MEASURING CHANGE IN KEY HRQL OUTCOMES USING MOS SF-36 SUBSCALES VS VSAQ AND BDI WITH PATIENTS UNDERGOING CABG SURGERY

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(ABSTRACT)

Health-related quality of life (HRQL) measures taken before and after coronary artery bypass grafting (CABG) aid in determining meaningful patient-perceived outcomes associated with alternative clinical interventions. This study compared performance of the Medical Outcomes Study Short Form-36 (MOS SF-36) subscales for Physical Functioning (PF), Role Physical (RP), Mental Health (MH), and Role Emotional (RE) against two other questionnaires, i.e. the Veteran's Specific Activity Questionnaire (VSAQ: self-efficacy for vigorous physical activity) and the Beck Depression Inventory (BDI-II: mental-emotional functioning). Seventy-one patients (59-M; 12-F; age, Mean $\pm$ SD = 63 $\pm$ 8.6 years) were administered these three questionnaires just before and 3 months following CABG surgery. Score distributions were evaluated for the pre- and post-surgery measurements, as were change scores after CABG. All measures except the MOS SF-36 subscales for RP and RE showed statistically significant change after CABG ($p<0.01$). Only the subscales of RP and RE demonstrated substantial ceiling (21.0% and 56.3%) and floor effects (49.3% and 16.9%). Evaluation of individual change scores after CABG indicated that 59% and 62% of the patients, respectively, had clinically meaningful increases in the two measures of physical capability, i.e. PF and VSAQ. In contrast, 60% and 72% of patients, respectively, showed no clinically meaningful changes in the two measures of emotional functioning, i.e. RE and BDI-II scores. Chi-square analyses revealed that use of scales with similar definitional constructs resulted in significantly different surgical outcomes for the following: PF vs VSAQ ($p<0.001$), RP vs VSAQ ($p<0.02$); and MH vs BDI-II ($p<0.0001$). These findings illustrate the limitations in performance of the MOS SF-36 for assessing changes of importance in

HRQL after CABG. The VSAQ and BDI-II, two simple measures of physical and emotional functioning that are fundamentally similar to those contained in the MOS SF-36, appear to be sensitive markers for detecting changes in these important outcomes after CABG surgery.

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INTRODUCTION

FOREWORD

The research reported here in was derived from a broad-based project conducted at Carolinas Medical Center in Charlotte, NC, between November, 1996 and December, 1998, under the supervision of Dr. Joseph Cook. The content beyond this page should be viewed as an independent project. Therefore, a brief description of the above mentioned project is warranted.

The purpose of Dr. Cook's study was to validate the observation by clinicians that the physical fitness of patients, in the broadest sense of the term, is an important factor in influencing the outcomes of first time coronary artery bypass grafting (CABG), particularly in an elderly cohort. Approximately 200 patients aged 46 to 81 who were admitted to Carolinas Medical Center for first time CABG between November, 1996 and December, 1997 were recruited for the study. A battery of short standard tests of physical fitness, exercise tolerance, psychological function, and quality of life was administered to all CABG subjects. A dual-energy x-ray absorptiometry (DEXA) scan was also administered to measure body composition and bone density. The battery of tests was administered pre-operatively and again at 3 and 12-months post-operatively.

Once an accounting was made for comorbid diseases known to influence surgical outcomes, the results of the pre-operative battery of tests were analyzed to determine if the physical fitness factors thought to influence surgical morbidity, mortality, and quality of life following CABG were, in fact, independent predictors of these surgical outcomes.

INTRODUCTION

Coronary artery disease (CAD), one of the more prevalent forms of cardiovascular disease, remains the single leading cause of death in the United States today. In 1994 alone, nearly 1 million lives were claimed by cardiovascular disease. Even more staggering is the fact that nearly 14 million people alive today have a history of heart attack, angina, or both (American Heart Association, 1997).

These statistics offer a glimpse of the present and the probable future of the demand for cardiac treatments. Such treatments may include coronary artery bypass grafting (CABG), balloon angioplasty, and other invasive and non-invasive procedures, as well as community interventions such as cardiac rehabilitation. In order to effectively and efficiently meet the aforementioned demand, attention must be appropriately divided among all health care professions. Economists, policy makers, educators, and clinicians must have a common focus to achieve a high standard of patient care and to conserve resources, thus extend appropriate care to all those most likely to enjoy a favorable outcome.

The act of making important decisions regarding the level of cardiac interventions must ultimately begin and end with the patient in mind. In other words, assessing a patient's health outcomes, such as perceived quality of care following a treatment, becomes an integral part of optimizing the decision making process in years to come. When evaluating the effectiveness of patient care, the construct of heath-related quality of life (HRQL) should be used as an important complement to the more traditional physiologic and biologic measures of health outcomes. Patient perceived HRQL "represents the functional effect of an illness and its consequent therapy upon a patient," (Schipper, Clinch, & Olweny, 1996). Measures of HRQL center on the physical, emotional, and social domains of health. Clinicians are increasingly called upon to assess patient outcomes within these critical domains.

Following an intervention, many clinicians have traditionally assessed patient outcomes relative to mortality, symptoms reported, improvement in exercise tolerance,

psychological function, and measures of independence (Oldridge, 1997). Presently, more and more clinicians incorporate the use of HRQL as an outcomes measure. The Medical Outcomes Study Short Form (MOS SF-36) frequently is used to assess patient perceived HRQL. The Nottingham Health Profile (NHP), Sickness Impact Profile (SIP), and Quality of Well Being Scale (QWB) are other most widely used HRQL assessment tools. Selected components of HRQL, such as physical and mental health, have been assessed frequently with a variety of instruments such as the Veterans Specific Activity Questionnaire (VSAQ), Duke Activity Survey Index (DASI), Beck Depression Index (BDI-II), and State-Trait Anxiety Inventory (STAI).

STATEMENT OF THE PROBLEM

Prior to administering the HRQL instrument, clinicians much first critically evaluate the overall performance of the selected instrument. Katz, Larson, Phillips, Fossel, & Liang (1992) suggest that such an instrument be evaluated in terms in of its appropriateness for specific populations and assessment needs, its established validity and reliability, and in particular, its ability to detect clinically significant change as a result of an intervention.

Since its development, the MOS SF-36 has become one of the most widely accepted HRQL instruments in clinical settings. The MOS SF-36 is short, efficient, and easy to understand, score, and interpret. Reliability and validity have been well established (McHorney, Ware, Lu, & Sherbourne, 1994; McHorney, Ware, & Raczek, 1993; Stewart, Hays, & Ware, 1988); and the MOS SF-36 has been administered to large patient samples in both general and disease-specific populations (Tarlov et al.,1989; Stewart & Ware, 1992; Katz et al., 1992; Jette & Downing, 1996; Kiebzak, Vain, Gregory, Mokris, & Mauerhan, 1997). On the other hand, the literature suggests that the MOS SF-36 has limitations. In particular, this instrument has been shown to have both "ceiling" and "floor" measuring effects (Andresen, Patrick, Carter, & Malmgren, 1995). These effects refer to the responder receiving the lowest or the highest possible score for a particular subscale . Floor and ceiling effects may ultimately decrease the instrument's ability to detect clinically significant changes following an intervention.

The MOS SF-36 exists in "packages" such as the Summit Pinnacle ™ Health Status Questionnaire (Summit Medical, 1995; Minneapolis, MN), which is designed to measure functional status, well being, and risk of depression in adults. Even with its known limitations, the MOS SF-36 continues to be purchased and adopted by many institutions because it is easily administered, scored, and interpreted. Clinicians, therefore, may be making purchase decisions before they are well informed of the instrument's overall performance ability. In other words, clinicians may evaluate patient outcomes over the course of an intervention with HRQL instruments, such as the MOS SF-36, because they are easy to administer, score and interpret; yet they may be insensitive to detecting clinically significant change.

RESEARCH OBJECTIVE

This study compared performance of the Medical Outcomes Study Short Form-36 (MOS SF-36) subscales for Physical Functioning (PF), Role Physical (RP), Mental Health (MH), and Role Emotional (RE) against two other questionnaires, i.e. the Veteran's Specific Activity Questionnaire (VSAQ: self-efficacy for vigorous physical activity) and the Beck Depression Inventory (BDI-II: mental-emotional functioning) in patients who underwent first time CABG. More specifically, the research objectives of the current study were:

1) To evaluate and compare definitionally similar scales of the MOS SF-36 with the VSAQ and BDI-II when administered to patients before and 3 months following CABG surgery
2) To analyze the magnitude and direction of change scores following CABG surgery for the MOS SF-36 subscales of interest, VSAQ, and BDI-II
3) To determine the concordance of change scores on a patient-by-patient basis for the MOS SF-36 subscales vs VSAQ and MOS SF-36 vs BDI-II

SIGNIFICANCE OF THE STUDY

The importance of evaluating HRQL is not new to the field of health care outcomes research. As early as 1914, the assessment of health care outcomes, such as functional status, were regarded as a means to improve overall quality of patient care (Codman, 1914). Even with continual changes in the structure of health care, this early concern for outcomes remains quite evident today. Prominent research agencies (National Institutes for Health, Agency for Health Care Policy and Research, and National Institute on Disability and Rehabilitation Research) recognize and support numerous projects aimed at determining meaningful and appropriate measures of health care outcomes for clinical purposes.

As the number of individuals living with CAD increases with each year, the need for cardiac interventions will continue to soar. Therefore, research surrounding the construct of HRQL, in this population, must endure to better define the patient-perceived value of a particular treatment. To this end, instruments which measure HRQL, such as those mentioned previously, have been constructed to represent the most important health concepts related to disease and treatment (Ware, 1993).

The MOS SF-36 was developed to assess eight health concepts. These include General Health Perception (GHP), Physical Functioning (PF), Mental Health (MH), Role Physical (RP), Role Emotional (RE), Bodily Pain (BP), Energy/Fatigue (EF), and Social Functioning (SF). Jette and Downing (1994) evaluated the eight MOS SF-36 health subscales among individuals entering a cardiac rehabilitation program to determine which health concepts were most affected by the treatment. The authors concluded that patients with cardiac disease were most limited in their performance of physical and mental tasks and the roles associated with physical and mental functioning (PF, MH, RP, RE). As a consequence of cardiac rehabilitation, the HRQL scores demonstrated the most improvement within these four MOS SF-36 subscales.

The MOS SF-36 has been widely used to assess the HRQL among cardiac patients entering rehabilitation programs (Jette & Downing, 1994; Lavie & Milani, 1995;

Milani, Lavie, & Cassidy, 1996), undergoing coronary angioplasty (Cleary, Greenfield, & McNeil, 1991), suffering from acute angina (Johnson et al., 1995), and hypertension (McHorney et al., 1994), To date, there is a lack of published literature utilizing the MOS SF-36, particularly the four physical and mental health constructs, to assess HRQL among patients undergoing CABG.

