______________________________ Date __________ S ____

Age __________ Sex: M ____ F ____ T ____

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	①	②	③	④
2. I feel secure	①	②	③	④
3. I am tense	①	②	③	④
4. I feel strained	①	②	③	④
5. I feel at ease	①	②	③	④
6. I feel upset	①	②	③	④
7. I am presently worrying over possible misfortunes	①	②	③	④
8. I feel satisfied	①	②	③	④
9. I feel frightened	①	②	③	④
10. I feel comfortable	①	②	③	④
11. I feel self-confident	①	②	③	④
12. I feel nervous	①	②	③	④
13. I am jittery	①	②	③	④
14. I feel indecisive	①	②	③	④
15. I am relaxed	①	②	③	④
16. I feel content	①	②	③	④
17. I am worried	①	②	③	④
18. I feel confused	①	②	③	④
19. I feel steady	①	②	③	④
20. I feel pleasant	①	②	③	④

Consulting Psychologists Press
577 College Avenue, Palo Alto, California 94306

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-2

Name ______________________________ Date __________

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	①	②	③	④
22. I feel nervous and restless	①	②	③	④
23. I feel satisfied with myself	①	②	③	④
24. I wish I could be as happy as others seem to be	①	②	③	④
25. I feel like a failure	①	②	③	④
26. I feel rested	①	②	③	④
27. I am "calm, cool, and collected"	①	②	③	④
28. I feel that difficulties are piling up so that I cannot overcome them	①	②	③	④
29. I worry too much over something that really doesn't matter	①	②	③	④
30. I am happy	①	②	③	④
31. I have disturbing thoughts	①	②	③	④
32. I lack self-confidence	①	②	③	④
33. I feel secure	①	②	③	④
34. I make decisions easily	①	②	③	④
35. I feel inadequate	①	②	③	④
36. I am content	①	②	③	④
37. Some unimportant thought runs through my mind and bothers me	①	②	③	④
38. I take disappointments so keenly that I can't put them out of my mind	①	②	③	④
39. I am a steady person	①	②	③	④
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	①	②	③	④

APPENDIX E

PHYSICAL FUNCTIONING QUESTIONNAIRE

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION FOR ANGINA PECTORIS

ID#______

PHYSICAL STATUS QUESTIONNAIRE

*NOTE - chest discomfort means any pain or discomfort in the arms, chest, throat or jaw for which you have consulted (or been followed by) a physician. The discomfort could be heaviness, tightness, burning, pressure, or any other sensation which your doctor calls angina or "heart pain". This discomfort may occur with exertion or at rest.

_____ 5. Since you were first diagnosed as having coronary artery disease, how would you describe your ability to exercise today?
A) improvement
B) none
C) deterioration

_____ 6. Walking on level ground, do you get *chest discomfort when you go
A) more than 5 blocks
B) up to 5 blocks
C) 1 to 2 blocks (The average block is 100 yards)
D) less than one block

_____ 32. When you are walking on level ground, do you become fatigued after
A) more than 5 blocks
B) up to 5 blocks
C) 1 to 2 blocks
D) less than one block

_____ 33. Do you characterize your walking as
A) brisk
B) normal
C) slow

_____ 7. How many flights of stairs can you comfortably climb without having to stop and rest?
A) more than two
B) two
C) one
D) less than one

_____ 34. When climbing hills or stairs, are you limited more by
A) fatigue (including legs)
B) chest discomfort
C) unknown

_____ 8. Are you unable, or do you find it difficult, to do grocery shopping (including carrying packages)?
A) no
B) yes

_____ 9. Can you do housework?
A) heavy (moving furniture)
B) medium (Vacuuming)
C) light (dusting)
D) none

ID#_______

_____ 9a. Are you employed?
A) full-time (40 hours/week or more)
B) part-time (greater than 24 hours/week)
C) less than 16 hours/week
D) unemployed or retired

_____ 10. Can you do gardening?
A) heavy (mowing - non-power, digging hard soil)
B) medium (power mowing, raking leaves)
C) light (weeding, watering)
D) none