As mentioned previously, the VSAQ and BDI-II are adequate instruments, which may also be used to assess the physical and mental health constructs of HRQL among CAD patients. The VSAQ is a valid and well accepted instrument used for the self-rating of cardiorespiratory functional capacity, that is, exercise tolerance. The VSAQ was developed with a particular patient population in mind, specifically, those individuals who experience physical limitations as a result of symptoms, medications, or other factors related to cardiovascular disease (Myers, Herbert, Ribisl, & Froelicher, 1994). Currently, there exists no published study that uses the VSAQ to evaluate changes in the HRQL, or physical health per se, among individuals undergoing a cardiac intervention such as CABG. Comparing the VSAQ scores before and after CABG may be another useful and important means of assessing the physical functioning and the role physical subscales constructed in the MOS SF-36 health survey.

The BDI-II was developed for the assessment of symptoms corresponding to criteria for diagnosing depressive disorders (Beck, Steer, & Brown, 1996). The BDI-II is one of the most widely accepted instruments for detecting possible depression in the general population. Given the high prevalence of depression and declining mental health among those diagnosed with CAD, Freedland, Carney, Lustman, Rich, & Jaffe (1992) used the BDI-II to assess depressive symptoms in 80 patients with CAD. Symptoms such as fatigue, irritability, dissatisfaction, sadness, insomnia, and health worries rated by the BDI-II were common among the patients, but the scores indicated depressive states that were relatively mild and nonspecific. The authors suggested that results might reflect the low number of CAD patients who were actually diagnosed with clinically significant depression. It is interesting to note that many of the depressive symptoms mentioned above are incorporated into the MOS SF-36 mental health and role emotional subscales.

To date, there are only two known studies which use versions of the BDI-II to evaluate change in depressive symptoms among CAD patients (Lesperance, Frasure-Smith, & Talajic, 1996; Timberlake et al., 1997). Furthermore, comparing the BDI-II scores for patients before and after CABG may represent another useful and important means of assessing the mental health and role emotional subscales in the MOS SF-36 health survey.

DELIMITATIONS

The following delimitations were established for this study:

1) All subjects underwent first time CABG at Carolinas Medical Center between November 1996 and December 1997, were >45 years of age at the time of surgery, and had not had an MI fewer than 5 days prior to surgery;

2) The sample of subjects were representative of the population who underwent CABG between November 1996 and December 1997 at Carolinas Medical Center;

3) Subjects were not included in the study if they had to undergo any other concomitant cardiovascular surgery;

4) Only those subjects were included who survived CABG, returned to Carolinas Medical Center for a 3-month follow-up, and completed each of the specific instruments which were administered for this study;

5) Subjects were not included if they presented any cognitive-emotive disorders that would have precluded completion of the specific instruments which were administered for this study;

LIMITATIONS

The following were viewed as important constraints that limited the interpretation of the data:

1) Under certain circumstances, questionnaires may have been sent and returned via mail, therefore, completed in the absence of verbal instruction and supervision. Consequently, accuracy in completion of these questionnaires may have been reduced;

2) Verbal instruction for questionnaire completion may not have been uniformly given to all subjects as various technicians administered the questionnaires;

3) This investigation was based on outcomes of those patients undergoing CABG and should not be generalized to other cardiovascular conditions and interventions, including cardiac rehabilitation;

BASIC ASSUMPTIONS

The following assumptions were made by the investigator:

1) All subjects responded to each questionnaire truthfully and to the best of their ability;

2) All subjects understood what was being asked in the questionnaire;

3) Subject responses were entered accurately into the computer database;

4) The determination of change scores used to classify subjects as INCREASE, DECREASE, or NO CHANGE were based on rational standards for a clinically important change;

DEFINITIONS OF TERMS AND SYMBOLS

The following are definitions and symbols for key words used in this study:

CABG (Coronary Artery Bypass Graft)

An operation performed to restore the blood supply to the heart muscle by creating a new route (a bypass) for the blood to flow around the blockages (Levinson, 1995).

HRQL (Health Related Quality of Life)

A multidimensional construct that represents a person's satisfaction with the health-related aspects of life (Oldridge, 1997); and a patient's perception of the functional effect of an illness and its consequent therapy on that patient (Schipper et al., 1996).

VSAQ (Veterans Specific Activity Questionnaire)

An instrument used to evaluate patients perception of the upper limit of their sustainable exercise tolerance, expressed in multiples of resting metabolic equivalents

(METs). Possible scores range from 1-13 METs with the lower MET levels signifying lesser abilities; a score of physical self-efficacy (Myers et al., 1994).

BDI-II (Beck Depression Inventory-Second Edition)

A 21-item self-reported instrument for measuring the presence and severity of depressive symptoms in adults and adolescents aged 13 years and older. This edition of the inventory was developed for the assessment of symptoms corresponding to criteria for diagnosing depressive disorders. Scores range from 0-63 with the lower scores demonstrating minimal depressive symptoms and the higher scores indicating severe depressive symptoms (Beck, 1996).

MOS SF-36 (Medical Outcomes Study Short Form-36 Items)

A health related quality of life instrument, which allows for a comprehensive and convenient evaluation of patients' impression of their health from a variety of perspectives, including physical, mental, and social. The questionnaire includes eight self-rated subscales, each of which is scored individually on a scale of 0-100 with a higher score being consistent with a greater perceived HRQL

The following MOS SF-36 subscales were evaluated for this investigation and are defined by Ware & Sherbourne (1992):

PF (Physical Functioning)

A 10-item scale (0, 5, or 10 points possible for each item) which reflects the types and the severity of physical limitations, including lifting and carrying groceries, climbing stairs, bending, kneeling or stooping, and walking moderate distances.

RP (Role Physical)

A 4-item scale (0 or 25 points possible for each item) with questions related to the physical role limitations in kind of work or other usual activities, including how much individuals feel that their health problem has reduced the amount of time spent in work or everyday activities and the difficulty in performing work or these activities.

MH (Mental Health)

A 5-item scale (0, 4, 8, 12, 16, or 20 points possible for each item) used to evaluate each of four major mental health dimensions: anxiety, depression, loss of behavioral/emotional control, and psychological well-being

RE (Role Emotional)

A 3-item scale (0 or 33.3 points possible of each item) with questions on mental health-related role limitations in type of work or other everyday activities, including the extent to which individuals feel that their health problem has reduced the amount of time spent in work or these activities and the difficulty in performing work or these activities.

SUMMARY

There is a continuing need to assess patients perceived HRQL before and after cardiac treatments. In turn, this information allows clinicians to make better health care decisions in the future. More and more, clinicians are using standardized questionnaires to evaluate the physical and mental health domains of HRQL in conjunction with traditional outcome measures such as mortality, morbidity, and symptom report. Before administering such questionnaires, it is important that clinicians determine the appropriateness of the questionnaire for the specific population and determine that the questionnaire meets the needs for the patient and clinician. Furthermore, when evaluating the outcomes of a specific cardiac intervention, such as CABG, it is of great importance that a questionnaire is able to detect clinically significant changes over time. The MOS SF-36 is frequently used to evaluate HRQL in cardiac patients, however, it has well known limitations. This investigation presented alternative instruments, the VSAQ and BDI-II, which can be used to evaluate patients' perception of their physical and mental health. In terms of their utility and relevance, each of the above mentioned instruments (MOS SF-36, VSAQ, and BDI-II) have been well studied and documented under separate conditions. However, there is a lack of adequate research demonstrating the instruments ability to measure change in patient perceived physical and mental health before and after CABG.

Chapter II

REVIEW OF LITERATURE

INTRODUCTION

To better comprehend the significance of the research carried out in this investigation, the following review of literature was composed. This review begins by guiding the reader towards an understanding of existing outcomes-based research. To this end, health outcomes are defined and various outcome variables are discussed. Next, the need for outcomes-based research is discussed with special attention given to the relationship between measuring health care outcomes and making better health care decisions.

The review progresses by underscoring the importance of evaluating health related quality of life (HRQL) as a primary outcome measure of the quality of patient treatments. A number of definitions to clarify the meaning of HRQL are then proposed. Next, the need for assessing HRQL is discussed from the perspective of the patient, as opposed to the clinician, researcher, or policy maker.

Rationale for what constitutes a useful questionnaire for the measurement of patient-perceived HRQL is presented. Therefore, brief descriptions of the structure, classes, purposes, and properties of HRQL instruments are provided. This section will help the reader decide if a particular instrument matches their specific assessment needs. Next, a list of some of the most widely accepted instruments used to measure HRQL in coronary disease patients is presented.

The review continues briefly, with a discussion of three instruments that were selected for the current study. Issues such as development, item-selection, scoring, limitations, validity, and reliability have been addressed.

The final section of this review provided a brief description of coronary artery bypass grafting (CABG), followed by a discussion of the outcomes commonly measured in CABG patients. These investigations measured outcomes such as left ventricular function, length of hospital stay, 3 year mortality rates, financial costs, reduction of medications, and complications. The aforementioned outcomes provide valuable

information to the clinician; however, they do not provide an adequate assessment of patient-perceived outcomes. This section proceeded to present previous research that has measured HRQL in patients undergoing CABG, specifically, the physical and mental health domains. The goal of this section was to introduce the reader to various means for assessing the physical and mental health status of patients before and after CABG, as well as, to briefly report findings from related studies.

UNDERSTANDING OUTCOMES-BASED RESEARCH

Defining Outcomes

To gain an understanding of outcomes-based research, it is first necessary to describe how the term "outcomes" applies to a patient population. Health outcomes have typically been defined as the measurement of "those changes, either favorable or adverse, in the actual or potential status of persons, groups, or communities that can be attributed to prior or concurrent care," (Donabedian, 1985). In a recent symposium on Heart Disease and Rehabilitation, Herbert (1996) presented a more simplified meaning of patient outcomes as "those consequences of a health care service on a patient…it includes the intended or unintended effects [of a treatment]."

The PRECEDE Framework, as proposed by Green, Kreuter, Deeds, & Partridge (1980), suggests that outcomes are typically classified into one of three domains: health (morbidity, mortality, and quality of life); clinical (weight, blood pressure, exercise capacity, medication usage, symptom management, hospitalizations, etc.); and behavioral (compliance with diet and exercise, smoking cessation, relaxation skills, social skills, etc.). In order to achieve a global approach to measuring patient outcomes, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) has adopted the PRECEDE Framework model to be used in cardiac health education. According to Pashkow et al. (1995), the goal of cardiac rehabilitation is to bring about a positive health outcome in the participants; it is through clinical and behavioral interventions that an attempt is made to influence their health outcomes. In essence, this same approach can be applied to the assessment of patient outcomes within other cardiac interventions such as drug therapy, angioplasty, atherectomy, and coronary artery bypass grafting (CABG).

Nelson, Wasson, & Krik (1987) proposed another approach to understanding patient outcomes and to ultimately improve the quality of health care services. The authors discussed four primary treatment outcomes: functional outcomes (functional health status, risk status, and well being); clinical outcomes (mortality, morbidity, and complications); patient satisfaction (perceived benefit of care); and costs (health care and social expense). Finally, Wilson & Cleary (1995) and Rejeski, Brawley, & Shumaker (1996) discussed additional outcome models, which also seek to better inform clinicians of the importance and need for measuring patient outcomes.

Although these models may differ in terms of classifying outcomes, there is a central component that binds the previously mentioned literature. In an attempt to define outcomes, the authors (clinicians and researchers) have developed models and frameworks that center on quality of care and include the assessment of patient perceived quality of life. Inevitably, the importance of assessing patient's health related quality of life before and after health care services becomes quite evident throughout the outcomes-based literature.

Why is Outcomes-Based Research Needed

The importance of using health care outcomes as major indicators of the quality of medical care in both clinical decision making and policy decision making dates back to as early as the turn of the 20th century. Codman (1914) believed the study of health care outcomes was "a means to improved quality of patient care". Although this early concern for outcomes has remained quite evident through the years, the structure of health care is not as certain.

According to a report by the U.S. Department of Health and Human Services (1995), an economic evaluation revealed that between 1960 and 1992, health care costs increased an astounding 2,160% per capita. Subsequently, within any given health care institute, cardiac care services are constantly competing for the same limited resources. As a result, Oldridge (1997) suggests that methodologies for measuring outcomes before

and after cardiac treatments needs to be continually developed in order to give some order to courses of action and to prioritize the use of limited funds and resources.

Aside from the restructuring of health care, it is also the changing patient demographics of those seeking treatment that lends further need for outcomes-based research (Herbert, 1996). For instance, the "average" population of patients undergoing invasive cardiac procedures, such as CABG, is changing in terms of age, sex, race, educational level, financial status, etc.

UNDERSTANDING THE OUTCOME OF HEALTH RELATED QUALITY OF LIFE

Defining Health Related Quality of Life

As previously mentioned, the importance of evaluating traditional health care outcomes has been well documented. Furthermore, recent developments in the literature underscores the importance of evaluating patient-perceived health related quality of life (HRQL) as a primary outcome measure of the quality of health care services. The National Institute of Health now mandates that HRQL be evaluated in most clinical trials. Likewise, the Food and Drug Administration accepts HRQL measures in the approval of certain treatments (Rejeski et al., 1996).

Over the years, a number of definitions have been proposed to clarify the meaning of HRQL (Patrick & Erickson, 1993; Testa & Simonson, 1996; and Schipper, Clinch, & Olweny, 1996). It was only until recently that one definition, in particular, has been agreed upon by many clinicians and researchers. Schipper et al. (1996) states that HRQL "represents the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient." Additionally, Patrick & Erikson (1993) believe that HRQL is modified by factors such as physical and/or mental impairments, function, stress, perceptions, and social opportunities. Patrick & Erikson also state that factors such as disease, injury, treatment, and administrative policy help to influence HRQL.

When coming to accept one definition of HRQL over another, Guyatt, Feeny, & Patrick (1993) point out that it is important to take note of the fact that the "boundaries of a definition usually depend on why one is assessing this health outcome as well as the particular concerns of patients, clinicians, and researchers".

Why Measure Patient-Perceived HRQL

Though cardiovascular disease remains the single leading cause of death in the U.S. today, the Department of Health and Human Services (1994) estimated a 52% decrease in mortality between 1950-1993 from cardiovascular disease. According to Oldridge et al. (1998), an increase in such survival rates translates to more individuals being left with some form of disability, a decrease in HRQL, or both.

As noted earlier, the literature has emphasized the importance of studying HRQL to aid clinicians, researchers, and policy-makers towards better decision making. However, in their examination of clinical and sociodemographic characteristics which predict HRQL, Oldridge et al. (1998) discussed the need for such research from a patient point of view. The authors state, "Patients generally make decisions about their health care by estimating the effects of outcomes important to themselves such as survival and HRQL rather than measures such as lipoprotein levels, blood pressure, and the electrocardiogram. They then compare intervention outcomes in terms of both benefits and harms, and finally decide whether or not those outcomes are worth the costs."

In their review of literature, Guyatt et al. (1993) also discussed the value of assessing HRQL from the patient standpoint. The authors stated that while the observation of certain physiologic measures provides valuable information to the clinician, these are of limited concern to the patient. Guyatt et al. (1993) further justified the need for measuring HRQL by explaining the "commonly observed phenomena" that any two given patients with the same clinical criteria often have dramatically different responses to the treatment or intervention. In a review of literature on outcome assessment, Oldridge (1997) summarized the need for HRQL research quite

simplistically by explaining that HRQL research is an attempt to identify what works best for all of those involved in health care decision making.

MEASURING HRQL IN A PATIENT POPULATION

Selecting a HRQL Instrument

The outcomes-based literature is in accordance in terms of demonstrating the need for evaluating HRQL as a primary outcome measure for patient interventions. Likewise, when it comes to determining which instruments to use when measuring HRQL in patients, the rationale behind what constitutes a "good" instrument remains fairly universal and consistent throughout the literature. The decision about which instruments to use in a practical setting is dependent upon the structure of the instruments, their classes, purposes, properties, and interpretability.

Structure of HRQL Instruments

Some HRQL instruments consist of a single question in regards to a patient's quality of life. More commonly, however, instruments are in the form of questionnaires aimed at evaluating the multidimensionality of the HRQL construct. For instance, questionnaires consist of many items that make up a number of domains such as physical, emotional, social functioning, self-care, and pain. A domain refers to the area of behavior or experience that is attempting to be evaluated (Guyatt et al., 1993).

Classes of HRQL Instruments

Typically, HRQL instruments are classified as either generic or specific. Generic instruments seek to measure HRQL across a broad spectrum of patient populations, diseases, and interventions. These instruments are usually multidimensional. According to Oldridge (1997), generic instruments that cover one HRQL domain are called *single-indicator instruments*. Such instruments may include concepts like mortality rate, symptoms, and impairment. *Health profiles* measure different aspects of HRQL and allow comparisons of various diseases. Finally, *health state preference instruments* measure choices which patients can express as being important and can reflect the desirability of a given treatment outcome.

Specific instruments seek to measure HRQL in populations with distinct conditions, diseases, and symptoms. The use of specific instruments, Oldridge (1997) believes, makes sense to both respondents and health professionals; and minimizes burden on the respondent.

Purposes of HRQL Instruments

Measures of HRQL are commonly developed with one of two goals in mind; to be discriminative or evaluative. First, the instrument may attempt to differentiate between patients according to their condition or treatment. For instance, distinctions can be made about which patients will have a better HRQL from those who will have a diminished HRQL. Guyatt et al. (1993) refers to these instruments as *discriminative* and sites an example, "If we want to discriminate between those with and without thyroid disease, we would be unlikely to include fatigue as an item because fatigue is too common among people who do not have thyroid disease."

According to Oldridge (1997), a HRQL instrument should be *evaluative*. It should measure how much HRQL has changed over time. "If the objective of the study is to determine improvement in HRQL," Oldridge questions, "is the instrument sufficiently sensitive to detect the small, but clinically, significant changes that frequently occur as a result of [an intervention]?"

Properties of HRQL Instruments

A favorable HRQL instrument must meet standards of validity, reliability, responsiveness, and interpretability (Pashkow et al., 1995; Testa & Simonson, 1996). *Validity* refers to the degree that the instrument measures what it was designed to measure. Among outcomes-based research, validity is typically determined by comparing the results from one instrument to those of a criterion standard (Guyatt et al., 1993).

Reliability refers to the reproducibility of an instrument when it is administered repeatedly. Reliability can also refer to the extent of error that the instrument presents. In other words, does the instrument produce the same results time and time again (stability

reliability)? Also, is the instrument able to distinguish between varying persons (internal consistency reliability)? A reliable HRQL instrument should consistently demonstrate approximately the same responses when evaluated repeatedly among patients with a stable HRQL.

The *responsiveness* of an instrument is of particular interest to those clinicians seeking to evaluate HRQL over the course of a treatment. Responsiveness refers to an instrument's ability to detect a change in HRQL (or a particular domain), even if that change is minimal. Guyatt et al. (1993) state that responsiveness will be "directly related to the magnitude of the difference of scores in patients who have improved or deteriorated and the extent to which patients who have not changed provide more or less the same scores."

Finally, in a review of outcome assessment, Oldridge (1997) discussed the concept of a "minimal clinically important difference" in reference to the *interpretability* of a HRQL instrument. The author asked, "Does a change in the score over time represent trivial, small, moderate, or large improvement or deterioration in how the person feels?"

In an attempt to determine a minimal important change in a quality of life questionnaire, Juniper, Guyatt, Willan, & Griffith (1994) allude to the simplicity of determining statistical significant changes in HRQL. They mentioned, however, "placing the magnitude of these changes in a context that is meaningful for health professionals has not been so easy." The authors developed a global rating of change to classify patients according to whether they had improved or deteriorated. Patients were simply asked, "Since your last clinic visit, has there been any change in activity limitation, symptoms, emotions, etc?" If patients indicated that there had been no change, they were given a score of "0"; if patients indicated that they had gotten a great deal worse, or better, they were given a score of a "-7", or "7", respectively. It is important to note that the concept of a clinically significant change in HRQL becomes most important when interpreting study results and applying those results to health care decision making.

Instruments Commonly Used to Measure HRQL

In a review of outcome assessment in cardiac rehabilitation programs, Pashkow et al. (1995) presented information on some of the most widely accepted, valid, and reliable instruments used to measure HRQL, or selected domains of HRQL, in coronary disease populations. As mentioned earlier, it is important for clinicians to decide which instrument(s) to use based on their particular assessment needs.

Below is a list of selected instruments commonly used to measure HRQL, particularly the physical and mental health domains of HRQL. This information was modified after Pashkow et al. (1995).

Instrument	*Acronym*	*Number of Items*	*What is Measured*
Medical Outcomes Study Short Form	MOS SF-36	36	Physical, psychological and social functioning
Nottingham Health Profile	NHP	45	Energy, pain, emotion, sleep, mobility, social isolation, and ADL
Sickness Impact Profile	SIP	136	Physical, psychological, and five independent factors
Quality of Well-Being Scale	QWB	18-62	Mobility, physical activity, social activity, self care, and symptoms
Illness Effects Questionnaire	IEQ	20	Biologic, psychological, and social aspects
Minnesota Living With Heart Failure Questionnaire	LHFQ	21	Physical, socio-economic, and psychological impairment
The New York Heart Association	NYHA	4	Physical activity performance functional classification

The Specific Activity Scale	SAS	5	Activities of daily living
Duke Activity Survey Index	DASI	12	Functional status
Human Activity Profile	HAP	105	Activity level
Hopkins Symptom Checklist-revised	SCL-90-R	90	Nine subscales, i.e., somatization depression, anxiety, and hostility
Beck Depression Inventory	BDI	21	Depression and mood state
State-Trait Anxiety Inventory	STAI	40	Anxiety
Profile of Mood States	POMS	65	Various mood states (e.g., tension, anger, depression, confusion

Instruments Selected for the Current Study

This section is intended to provide valuable information regarding three instruments, which were selected for the current investigation. The MOS SF-36, BDI-II, and VSAQ questionnaires seek to measure the physical and/or mental health domains of HRQL among patient populations. The following brief descriptions will focus on issues such as development, purpose, item selection, limitations, scoring, reliability, and validity for the given instruments.