_____ 11. Do you get chest discomfort when you are at rest? (e.g., in a chair or on the sofa or bed)
A) no
B) yes

_____ 12. Are you awaken during the night because of chest discomfort?
A) no
B) yes

_____ 14. Do you get chest discomfort during sexual intercourse, or does fear of chest discomfort prevent intercourse?
A) no
B) yes
C) impotence
D) do not know

_____ 16. On the following scale, where would you grade your ability to perform exercise?
A) I consider my exercise capability normal
B) moderate exercise results in chest discomfort
C) mild exercise results in chest discomfort
D) chest discomfort occurs at rest

_____ 15. Do you complain of dizziness or light-headedness?
A) no
B) yes

_____ 20. Has your weight changed recently?
A) no
B) yes, decreasing
C) yes, increasing
D) do not know

_____ 35. Do you have swelling of the feet, ankles or legs?
A) no
B) a little
C) moderate
D) severe

_____ 22. Have you noticed any new symptoms which you attribute to one of your medications?
A) no
B) yes,____(specify)

ID#________

_____ 23. Do you have chest discomfort?
A) no (skip rest of questions)
B) yes

_____ 24. Pick the nearest description of your chest pain or discomfort from the following:
A) crushing or squeezing
B) sharp, like a knife
C) aching
D) other

_____ 25. Is the chest discomfort...
A) in the middle to the chest
B) the left side of the chest
C) other

_____ 26. Is the chest discomfort relieved by nitroglycerine...
A) less than 5 minutes
B) more than 5 minutes
C) not at all
D) not tried

Does the chest discomfort spread to...
_____ 36. left arm A) no B) yes
_____ 37. jaw or teeth A) no B) yes
_____ 38. your abdomen A) no B) yes
_____ 39. elsewhere A) no B) yes

_____ 28. Do you have chest discomfort...
A) more than once a day
B) more than once a week
C) occasionally

_____ 29. Does the chest discomfort usually last...
A) a few seconds
B) a few minutes
C) 20 minutes or longer

_____ 30. Have you needed to use more nitroglycerine lately for your chest discomfort?
A) no
B) yes

_____ 31. Is your chest discomfort related to exertion?
A) no
B) yes

_____ 35. Do you feel that your chest discomfort interfers with your recreational or leisure time?
A) no
B) yes

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION FOR ANGINA PECTORIS

Class I: "Ordinary physical activity does not cause...angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation."

Class II: "Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than 2 blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions."

Class III: "Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace."

Class IV: "Inability to carry on any physical activity without discomfort - anginal syndrome <u>may be</u> present at rest" (Campeau, 1976 pp. 522).

APPENDIX F

DEMOGRAPHIC DATA AND MEDICAL HISTORY

ID#________

DEMOGRAPHIC DATA AND MEDICAL HISTORY

Demographic Variable	Categories
Sex	Male
	Female
Marital Status	Single
	Married
	Divorced
	Widowed
	Separated
Ethnic Background	Asian
	Black
	Caucasian
	Hispanic
	Other
Religious Preference	Protestant
	Catholic
	Jewish
	Other
	None
Employment Status	Employed
	Not Employed
	Retired
Age (Year of Birth)	________
Risk Factors	Smoking
	Hypertension
	Cholesterol >200
	Exercise
	Stress
	Diabeties

Baseline Medical Characteristic Variable	Categories
Predominant Symptoms	Chest Pain
	Arrythmias
	Fatigue
	DOE
	Asymptomatic
Symptom Duration	No Symptoms
	> 1 yr.
	6 - 12 mo.
	3 - 6 mo.
	1 - 3 mo.
	< 1 mo.
Angina Class	I
	II
	III
	IV
Post PTCA	
ICU/CCU	Yes / No
TCU	Yes / No
Other	Yes / No
Drips	Yes / No
Lines	Yes / No
Arrythmias	Yes / No
Angina	Yes / No
Other	Yes / No
Heart Attack	Yes / No
Date 1st	________
Date 2nd	________
Number Occluded	1 artery
	2 arteries
	3 arteries
Complex PTCA	
100%	Yes / No
Tandem	Yes / No
Bifurication	Yes / No
Staged Proc.	Yes / No

APPENDIX G

INTRODUCTORY LETTER FROM INVESTIGATOR

128 Holladay Ave.
San Francisco, CA 94110

Dear

My name is Judi Faris and I am a graduate student in nursing at the University of California at San Francisco. Before I decided to go to graduate school, I worked for the physicians who are performing your angioplasty and have participated in research regarding this procedure for a number of years.