Medical Outcomes Study Short Form 36-Item

The Medical Outcomes Study Short Form (MOS SF) health survey was developed by Tarlov et al. (1989). The Medical Outcomes Study was a 2-year observational study designed to help clinicians better understand how specific components of the health care system affect outcomes of care. To this end, one of the main objectives of the study was "to develop more practical tools for monitoring patient outcomes, and their determinants, in routine practice," (Tarlov et al.). Thus, a 20-item short form (MOS SF-20) was administered to 11,336 MOS participants. Through the accumulation of considerable research, this health survey continued to be refined, resulting in the current 36-item short form (MOS SF-36) (Ware & Sherbourne, 1992).

The MOS SF-36 is referred to as a generic measure of HRQL because it assesses health concepts that represent basic human values which are relevant to everyone's functional status and wellbeing (Ware, 1993). Eight concepts of health, or health related quality of life, are measured by the MOS SF-36: General Health Perception, Bodily Pain, Energy/Fatigue, Physical Functioning, Social Functioning, Mental Health, Role Physical, and Role Emotional. Each of the eight scales consists of 2-10 items, which are then computed independently resulting in total scores ranging from 0-100. The lower the total scores, the more suggestive of a diminished HRQL; the higher the total scores, the more suggestive of an enhanced HRQL. It is important to note that the eight dimensions are not compiled together, but evaluated as eight distinctive constructs of one's HRQL.

The MOS SF-36 has been the focus of numerous investigations in terms of its relative performance, validity, reliability, and sensitivity (McHorney, Ware, Rogers, Raczeck, & Lu, 1992; McHorney, Ware, & Raczeck, 1993; McHorney, Ware, Lu, & Sherbourne, 1994; Katz, Larson, Phillips, Fossel, & Liang, 1992; Haley, McHorney, & Ware, 1994; Stewart, Hays, & Ware, 1988; and Andresen, Patrick, Carter, & Malmgren, 1995). McHorney et al. (1994) performed tests of data quality, scaling assumptions, and reliability of the MOS SF-36 with 3,445 patients differing in societal characteristics, diagnoses, and disease severity . Diagnoses consisted of hypertension, diabetes, CHF, recent MI, clinical depression, and symptomatic depression. The severity of patient's conditions was classified as being an uncomplicated or complicated medical condition, psychiatric and uncomplicated medical condition, or psychiatric and complicated medical condition. On average, the survey was complete enough to compute scale scores for more than 96% of the sample. Across patient groups, item-internal consistency and item-discriminant validity passed with 97% and 92% ($r > .40$), respectively. The reliability across diverse patient groups ranged from .65 to .94 (median = .85) among all scales.

It has been reported that the MOS SF-36 has inherent performance constraints, or measurement limitations known as floor and ceiling effects (McHorney et al., 1994; Andersen et al., 1995). For a combined sample of 3,445 patients with varying diagnoses,

McHorney et al. (1994) observed noteworthy floor effects for the Role Physical (24%) and Role Emotional (18%) scales, while substantial ceiling effects were observed for the Role Physical (37%), Role Emotional (56%), and Social Functioning (46%) scales. Finally, moderate ceiling effects were also noted for the Physical Functioning (19%) and Bodily Pain (18%) scales. When broken down by patient subgroups, those with hypertension (n = 2,089) demonstrated substantial floor and ceiling effects for Role Physical (23% and 39%, respectively) and substantial ceiling effects for Role Emotional (65%). Only modest ceiling effects were noted for Physical Functioning and Mental Health (16% and 6%, respectively). Patients having suffered a recent MI (n = 107) demonstrated only modest floor and ceiling effects for Physical Functioning and Mental Health, while moderate to substantial floor and ceiling effects were noted for Role Physical (27% and 31%, respectively) and Role Emotional (17% and 58%, respectively).

Another pivotal investigation performed by McHorney et al. (1993) evaluated the MOS SF-36 under psychometric and clinical tests of validity in measuring the physical and mental health constructs of HRQL. This study demonstrated that the Physical Functioning, Role Physical, and Bodily Pain scales best represented the physical health domain, while the Mental Health, Role Emotional, and Social Functioning scales best represented the mental health domain by achieving strong associations of relative validity ($RV \geq 0.50$). The scales Energy/Fatigue and General Health Perception demonstrated moderate to substantial associations with physical and mental health ($.10 < RV < .50$). As explained briefly by McHorney et al., RV was computed by the ratio of the common-factor variance of each subscale relative to the subscale with the greatest common-factor variance. The common factor variance of each subscale is the square of each subscale correlation. Johnson et al. (1995) compared the reliability and validity of the MOS SF-36 in a population of black and white patients who presented to the emergency room with acute chest pain. The instrument was administered to 1,160 patients. Reliability coefficients were similar among the eight scales, and the internal consistency of each of the eight scales was high for both groups (0.64 – 0.93). The authors concluded that race was not a significant predictor of HRQL in any of the eight subscales.

A critical component of a well accepted HRQL instrument, as mentioned earlier, is its ability to detect clinically significant changes over time (sensitivity). Katz et al. (1992) compared the sensitivities to clinical change in short measures of health status (to include the MOS SF-36) versus a longer, established instrument (Sickness Impact Profile). Sensitivity was expressed as the standardized response mean (SRM) which was calculated as the group mean change in score divided by the individuals' standard deviation of the change score. Physical and global construct SRMs of the short measures ranged from >0.85-1.27 (a higher SRM relates to greater sensitivity to clinical change) and were as large, or larger, than what these authors reported with the Sickness Impact Profile, using the same subjects. The Sickness Impact Profile, however, demonstrated a greater sensitivity to clinical change among the psychological constructs (SRM = 0.75) than did the shorter measures (SRM = 0.55-0.74). The downfall with using the SRM to determine significant changes in HRQL is that it is based on a group analysis. The mean group change score is used for determining the sensitivity of individual change scores for HRQL.

The investigations previously discussed in this section provide evidence to support use of the MOS SF-36 among diverse populations. As a result of such investigations, the MOS SF-36 has become one of the most widely accepted and utilized instruments for measuring HRQL before and after patient treatments. It is important that clinicians and researchers choosing to administer the MOS SF-36 take note of its potential limitations and seek to explore other instruments, which may be just as clinically useful in measuring the physical and mental health domains of HRQL.

Beck Depression Inventory-Second Edition

The Beck Depression Inventory-Second Edition (BDI-II) is *not* for clinically diagnosing depression, yet is one of the most widely used instruments for assessing the presence and degree of depressive *symptoms* in patient populations. The BDI was originally developed in 1961 and later revised in 1979 (BDI-IA). With 30+ years of clinical experience and research with the BDI, the most recent version, BDI-II, reveals substantial changes from the original BDI (Beck, Steer, & Brown, 1996).

The BDI-II is a 21-item self-report instrument designed to assess symptoms corresponding to criteria for diagnosing depressive disorders as found in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV). This differs from the previous seven-item inventory, thereby allowing for a more specific evaluation. The 21-items are rated on a four-point scale (0-3) with total scores ranging from 0-63. According to Beck et al. (1996), BDI-II total scores ranging from 0-13 represent the presence and degree of depressive symptoms which may suggest "minimal" depression; 14-19 may suggest "mild" depression; 20-28 may suggest "moderate" depression; and 29-63 may suggest "severe" depression.

Beck et al. (1996) demonstrated an internal consistency coefficient for the BDI-II of 0.92 for a sample of 500 psychiatric patients. Here, internal consistency refers to an estimate of the reliability that represents the consistency of scores within a test. The method used to estimate the reliability within this population was same-day test-retest. When the BDI-II was administered one week apart to a sub-sample of 26 outpatients, stability reliability was found to be 0.93 ($p < .001$). Demonstrating construct validity, a correlation of 0.93 ($p < .001$) between the BDI-IA and BDI-II was found within a sample of 191 outpatients. Here, construct validity demonstrates the degree to which a test measures a hypothetical construct. Within this sample the test results are related to the DSM-IV. The BDI-II, however, consists of items that more thoroughly evaluate different symptoms of depression based on the DSM-IV. The BDI-II portrays confidence in assessing the presence and degree of depressive symptoms in varying patient groups. This instrument is widely accepted, valid, and reliable, therefore establishing itself as another means for measuring the mental health construct of HRQL among patient groups before and after clinical treatments.

Veteran's Specific Activity Questionnaire

The Veteran's Specific Activity Questionnaire (VSAQ) was developed to predict maximal treadmill performance in patients with coronary artery disease (Myers, Do, Herbert, Ribisl & Froelicher, 1994). The VSAQ was essentially designed to gauge which specific daily activities may be limited due to symptoms commonly associated with

CAD. These activities range from recreational to competitive activities and from self-care to house/yard work activities. Each activity level is organized by increasing difficulty in terms of metabolic equivalents (METs). The activities range from 1-13 METs. Patients limited by CAD symptoms are expected to score within 3-7 METs. Pierson, Callaghan, Cook & Herbert (1998) compared maximal treadmill performance to the VSAQ and found the VSAQ to be quite accurate in estimating MET levels in 71 patients undergoing CABG surgery (actual r = 0.79; age-adjusted r = 0.91).

The VSAQ along with two other activity questionnaires (DASI and SAS) were evaluated on the ability of such instruments to predict functional capacity among 104 cardiac patients (Pitbladdo, Brubaker, Johnston, Collier, Miller, & Rejeski, 1996). Measured METs (MMET) were determined by the peak level of oxygen consumption observed during maximal exercise tests and then correlated with the estimated MET levels achieved with each questionnaire. The VSAQ demonstrated a higher correlation to MMET (r = .62) than did the DASI (r = .59) or the SAS (r = .57).

Myers et al. (1994) state that the preciseness of an instrument such as the VSAQ "depends on individual differences in perception of, familiarity with, and tolerance to similar activities." The VSAQ has been established as a valid self-rating of functional capacity and may provide clinicians and researchers with another means for evaluating the physical health construct of HRQL among patient populations before and after clinical treatments.

MEASURING HRQL IN A SPECIFIC PATIENT POPULATION: INDIVIDUALS UNDERGOING CABG SURGERY

As suggested by earlier sections of this review, there exists a myriad of clinical investigations that seek to evaluate the use of HRQL instruments in various patient groups. The objective of this section of Chapter II is to introduce the reader to the instrumentation used to assess patient perceived HRQL, especially its physical and mental health domains, in a specific patient group.

General Description of Coronary Artery Bypass Graft Surgery

The surgical reconstruction of blocked arteries is known as coronary artery bypass grafting (CABG). This procedure is performed in order to restore the blood supply to the heart muscle by creating a new route, via a bypass, for the blood to flow around the blockages (Levinson, 1995). According to the American Heart Association (1997), CABG remains the most common form of open-heart operations performed in the U.S. today. In fact, in 1995 almost five times as many CABG procedures (573,000) were performed compared to any other open-heart procedure.

The primary objective in performing CABG is to bring about relief from symptoms related to CAD, such as angina and dyspnea (Engblom, Korpilahti, Hamalainen, Ronnemaa, & Pukka, 1997; Sjoland et al., 1997; Duits, Boeke, Taams, Passchier, & Erdman, 1997; Ayanian, Guadagnoli & Cleary, 1995). Furthermore, improvements in surgical techniques and perioperative care has significantly reduced the risk of patient mortality associated with CABG procedures (Jaeger, Hlatky, Paul, & Gortner, 1994; Duits et al.).

Common Outcomes Measured in CABG Patients

The effects of CABG have typically been evaluated in terms of length of hospital stay, morbidity, mortality, complications, hospital costs, test results, survival rates, and rates of return to work. Even long term follow up studies on rates of graft closure have been reported (Alderman, 1996). To date, numerous investigations have focused their attention on outcomes such as those mentioned above (Shapira, Isakov, Yakinevich, & Topilsky, 1995; Peterson, Cowper, Jollis, Bebchuk, & Delong, 1995; Mick, Simpfendorfer, Arnold, Piedmonte, & Lytle, 1991; Katz & Chase, 1997; Merrill, Stewart, Frist, Hammon, & Bender, 1989). Although these evaluations are important and provide valuable information to clinicians, the studies lacked adequate assessment of patient perceived outcomes.

In their review of quality of life in CABG patients, Duits et al. (1997) emphasized the importance of assessing outcomes in terms of "patient's perceptions of changes in

their state of health over time and how this effects their lives; in other words, assessing the health related quality of life." Similar concerns for evaluating the physical and mental health domains of HRQL in patients undergoing CABG have been addressed in studies by Jenkins, Staton, Savageau, Denlinger, & Klein (1983), Guadagnoli, Ayanian, & Cleary (1992), Sjoland et al. (1997) and Chocron et al. (1996).

Instrumentation and Measurement of HRQL in CABG Patients

The evaluation of HRQL among patient treatments is notably limited in the published clinical research. However, the limited number of studies which have investigated HRQL in patients before and after coronary revascularization, such as CABG, demonstrate significant overall improvements in patient perceived health status (Jaarsama, & Kastermans, 1997; Hoad & Crawford, 1990; Engblom et al., 1997; Sjoland et al., 1997; Chocron et al., 1996). The means for evaluating HRQL in the above-mentioned studies varied from a single-item survey to a more comprehensive instrument such as the Nottingham Health Profile (NHP). None the less, patients' perceived functional abilities, limitations, and roles associated with physical and mental health were enhanced as a result of CABG.

A majority of the literature related to the effects of CABG tends to focus not on HRQL, as a whole, yet on the physical and/or mental health impact on the patient. For instance, in the study of CABG patients aged 80+, Merrill et al. (1989) assigned each subject a New York Heart Association (NYHA) functional classification before and after surgery to determine changes in levels of physical activity. The authors concluded that the patients' functional capacity was enhanced as seen by improvements of all subjects by one to two functional classes.

Glower et al. (1992) evaluated the activity levels of 86 CABG patients (age 80-93 years) preoperatively and at discharge. Performance levels were assessed using the Karnofsky scoring system. These scores demonstrated a ≥ 20% increase in activity level for 89% of the survivors at discharge. Mean Karnofsky scores of 27%, at baseline, suggest that the patient needs institutional care, and 60%, at discharge, suggest that the

patient needs some help but is at home and can care for most personal needs. These results suggest an overall improvement in functional status.

Self-reported functional capacity was assessed with use of the Duke Activity Status Index (DASI) in 199 patients (aged 70-91) preoperatively and 1 year following CABG (Jaeger et al., 1994). The authors reported improvements in functional capacity among 74% of the subjects. DASI scores increased from 27.9 at baseline to 36.8 at 12 months ($p < 0.001$) with 58.2 being the highest possible score. According to Jaeger et al., this improvement is equivalent to a significantly higher exercise tolerance allowing for moderate exertion. These improvements in DASI scores, for instance, might reflect an individual's ability to perform activities such as stair climbing or recreational activities after CABG surgery (approximately 4-6 METs). Sjoland et al. (1997) assessed the physical health status in 2,121 CABG patients at four intervals: preoperative, 3 months, 1 year, and 2 years, postoperatively. The Physical Activity Score was used as a self-estimate of physical abilities and limitations and represents one dimension of an angina-specific questionnaire. A lower score suggests a higher estimation of physical abilities and fewer limitations. Significant improvements were reported with mean Physical Activity Scores of 4.3 preoperatively, 3.1 at 3 months postoperatively, and 2.8 at 1 and 2 years postoperatively ($p < 0.0001$).

A number of investigations have evaluated patients' perceptions of their physical functioning and limitations through the assessment of instrumental activities of daily living (IADLs) (Ayanian et al., 1995; Guadagnoli et al., 1992; Allen, Fitzgerald, Swank, & Becker, 1990). In these three investigations, self-administered surveys were used to evaluate patients' ability to perform IADLs such as stair climbing, shopping, housework, yardwork, driving a car, etc. Substantial increases were noted for all subjects in their abilities to perform IADLs up to 1 year following CABG surgery.

The available published outcomes-based research is replete with studies that have evaluated the physical health domain of HRQL before and after CABG surgery. Published studies that have evaluated the mental health domain are just as numerous.

Similarly, patient perceived mental health, or emotional functioning, can be evaluated with various HRQL instrumentation.

Sjoland et al. (1997) estimated quality of life, to include mental health, before, 3 months, 1 and 2 years following surgery in 244 CABG patients, with or without hypertension. The Psychological General Well-Being Index is a 22-item survey dealing with six assessments of well-being to include factors such as anxiety, depressed mood and vitality. Total scores range from 22-132 with the higher value corresponding to superior mental well-being. Significant improvements in the Psychological Well-Being Index were noted for both hypertensive and non-hypertensive patients at each interval following CABG. The improvement, however, was more marked for the hypertensive patients at 3 months (baseline 89.2; 3 months 101.5; $p < 0.05$) than non-hypertensive patients (baseline 91.3; 3 months 103.8; $p < 0.05$).

A five-item scale adapted from the Functional Status Questionnaire (FSQ) was used to evaluate perceived mental health, before and after CABG, in two studies, one by Allen et al., 1990 and another by Guadagnoli et al., 1992. The FSQ was designed to screen for physical disability and to monitor clinically meaningful changes in ambulatory care patients. Total scores on the FSQ range from 0 to 100, with 100 indicating maximal functional ability in the areas of IADL, mental health, social activity, and work performance. Guadagnoli et al. compared patient reported outcomes before and 6 months after CABG in patients ≥ 65 and < 65 years (n=99). The authors reported improvements in mental health for both age groups, however, the older patients demonstrated significantly better functioning than the younger subjects (≥ 65 group = 77.5; <65 group = 73.3; $p < 0.05$). Allen et al. compared the functional outcomes of PTCA (n=64) and CABG (n=106) patients 1, 6 and 12 months following the procedure. Similarly, Allen et al. noted significant improvements in mental health scores one year after the procedure (CABG baseline = 61, 12 months = 82; PTCA baseline = 67, 12 months = 77; $p = 0.0001$). Patients in the CABG group, however, estimated their mental health to be better than those in the PTCA group at each interval.

Finally, Timberlake et al. (1997) evaluated patterns of depression for 8 days, 8 weeks, and 12 months following CABG in 121 patients (mean age 56 years) using the 21-item BDI as an indicator of clinical depression. With the cut-off point being a score of ≤ 9 (associated with "minimal" depression), the authors reported 37% of patients were found to be depressed preoperatively. By 8 days, 50% were depressed, by 8 weeks the figure decreased to 24%, and by 12 months only 23% of the patients were depressed.

SUMMARY

The literature presented in this review indicates the current need for evaluation of HRQL in those individuals who are provided with health care services. More specifically, patient-perceived physical and mental health status should be assessed before and after treatments such as CABG. With restructuring of the health care system and changing patient demographics, such evaluations provide valuable decision-making information not only to clinicians, researchers, and policy makers, but to the patients as well.

Countless instruments used to measure HRQL are reported throughout the literature. Some of the most widely accepted instruments differ in terms of their structure, class, purposes, properties, and interpretability. Therefore, clinicians must base their instrument selection on their particular assessment needs. For the current investigation, the MOS SF-36, BDI-II, and VSAQ were selected to measure physical and/or mental health in patients undergoing CABG. The MOS SF-36 has been administered under numerous conditions and to diverse patient groups, yet bears substantial limitations. Investigations with the BDI-II and VSAQ among patient groups, although scarce, provide evidence for their clinical use in evaluating treatment outcomes.

This review introduced the reader to the instrumentation currently being used to assess HRQL in patients undergoing CABG. Nearly all of the studies reported improvements in health status as a result of CABG, as measured by the various instruments. To date, however, there exists no study which has investigated the comparative performance of the MOS SF-36, BDI-II, or VSAQ in measuring the physical and/or mental health status of patients before and after CABG.

Chapter III

JOURNAL MANUSCRIPT

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MEASURING CHANGE IN KEY HRQL OUTCOMES USING MOS SF-36 SUBSCALES VS VSAQ AND BDI-II WITH PATIENTS UNDERGOING CABG SURGERY

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(ABSTRACT)

Health-related quality of life (HRQL) measures taken before and after coronary artery bypass grafting (CABG) aid in determining meaningful patient-perceived outcomes associated with alternative clinical interventions. This study compared the results of the Medical Outcomes Study Short Form-36 (MOS SF-36) subscales for Physical Functioning (PF), Role Physical (RP), Mental Health (MH), and Role Emotional (RE) with the results of two other questionnaires, i.e. the Veteran's Specific Activity Questionnaire (VSAQ: self-efficacy for vigorous physical activity) and the Beck Depression Inventory (BDI-II: mental-emotional functioning). Seventy-one patients (59-M; 12-F; age, Mean $\pm$ SD = 63 $\pm$ 8.6 years) were administered these three questionnaires just before and 3 months following CABG surgery. Score distributions were evaluated for the pre- and post-surgery measurements, as were change scores after CABG. All measures except the MOS SF-36 subscales for RP and RE showed statistically significant change after CABG ($p<0.01$). Only the subscales of RP and RE demonstrated substantial ceiling (21.0% and 56.3%) and floor effects (49.3% and 16.9%). Evaluation of individual change scores after CABG indicated that 59% and 62% of the patients, respectively, had clinically meaningful increases in the two measures of physical capability, i.e. PF and VSAQ. In contrast, 60% and 72% of patients, respectively, showed no clinically meaningful changes in the two measures of emotional functioning, i.e. RE and BDI-II scores. Chi-square analyses revealed that use of scales with similar definitional constructs resulted in significantly different surgical outcomes for the following: PF vs VSAQ

($p<0.001$), RP vs VSAQ ($p<0.02$); and MH vs BDI-II ($p<0.0001$). These findings illustrate the limitations in performance of the MOS SF-36 for assessing changes of importance in HRQL after CABG. The VSAQ and BDI-II, two simple measures of physical and emotional functioning that are fundamentally similar to those contained in the MOS SF-36, appear to be sensitive markers for detecting changes in these important outcomes after CABG surgery.

INTRODUCTION

In the United States, nearly 14 million people alive today have a history of coronary artery disease (CAD).[1] Although staggering, this statistic exemplifies the vast number of those undergoing coronary revascularizations each year. In turn, the act of making important decisions regarding the outcomes of various interventions for CAD must ultimately incorporate patients' perceptions of how their health and function has changed, as well as through reference to traditional laboratory measures of function or morbidity/mortality outcomes. In other words, assessing a patient's health outcomes, such as perceived daily functioning following a treatment, serves as an integral component in optimizing clinical decision making.