I would like to ask you to participate in a study that looks at change in an individual's quality of life after percutaneous transluminal coronary angioplasty (PTCA). The study also includes questions about how you feel, specifically how you feel this moment and questions about how you feel generally. A third part of the study asks questions about your chest discomfort, the types of activities that are associated with this discomfort and about your activities of daily living. It is anticipated that this research will assist physicians, nurses and other health professionals in teaching, and in helping the angioplasty patient adjust after discharge from the hospital.

Your participation in this study is entirely voluntary. If you decide to participate, please complete the enclosed questionnaires. It should take approximately 45 minutes of your time. Confidentiality will be protected as far as is possible under the law. Your name does not appear on any of the questionnaires, code numbers will be assigned to all patients who agree to participate, and I will be the only person who will see your answers. It is possible that some of the questions may be annoying or embarassing to you. Although this is not intended, should you feel uncomfortable about answering specific questions, you may leave them blank.

If you do decide to participate, it is very important that the questionnaires be completed and returned to me as soon as possible. If you feel that they may not reach me before your scheduled trip to Seton Medical Center, you may bring the <u>completed</u> questionnares with you to the hospital. I will collect them from you before your angioplasty.

I will be reviewing your past medical history to learn facts concerning your cardiac history. This information will be coded in the same manner as your questionnaires.

Six weeks after your angioplasty, I will send you a second set of questionnaires and a return envelope to learn your impressions about the same items now that you are home and on the road to recovery. Please mail them back to me as soon as you have completed them. You are free to withdraw from the study at any time.

I have also enclosed two copies of the consent form that you should read, sign and return one copy with the completed questionnaires. The second copy is yours to keep along with the "Experimental Subjects Bill of Rights". I will telephone you in a few days to see if you have received the study materials and answer any questions you may have about the study. Should any questions develop later or you wish to talk with me sooner, please do not hesitate to call me. I can be reached at (415) 648-9183; if I am not home, I have an answering machine and would be happy to return your call if you let me know when I can best reach you.

If you decide you do not wish to participate in this research and do not wish to be contacted further, please indicate your intention on the enclosed blue form and return it to me with the unused questionnaires as soon as possible. A stamped, addressed envelope is provided for your convenience. Because there is so little time between the initial mailing of the questionnaires and my follow-up phone call, I may not receive your "blue form" in time. However, this does not waive your right to decline to participate when I call.

Your participation in this study will be a valuable contribution as it will provide different information about the PTCA patient from the patient's perspective. If you would like a summary of the findings of this study, please check the "yes" option at the bottom of the consent form.

Sincerely,

Judi A. Faris, R.N., CCRN
Master of Science Candidate, Nursing
University of California, San Francisco

APPENDIX H

PATIENT CONSENT FORM

University of California, San Francisco
Consent to Be a Research Subject

I have been asked to participate in an investigational study being conducted by Judi Faris, R.N. The purpose of this study is to understand more about the experience of people who undergo Percutaneous Transluminal Coronary Angioplasty (PTCA). More specifically, this study will focus on the Quality of Life of patients who have been treated with PTCA. Because I am scheduled for this procedure at Seton Medical Center, I have been invited to participate in this study.

I can agree to be in this study by signing and returning this form. If I return this form, this is what I can expect to happen:

1) Approximately 1-2 weeks before my PTCA, I will be asked to complete 3 questionnaires about how I currently perceive my quality of life, my physical activity level and how I am feeling today. This will take about 45 minutes. Once the questionnaires are completed, I will return them in the stamped, addressed envelop provided. The investigator has requested that the questionnaires be completed before coming to the hospital.

2) Six weeks after my discharge from the hospital, I will be asked to again complete these questionnaires. I will return these questionnaires by mail in the same manner as before my PTCA.