Health-related quality of life (HRQL) measures taken before and after CABG complement traditional outcome measures and aid in determining patient-perceived physical and mental health status.[2] The MOS SF-36, a valid and reliable instrument,[3,4,5,6,7,8] has been administered under numerous conditions and examined in patient groups with diverse cardiac diagnoses.[9,10,11] However, important limitations of the MOS SF-36 have been noted in previous investigations.[5,8] The VSAQ (measures of self-efficacy for vigorous physical activity) and BDI-II (measures mental-emotional functioning) are also valid and reliable instruments which evaluate the physical and mental health constructs of HRQL.[12,13,14] In a validation study, Myers et al. [12] confirm that the VSAQ is a quick, simple, and sound indicator of peak VO_2 in a cardiac population. Beck et al. [14] point out that the BDI-II was built on 35 years of accumulated psychometric data and clinical experience which attributes to its ease in administration, scoring, and interpretation. Although published investigations among cardiac patients using the VSAQ and BDI-II indeed is limited, Myers et al. [12] and Beck et al. [14] provide evidence for their clinical use in evaluating sensitivity to treatment outcomes.

Consequently, this study compared the results of the MOS-SF-36 subscales for Physical Functioning (PF), Role Physical (RP), Mental Health (MH), and Role Emotional (RE) and the results of the VSAQ and BDI-II among patients just before and 3 months following CABG surgery. Specifically, comparisons of various performance measures

were evaluated; magnitude and direction of change for the group were analyzed; concordance of change scores on an individual basis was determined; and clinically important changes were quantified.

METHODS

The pool of potential subjects consisted of all patients admitted to Carolinas Medical Center in Charlotte, NC for CABG between November 1996 and December 1997 (N = 904). Recruitment took place between 1 and 7 days prior to surgery. To be included, patients must have been undergoing first time CABG, must have been >45 years of age, not undergoing any other concomitant cardiovascular surgery, and not exhibiting evidence of cognitive-emotive disorder that would preclude completion of HRQL instruments. Consecutive patients who met the above criteria and agreed to participate in the study made up the subject pool (N = 200). A subset of 71 patients (59 males; 12 females; mean age = 63 ± 8.6 years) who completed the pre-surgical and 3 month post-surgical battery of HRQL questionnaires was selected from the subject pool for this investigation. The primary reason that more than half of the patients included in the pool were not selected for this investigation was the inability of patients to complete the three-month follow-up. It is important to note that 14% of the subjects selected for this investigation did not return to the medical center for the follow-up, yet completed each of the three questionnaires via mail. Clinicians, therefore, must realize that this small group of patients may have differed substantially from the rest of the subjects in terms of their pattern of outcomes.

In general, the patients making up the subject pool were quite unhealthy. For instance, before surgery, the average NYHA classification was III and the average ejection fraction was only 46%. The 71 subjects selected for this investigation were, however, typical of other patients undergoing first time CABG at Carolinas Medical Center during the time of recruitment. In order to determine significant differences between the research patients (N = 71) and the non-research patients (N = 904) a variety of comparisons were made. Risk factors for heart disease such as gender, positive family history, prior MI, and smoking history, as well diagnoses such as hypercholesterolemia,

PVD, diabetes, COPD, and CHF were evaluated using Chi-Square analyses. No significant differences were found between the two groups for any of the above mentioned risk factors/diagnoses. Likewise, the subjects were comparable to patients in other CABG studies.[15, 16]

The MOS SF-36 is a generic instrument that was used in this study to measure eight components of HRQL.[17] For the purpose of this investigation, however, only the two physical health (Physical Function = PF; Role Physical = RP) and two mental health (Mental Health = MH; Role Emotional = RE) subscales were evaluated. Each of these subscales consists of 3-10 items. When computed independently, the subscales result in total scores ranging from 0-100 with low total scores indicative of diminished HRQL and higher scores suggestive of an enhanced HRQL. The BDI-II is a 21-item instrument designed to assess the presence and degree of depressive symptoms in patient populations.[14] The BDI-II items are rated on a four-point scale (0-3) with total scores ranging from 0-63 points. According to Beck et al.[14] total scores ranging from 0-13 suggest minimal depression; 14-19 mild depression; 20-28 moderate depression; and 29-63 severe depression. The VSAQ was designed for CAD patients to gauge which daily activities may be difficult or impossible for them to perform.[12] These activities range from recreational to competitive and from self-care to house/yard work activities. Each activity level is organized by increasing difficulty in terms of metabolic equivalents (METs). The activities range from 1-13 METs.

All statistical analyses were performed with JMP Start Statistics software (SAS Institute Inc.; Cary, NC; 1996). Once scaling characteristics, measures of central tendency and variability were determined, Spearman Rho correlations were performed on pre- to post-surgery change scores to establish levels of agreement between the MOS SF-36 subscales, and the VSAQ or BDI-II. All change scores were also tested for significance using Wilcoxon Signed-Rank test for related samples. Correlations between 3 month post-CABG VO_2 peak data versus 3 month post-CABG VSAQ, PF, and RP were also determined among a subset of 51 subjects. Finally, standards were established for clinically meaningful changes in each measure and then the distributions of change in

classifications after CABG were analyzed for degree of concordance between definitionally-like measures were performed using Chi-square analyses. To determine the level of agreement above that of chance, Kappa values were also established. The level of statistical significance was set at $p<0.05$ for all analyses.

RESULTS

Clinical characteristics of the sample are displayed in Table I as percentages of the 71 subjects with known risk factors or diagnoses prior to CABG. It is important to note that the occurrence of angina in patients before CABG was greater than any other risk factor or diagnoses (87%). Therefore, angina may demonstrate an unknown influence on this investigation. For instance, when assessing physical functioning, results may have differed between patients who did not suffer from symptoms of angina, as opposed to those patients whose symptoms of angina were either sudden onset or progressively worsened. Table II presents means for the MOS SF-36 subscales, VSAQ, and BDI-II scores at the pre-surgery and 3 months post-surgery intervals, as well as for change scores. Patients scored higher on the MH subscale at pre-surgery (77.3) than on the PF, RP, or RE subscales. Likewise, post-surgical mean scores for MH were also higher (80.6). Patient-estimated MET levels, as measured by the VSAQ, were relatively low for both pre-surgery (4.4) and post-surgery (5.9) intervals. The BDI-II mean scores demonstrated a minimal degree of depressive symptoms in patients before and 3 months after CABG (7.9 and 5.8, respectively). It is important to note that these values are raw scores, not percentages of patients with depressive symptoms.

The VSAQ and PF subscales demonstrated statistically significant pre- to post-surgery change scores ($p \leq 0.01$) with mean change scores of 1.5 and 14.1, respectively. On the other hand, change scores for RP and RE were not statistically significant from pre- to post-surgery. Figure I illustrates the extent to which changes after CABG among definitionally similar measures were significantly correlated. Post-CABG change scores for the MOS SF-36 subscales (PF and RP vs the VSAQ; and MH and RE vs the BDI-II) were significant ($p < 0.05$). The highest correlation coefficient ($r = .58$) was demonstrated for change in MH vs change in BDI-II. Despite definitional similarity of such measures

as MH and BDI-II, there is a considerable degree of unexplained variance between the measures. For example, the above-mentioned correlation of r = .58 accounts for only 34% of explained variance (r^2 = .34) therefore, 66% of the variance is unexplained (1 - r^2 = .66). The same holds true for measures taken pre- and post-surgery. For instance, a pre-surgery correlation of r = .61 for VSAQ vs PF, demonstrates that greater than one-third (37%) of the performance of one scale is associated with, or explained by, the factors involved in the performance of the other scale. Attributing to this variance may be the fact that a patient will read the instructions, read the items, attach a particular meaning to the measure, and will then proceed to a definitionally similar construct and interpret that measure as something different. The MOS SF-36 subscales demonstrate known limitations and given the amount of variance that is unexplained between these subscales and definitionally similar measures, added weight can be given to the VSAQ and BDI-II to suggest they may be better measures of physical and mental health before and after CABG.

The percentages of subjects who were classified as having increased, decreased, or demonstrated no change in HRQL following CABG are displayed in Figure II. A brief explanation of the rationale used to establish these clinically meaningful changes will be discussed later. A majority of the subjects demonstrated improvements in their perceived physical functioning, as assessed by the PF subscale (59%) and the VSAQ (62%). It is important to note the high percentage of patients who reported neither an increase nor a decrease in their mental-emotional functioning as assessed by the MH subscale (60%) and the BDI-II (72%). Finally, as seen in Table III, Chi-square analyses revealed significant differences between the distribution of classifications of change for PF vs VSAQ ($p < 0.001$); RP vs VSAQ ($p \leq 0.02$); and MH vs BDI-II ($p < 0.0001$). Kappa values of .22-.37 demonstrate that the above mentioned differences are greater than expected to occur due to chance alone (.81-1.00 would be an almost perfect strength of agreement).

DISCUSSION

Prior to administering a HRQL instrument, clinicians must first critically evaluate the overall performance of the selected instrument. Katz et al.[6] suggest that such an instrument be evaluated in terms of its appropriateness for specific populations and assessment needs, established validity and reliability, and in particular, its ability to detect clinically significant changes as a result of an intervention. Since its development, the MOS SF-36 has become one of the most widely accepted HRQL instruments used in clinical settings. The MOS SF-36 is short, efficient, and easy to understand, score, and interpret. Despite these favorable attributes, the MOS SF-36 has been shown to demonstrate substantial floor and ceiling effects. [5,8] These inherent limitations may decrease the instrument's ability to detect clinically significant changes following a treatment. To date, we can find no published evidence comparing the results of the MOS SF-36 subscales with other physical and/or mental health questionnaires that have favorable psychometric properties and have proven clinically useful with cardiac patients.

Pre- to post-surgery mean scores revealed an 8% and 14% increase in RP and PF subscales, respectively. However, the RE and MH subscales demonstrated only 1% and 3% increases for pre- to post-surgery mean scores. Furthermore, mean change scores for PF and MH were significant at the $p < 0.01$ level, while RE and RP were not. Recall that following CABG, a majority of patients were classified as having improved in physical functioning as measured by the VSAQ and PF subscale (62% and 59%, respectively), while a high percentage of patients were classified as neither increasing nor decreasing in mental-emotional functioning as measured by the BDI-II and MH subscale. It is possible that those measures that did not demonstrate much change in mean values or classifications (MH, RE, BDI-II) may be, by definition and meaning, of less importance to the individual patient.