3) As a result of answering this questionnaire there is possible loss of my privacy. My name will not be used anywhere in the study and a code number will be assigned to my questionnaires; all questionnaires will be kept locked so my confidentiality will be protected as much as possible under the law.

4) There will be no direct benefit to me from participating. The investigators hope to learn more about quality of life which may ultimately benefit future patients who have PTCA.

5) My participation in this research IS ENTIRELY VOLUNTARY. I am free to withdraw at any time, without jeopardy to my status or care as a patient in this hospital. My medical record will be reviewed by the investigator to learn details of my past cardiac history.

This information was explained to me by Judi Faris, R.N. If I have any questions about the study at any time, I may call her at (415) 648-9183.

I have been given a copy of this consent form to keep and a copy of "Experimental Subjects Bill of Rights".

Date:____________________ (Signature)__________________________

I would like to receive a summary of the study findings. YES___ NO___
5/15/86

ID#______

RETURN THIS FORM ONLY IF YOU DECLINE TO PARTICIPATE

____ I do not wish to participate in this research study, and request that I not be contacted further by the investigator regarding this project.

Quality of Life after Percutaneous Transluminal Coronary Angioplasty

ID#______

RETURN THIS FORM ONLY IF YOU DECLINE TO PARTICIPATE

____ I do not wish to participate in this research study, and request that I not be contacted further by the investigator regarding this project.

Quality of Life after Percutaneous Transluminal Coronary Angioplasty

ID#______

RETURN THIS FORM ONLY IF YOU DECLINE TO PARTICIPATE

____ I do not wish to participate in this research study, and request that I not be contacted further by the investigator regarding this project.

Quality of Life after Percutaneous Transluminal Coronary Angioplasty

APPENDIX I

LETTER TO REFERRING PHYSICIAN

128 Holladay Ave.
San Francisco, CA 94110

Dear Dr.

Your patient, ________________, has been invited to participate in a study; "Quality of Life After Percutaneous Transluminal Coronary Angioplasty". The study consists of self-administered questionnaires covering quality of life, state-trait anxiety and physical functioning. The questionnaires were mailed to the patients after the investigator was notified the patient had been scheduled for PTCA. Should your patient agree to participate in the study, they return the completed questionnaires to the investigator in the self-addressed, stamped, envelop provided. Six weeks after PTCA the same questionnaires will be mailed to the patient, again with a stamped, return envelop enclosed.

Completion of this study is fulfilling partial requirements for a Master of Science and is being supervised by UCSF Faculty. Drs. Myler, Stertzer and Clark have given their permission for patient access. The study protocol was reviewed and approved by the Committee on Human Research of Seton Medical Center and UCSF, Moffitt Hospital.

Please contact me (415) 648-9183, should you have any questions concerning this study. I would be happy to share with you my data when available. Please notify me if you desire this information.

Sincerely yours,

(Mrs.) Judi A. Faris, R.N., CCRN
Master of Science Candidate,
School of Nursing
University of California,
San Francisco

APPENDIX J

FOLLOW-UP LETTER TO NON-RESPONDENTS

128 Holladay Ave.
San Francisco, CA 94110

Dear

My name is Judi Faris and I am graduate student in nursing at the University of California at San Francisco. If you recall, I talked to you prior to your recent angioplasty at Seton Medical Center.

I would like to again thank you for agreeing to participate in the study, "Quality of Life After Percutaneous Transluminal Coronary Angioplasty". During our pre-PTCA conversations, I mentioned that it would be necessary for you to complete a second set of questionnaires post-PTCA so that a comparison could be made between the responses. I am hopeful you will find time to complete the questionnaires today.

It is anticipated this study will yield some very valuable and useful information about the impact PTCA has on an individual's life. Please return your questionnaire so your information can be part of the study. If you have any questions, or I may be of any assistance to you, please do not hesitate to call me (415) 648-9183.