On the other hand, minor increases in the physical and mental health roles (RE and RP) can also be attributed to significant limitations with the subscales; moderate to high floor and ceiling effects. Figure III displays the percent of patients demonstrating ceiling and floor effects for each of the instruments. Coefficients of Variation (CV) are

also presented for each instrument at pre- and post-CABG intervals. RP and RE demonstrated moderate to high floor effects (49.3% and 16.9%, respectively), as well ceiling effects (21.1% and 56.3%, respectively). The VSAQ and BDI-II showed no ceiling effects and only modest floor effects (5.6% and 4.2%, respectively). Subsequently, these particular subscales may not display a true representation of the patients potential to improve in these aspects of perceived HRQL. These data suggest scaling characteristics that contribute to the poor sensitivity of measures such as RP and RE. Along with ceiling and floor effects, calculations of CV (SD/Mean) add a simple index of variability in the distribution of scores to help explain why some measures performed better than others did. For instance, MH demonstrates low pre-surgical variability, or SD (± 14.5), and a high pre-surgical mean (77.3), therefore CV would be low (.19). Likewise, VSAQ demonstrates relatively high pre-surgical variability (± 2.4) and a low pre-surgical mean (4.4), therefore CV would be higher (.55). When comparing measures of HRQL, as in the present study, if a measure exhibits a high reliability coefficient as well as a high CV, it is the preferred measurement tool. Therefore, at the pre-surgical interval, VSAQ and BDI-II prove to be the better measures over PF and MH, respectively.

When testing the reliability of the MOS SF-36 across diverse patient groups, McHorney et al.[5] also reported significant floor and ceiling effects. Analyses were conducted among 3,445 patients varying in sociodemographic characteristics, diagnoses, and disease severity. Patients responded to MOS SF-36 at one given point in time. Their results displayed patient scores affected by floor effects of less than 2% for all subscales except RP and RE which showed 24% and 18%, respectively. Substantial ceiling effects were also noted for RP (37%) and RE (56%) while only rare to modest ceiling effects were noted for the other subscales.

One explanation for the moderate to high floor and ceiling effects, as well as the statistically insignificant pre- to post-surgery change scores noted in this investigation, may be due to the sheer number of items (or questions) pertaining to each subscale. For instance, even though each subscale of the MOS SF-36 is scored from 0-100, RE and RP

consist of only 3 or 4 items, allowing for only 4 or 5 possible total scores, respectively. In other words, a patient responding to items in the RE subscale will only be scored 0 or 33.3 points for each item answered, allowing for a total possible score of 0, 33.3, 66.7, or 100 points. Similarly, a patient responding to items in the RP subscale will only be allotted 0 or 25 points for each item answered, therefore the total possible scores are 0, 25, 50, 75, or 100 points. Inevitably, these scales will demonstrate significant floor and ceiling effects. On the other hand, the PF and MH subscales were developed with 10 and 5 items allowing for 21 and 26 possible total scores, respectively. Another dimension to the floor and ceiling limitation is the inability of the items in RP and RE to discriminate between various physical and mental health states. For example, patients forced to choose a "0" score may actually perceive themselves to be at different levels in a comparative sense, but the descriptors for the available choices don't allow them to be separated. With 56.3% of the patients scoring the highest possible score in RE, it is impossible to determine whether or not those patients perceive themselves at different mental states. Likewise, because of the limited possibility of total scores associated with the RE subscale (0, 33.3, 66.7, or 100), the 27% of patients who fall in the middle (neither floor nor ceiling) also can not be separated by varying mental health states.

The VSAQ and BDI-II were sensitive for detecting changes in physical and mental health states with patients undergoing CABG surgery. Highly significant change scores were reported for the instruments ($p < 0.01$). The mean change score for the VSAQ (1.5 METs) reflected a clinically meaningful increase in patient-perceived performance capacity for daily physical activities, or a decrease in the symptoms of CAD which may have limited an individual in performing daily activities. This mean change, for instance, might represent an individual who was limited to light yard work (4 METs) prior to CABG, but being able to sustain such activities as heavy carpentry or mowing the lawn with a push mower (6 METs) after surgery. VSAQ scores were compared to maximal treadmill performance in a subset of 51 patients from this investigation. The VSAQ was found to be quite accurate in estimating VO_2 peak for patients 3 months post-CABG ($r = 0.64$). VO_2 peak was also correlated with other measures of physical functioning such as PF ($r = 0.53$) and RP ($r = 0.2$) at 3 month post-CABG. These

findings may differ slightly from Myers et al. (VSAQ vs VO_2 peak; $r = 0.79$)[12] due to factors such as differences in the populations. For instance, the sample size for the current investigation was much smaller. Patients recruited by Myers et al. were healthier in that they were Veterans referred for diagnostic testing. Only 19% of the patients evaluated in Myers et al. had undergone previous CABG, they demonstrated fewer comorbidities, and were functionally better off with VSAQ scores averaging 6.3 METs. Pitbladdo et al.[13] demonstrated no significant differences between measured METs determined by GXT (7.9) and the MET levels determined by the VSAQ (8.7) in 104 CAD patients ($r = 0.62$).

As seen in Figure I, correlations between pre- to post-CABG change scores for the MOS SF-36 subscales versus the definitionally similar VSAQ and BDI-II (i.e. pre- to post-CABG change in PF vs pre- to post-CABG change in VSAQ) were statistically significant ($p < 0.05$), but low in general ($r = .24 - .48$). Although these correlations were statistically significant, there was a great deal of variance which could not be explained ($r^2 = .06 - .34$). For instance, only 6% of the variance between pre- to post-CABG change scores in the BDI-II can be attributed to pre- to post-CABG change scores in RE, while 94% of the variance between the two measures can not be explained. These values suggest that the MOS SF-36 subscales may be measuring different aspects of physical and mental health outcomes when compared to the VSAQ and BDI-II. As stated earlier, these differences may relate to the patient's meaning of a measure and, therefore, result in subtle differences in perception of what the measures were constructed to mean.

Individual change scores were classified as being a clinically meaningful increase, decrease, or no change. To aid in determining clinical rationale for classifying these changes, a small group of clinical exercise physiologists were asked to review each MOS SF-36 subscale, VSAQ, and BDI-II and to determine the number of points that reflected a change, they believed, would be considered clinically important. The group consisted of five Master's level exercise physiologists working in either cardiac rehabilitation or cardiac diagnostics.

Each clinician was instructed to first read each item, or question, pertaining to the specific subscale or questionnaire at hand, as well as it's respective responses, in order to gain a better understanding of item definition and meaning. Clinicians were then given the breakdown of scoring for the subscale or questionnaire at hand. It was then suggested to the clinician that he/she consider issues related to the patient's being evaluated. For example, the subjects were undergoing first time bypass surgery, therefore, may display various physical and mental symptoms (angina, chest wall pain, incision pain, anxiety, depression, and fear) before and after surgery. It was also suggested that the clinicians consider responses that may simply be a result of day-to-day chance. Given the factors previously mentioned (item definition and meaning, scoring, patient attributes, and response precision), the clinicians were then asked to determine how much change in point values from the item responses would signify a clinically meaningful change in the patient's HRQL for the particular subscale or questionnaire at hand. To help get at this answer clinicians were asked, for instance, if a change of 5, 10, 15 or 20 points for PF would be considered a clinically significant change in their mind. Also, what would a change of 5, 10, 15 or 20 points mean for a particular patient responding to the PF subscale?

Keeping with PF as an example if a particular patient scores 50 points before surgery and 60 points after surgery that is a change of 10 points. A change of 10 points for PF might represent a patient who before surgery perceived him/herself as being limited a lot in his/her ability to climb several flights of stairs (0 points) and limited a little in his/her ability to lift or carry groceries (5 points). After surgery, however, this patient may perceive his/herself as being limited only a little in his/her ability to climb several flights of stairs (5 points) and not limited at all in his/her ability to lift or carry groceries (10 points). To a clinician, this amount of change may demonstrate a meaningful increase in a patient's quality of life as a result of CABG surgery.

It is important to note that the selected cut-off points were arbitrary and may have dictated the results of this investigation. In other words, opinions for what constitutes a clinically significant may vary from one clinician to another. However, we believe that

the cut-points were, after all, reasonable for this analysis based on the meaning and definitions of the scale items themselves. For instance, when reviewing the VSAQ, clinicians can easily see that there is a substantial difference in the functional capacity of a patient scoring 2 METs before surgery and 3 METs after surgery; or 7 METs before surgery and 6 METs after surgery. Likewise, an increase of 8 points in the MH subscale may reveal a patient who felt downhearted and blue most of the time before surgery, and after surgery felt downhearted and blue only some of the time. Finally, the cut-points for the BDI-II are consistent with a patient who may have been getting very little pleasure from the things he/she enjoyed doing before surgery to getting much pleasure from the things he/she enjoyed doing after surgery.

Once classifications were assigned to each subject for each questionnaire, evaluations of individual change scores demonstrated that a majority of the patients displayed clinically meaningful increases in PF and VSAQ from pre- to post-surgery. A high percentage of patients did not demonstrate clinically meaningful changes in RE and BDI-II (Figure II). The latter findings may be attributed to the idea that emotional functioning was already adequate before surgery. Recall that the patients selected displayed minimal psychological distress both before and 3 months following CABG. Another possibility, as mentioned earlier, is that these patients may not perceive or reasonably expect that CABG would improve their mental functioning. It is also feasible that 3 months is too early for meaningful changes in mental well being to be demonstrated. For instance, other studies demonstrate significant increases in mental health status following CABG, but these have been noted at 6 and 12 months post-CABG.[18, 19]

Chi-square analyses revealed that use of scales with similar definitional constructs resulted in significantly different patient-perceived outcomes (Table III). For instance, a patient classified as having increased in PF may have decreased in VSAQ; or a patient with no change in BDI-II may have decreased in MH. Chi-square analysis tests whether or not an observed association is significantly higher than that expected to occur due to chance alone. However, chi-square analysis does not differentiate between greater than

expected disagreement or agreement. Therefore, the Kappa (K) statistic is used for measurement of observer agreement in nominal scales.[20] Simply put, K corrects for agreement expected by chance, alone. Landis and Koch[21] agree that determining the significance of K can be arbitrary, but have suggested the following guidelines: K values of < 0 - .20 signifies a poor to slight strength of agreement, whereas K values of .21- .40 demonstrates a fair strength of agreement. A substantial strength of agreement for K would be .61-.80 and an almost perfect strength of agreement would reveal $K > .81$.

Therefore, each of the chi-square analyses in Table III demonstrates only a slight to fair strength of agreement. In terms of this investigation, the relationship between the classifications of change for PF vs the classifications of change for VSAQ revealed a significantly higher association than that expected to occur due to chance alone. However, we are only slightly convinced that the association between the measures demonstrates greater than expected agreement due to chance as opposed to greater than expected disagreement due to chance. Therefore, due to the level of discordance among fundamentally similar measures, as revealed through chi-square analyses, clinicians aimed at assessing outcomes of CABG should be careful about which HRQL instruments are selected.

CONCLUSION

This investigation illustrated the limitations in the MOS SF-36 (i.e. floor and ceiling effects) for assessing changes of clinical importance in HRQL after CABG. The VSAQ and BDI-II were found to be two simple measures that assess HRQL which are fundamentally similar to MOS SF-36 subscales for physical functioning, role physical, mental health, and role emotional. In this particular subject group, the BDI-II appeared to perform better than it's definitionally similar MOS SF-36 subscales (mental health and role emotional), however, whether or not it is the choice instrument for assessing mental-emotional functioning in this subset of CABG patients cannot be determined since the pre- and post-surgery mean BDI-II scores revealed only a minimal degree of depressive symptoms with 72% demonstrating no change from pre-to post-surgery. The VSAQ, however, appears to be a very useful marker for assessing patient-perceived physical

functioning outcomes following CABG surgery. The VSAQ demonstrated significant pre- to post-CABG mean change scores, with a majority of improvements in perceived physical functioning measured by the VSAQ (62%) when compared to the MOS SF-36 subscales (physical functioning and role physical). The VSAQ demonstrates higher sensitivity than the MOS SF-36 subscales, as it reveals no ceiling and only modest floor effects. Therefore, results from the VSAQ in this investigation greatly supports its superiority in assessing patient-perceived physical functioning before and after CABG surgery.