Sincerely yours,

Judi A. Faris, R.N., CCRN
Master of Science Candidate, Nursing
University of California, San Francisco

APPENDIX K

COMMITTEE ON HUMAN RESEARCH APPROVAL

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO: HUMAN AND ENVIRONMENTAL
PROTECTION COMMITTEES
CLINICS 116

TO: Nancy A. Stotts, Ed.D. / Judi A. Faris, R.N.
N 611 Y / 128 Holladay Ave.; San Francisco, Ca 94110

RE: Quality of Life After Rercutaneous Transluminal Coronary Angioplasty

The UCSF Committee on Human Research (an IRB holding DHHS assurance #M-1169) has approved the above request to involve humans as research subjects.

APPROVAL NUMBER: 935914-01* **This number is a UCSF CHR number which should be used on all consent forms, correspondence and patient charts.**

APPROVAL DATE: July 7, 1986 **Full review** ______
Expedited review X

EXPIRATION DATE: July 7, 1987 **If the project is to continue, it must be renewed by the expiration date. If the number has an asterisk, the short-form renewal process may be used.**

SUBMISSION ADDENDA: No______ Yes X A yes indicates that there was correspondence between the Committee and the investigator during review of this submission.

CONDITIONS: Please note that the phrase "I understand" was still found in section #1 of the consent form and should be deleted.

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within five working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

LEGAL NOTICE: The University will defend and indemnify a principal investigator in legal actions arising from research activities involving humans only if the activities had current CHR approval.

QUESTIONS: Please contact the Human and Environmental Protection Committees office at (415) 666-1814, room Clinics 116.

Sincerely,
Carol S. Viele R.N., M.S
Carol S. Viele, R.N., M.S.
Chairman
Committee on Human Research

cc: Contracts and Grants
Drug Info and Analysis Service
SFGH
VAMC Research Office______

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO: HUMAN AND ENVIRONMENTAL PROTECTION COMMITTEES
CLINICS 116

TO: Nancy A. Stotts, Ed.D./Judi A. Faris, R.N.
N 611 Y/128 Holladay Avenue, San Francisco, CA 94110

RE: Quality of Life after Percutaneous Transluminal Coronary Angioplasty - MODIFICATION

The UCSF Committee on Human Research (an IRB holding DHHS assurance #M-1169) has approved the above request to involve humans as research subjects.

APPROVAL NUMBER: 935914-01A* **This number is a UCSF CHR number which should be used on all consent forms, correspondence and patient charts.**

APPROVAL DATE: October 9, 1986 **Full review** ______
Expedited review XX

EXPIRATION DATE: July 7, 1987 **If the project is to continue, it must be renewed by the expiration date. If the number has an asterisk, the short-form renewal process may be used.**

SUBMISSION ADDENDA: No XX **Yes** ______ **A yes indicates that there was correspondence between the Committee and the investigator during review of this submission.**

CONDITIONS: To emphasize the fact that the subject has the freedom to decline to participate whether or not he has returned the "blue form," a statement should be added to the letter to the effect that because there is so little time between the initial mailing to subjects and your follow-up telephone call, you may not receive their "blue form" in time; however, this does not waive the subject's right to decline to participate when you call.

Please submit two copies of the revised letter to Clinics 116.

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within five working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

LEGAL NOTICE: The University will defend and indemnify a principal investigator in legal actions arising from research activities involving humans only if the activities had current CHR approval.

QUESTIONS: Please contact the Human and Environmental Protection Committees office at (415) 476-1814, room Clinics 116.

Sincerely,
Carol S. Viele R.N. M.S.
Carol S. Viele, R.N., M.S.
Chairman
Committee on Human Research

cc: Contracts and Grants
Drug Info and Analysis Service
SFGH ______
VAMC Research Office ______

SETON MEDICAL CENTER
1900 SULLIVAN AVENUE • DALY CITY, CA 94015 • (415) 992-4000

June 12, 1986

Mrs. Judi A. Faris, R.N.
128 Holladay Avenue
San Francisco, CA 94110

Dear Mrs. Faris:

This is to certify that at the Research Committee meeting held on Friday, June 6, 1986 your research protocol "Quality of Life After Percutaneous Transluminal Coronary Angioplasty" and related consent form were approved.

The Committee requests that you submit a final report when this research study is completed.

Thank you.

Sincerely,

D Richard Reynolds, MD

D. Richard Reynolds, M.D.
Chairman, Research Committee

DRR/kwm