These findings stemmed from a considerable sample size that was typical of other patients undergoing CABG. Researchers and clinicians are, therefore, encouraged to generalize these results to patients who may be undergoing other coronary revascularization procedures. Surgeons, as well, may benefit from relaying the baseline results of such an investigation to potential candidates for CABG by informing patients of their expectations before surgery. Likewise, these findings provide clinicians with valuable information in regards to specific HRQL instruments that yield greater results for evaluating patient-perceived treatment outcomes.

REFERENCES

1. American Heart Association: *Cardiovascular Disease Statistics.* On the World Wide Web at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/cvds.html, 1997.
2. Oldridge N. Outcome Assessment in Cardiac Rehabilitation. *J Cardiopulmonary Rehab* 1997; 17:179-194.
3. McHorney C, Ware J, Rogers W, Racaek A, Lu R. The Validity and Relative Precision of MOS Short- and Long-Form Health Status Scales and Dartmouth COOP Charts. *Med Care* 1992; 30: MS253-MS265.
4. McHorney C, Ware J, Raczek A. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and Clinical Tests of Validity in Measuring Physical and Mental Health Constructs. *Med Care* 1993; 31: 247-263.
5. McHorney C, Ware J, Lu R, Sherbourne C. The MOS 36-Item Short-Form Health Survey (SF-36): III. Tests of Data Quality, Scaling Assumptions, and Reliability Across Diverse Patient Groups. *Med Care* 1994; 32: 40-66.
6. Katz J, Larson M, Phillips C, Fossel A, Liang M. Comparative Measurement Sensitivity of Short and Longer Health Status Instruments. *Med Care* 1992; 30: 917-925.
7. Haley S, McHorney C, Ware, J. Evaluation of the MOS SF-36 Physical Functioning Scale (PF-10): I. Unidemsionality and Reproducibility of the Rasch Item Scale. *J Clin Epidemiol* 1994: 47: 671-684.
8. Andersen E, Patrick D, Carter W, Malmgren J. Comparing the Performance of Health Status Measures for Healthy Older Adults. *J Am Geriatr Soc* 1995; 43: 1030-1034.
9. Jette D and Downing J. Health Status of Individuals Entering a Cardiac Rehabilitation Program as Measured by the Medical Outcomes Study 36-Item Short-Form Survey (SF-36). *Physcial Therapy* 1994; 74: 521-527.
10. Milani R, Lavie C, Cassidy M. Effects of Cardiac Rehabilitation and Exercise Training Programs on Depression in Patients After Major Coronary Events. *Am Heart J* 1996; 132: 726-732.

11. Cleary P, Greenfield S, McNeil B. Assessing Quality of Life after Surgery. *Control Clin Trials* 1991; 12: 189S-203S.
12. Myers J, Herbert W, Ribisl P, Froelicher V. A Nomogram to Predict Exercise Capacity from a Specific Activity Questionnaire and Clinical Data. *Am J Cardiol* 1994; 73: 591-596.
13. Pitbladdo M, Brubaker P, Johnston R, Collier B, Miller H, Rejeski W. Use of Activity Questionnaires to Predict Functional Capacity in Outpatient Cardiac Rehabilitation Participants. Presented at *AACVPR's 1996 Annual Meeting* in Baltimore, MD.
14. Beck A, Steer R, Brown, G. *BDI-II Manual*. San Antonio: The Psychological Corporation, 1996: 1-6.
15. Sjoland H, Caidahl K, Wiklund I, Haglid M, Hartford M, Karlson T, Herlitz J. Impact of Coronary Artery Bypass Grafting on Various Aspects of Quality of Life. *European J Cardio-Thor Surg* 1997; 12: 612-619.
16. Jaeger A, Hlatky M, Paul S, Gortner S. Functional Capacity After Cardiac Surgery in Elderly Patients. *J Am Coll Cardiol* 1994; 24: 104-108.
17. Ware J and Sherbourne C. The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection. *Med Care* 1992; 30:473-483.
18. Guadagnoli E, Ayanian J, Cleary P. Comparison of Patient-Reported Outcomes After Elective Coronary Artery Bypass Grafting in Patients Aged $\geq$ and < 65 Years. *Am J Cardiol* 1992; 70: 60-64.
19. Jenkins C, Stanton B, Savageau J, Denlinger P, Klein M. Coronary Artery Bypass Surgery: Physical, Psychological, Social, and Economic Outcomes Six Months Later. *JAMA* 1983; 250: 782-788.
20. Kramer M, Feinstein A. Clinical Biostatistics LIV. The Biostatistics of Concordance. *Clin Pharmacol Ther* 1981; 111-123.
21. Landis R, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics* 1977; 33: 159-174.

TABLE I Clinical Characteristics of Sample (n=71)[ab]

	Occurrence (%)
Myocardial Infarction	48
Diabetes	28
CVA[c]	6
PVD[d]	14
CHF[e]	8
COPD[f]	11
Angina	87
Smoking History	75
Current Smoker	25
Family History	65
Hypercholesterolemia	65
Hypertension	63

[a] Male (n= 59) 83%; Female (n= 12) 17%
[b] Mean Age ± SD (62.7 ± 8.57)
[c] Cerebral Vascular Accident
[d] Peripheral Vascular Disease
[e] Congestive Heart Failure
[f] Chronic Obstructive Pulmonary Disease

TABLE II. Descriptive Statistics for MOS SF-36, VSAQ, and BDI-II Scores

Instrument	Pre-Surgery	Post-Surgery	Δ Score
MOS SF-36[a] Subscales			
PF[b]	61.0 ± 26.6	75.1 ± 20.1	14.1 ± 26 (20.3, 8.0)*
RP[c]	34.5 ± 41	42.6 ± 40.6	8.1 ± 43.9 (18.5, -2.3)
MH[d]	77.3 ± 14.5	80.6 ± 14	3.3 ± 12.4 (6.4, 0.5)*
RE[e]	68.5 ± 39.8	69.5 ± 37.3	1.0 ± 41.8 (10.8, -8.9)
VSAQ[f]	4.4 ± 2.4	5.9 ± 2.3	1.5 ± 2.5 (2.2, 1)*
BDI-II[g]	7.9 ± 6.6	5.8 ± 6.5	- 2.1 ± 6.5 (3.7, 0.6)*

All values are Means ± SD; Δ Score Includes 95% Confidence Intervals, shown parenthetically

[a] Medical Outcomes Short Form-36 items
[b] Physical Functioning
[c] Role Physical
[d] Mental Health
[e] Role Emotional
[f] Veterans Specific Activity Questionnaire
[g] Beck Depression Inventory-2nd Edition
* Significant at $p < 0.05$

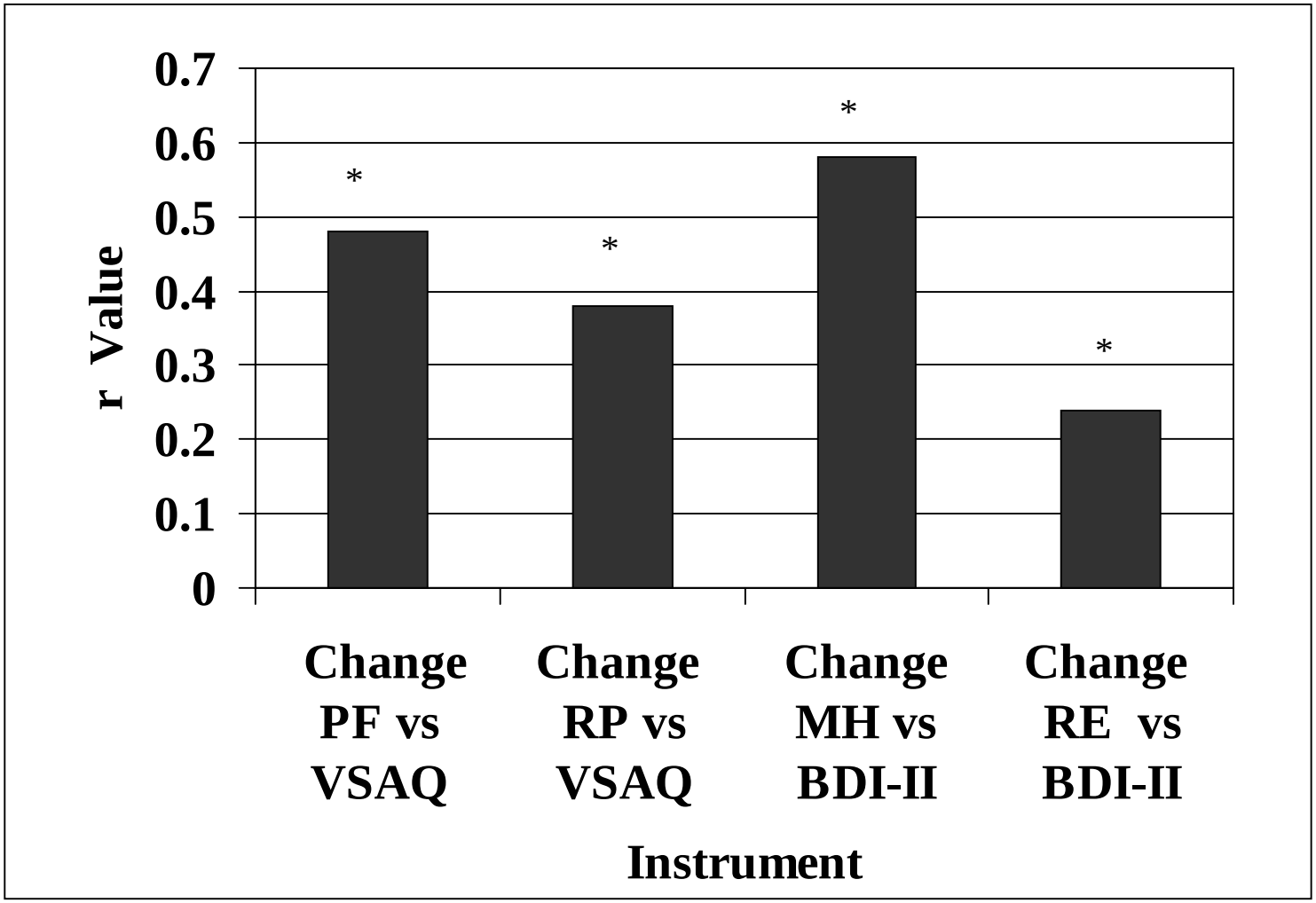

Figure I: Correlations Between Change Scores (Pre- and 3 Mo Post-CABG) for MOS SF-36 Subscales Versus VSAQ or BDI-II

* Significant at the level $p < 0.05$

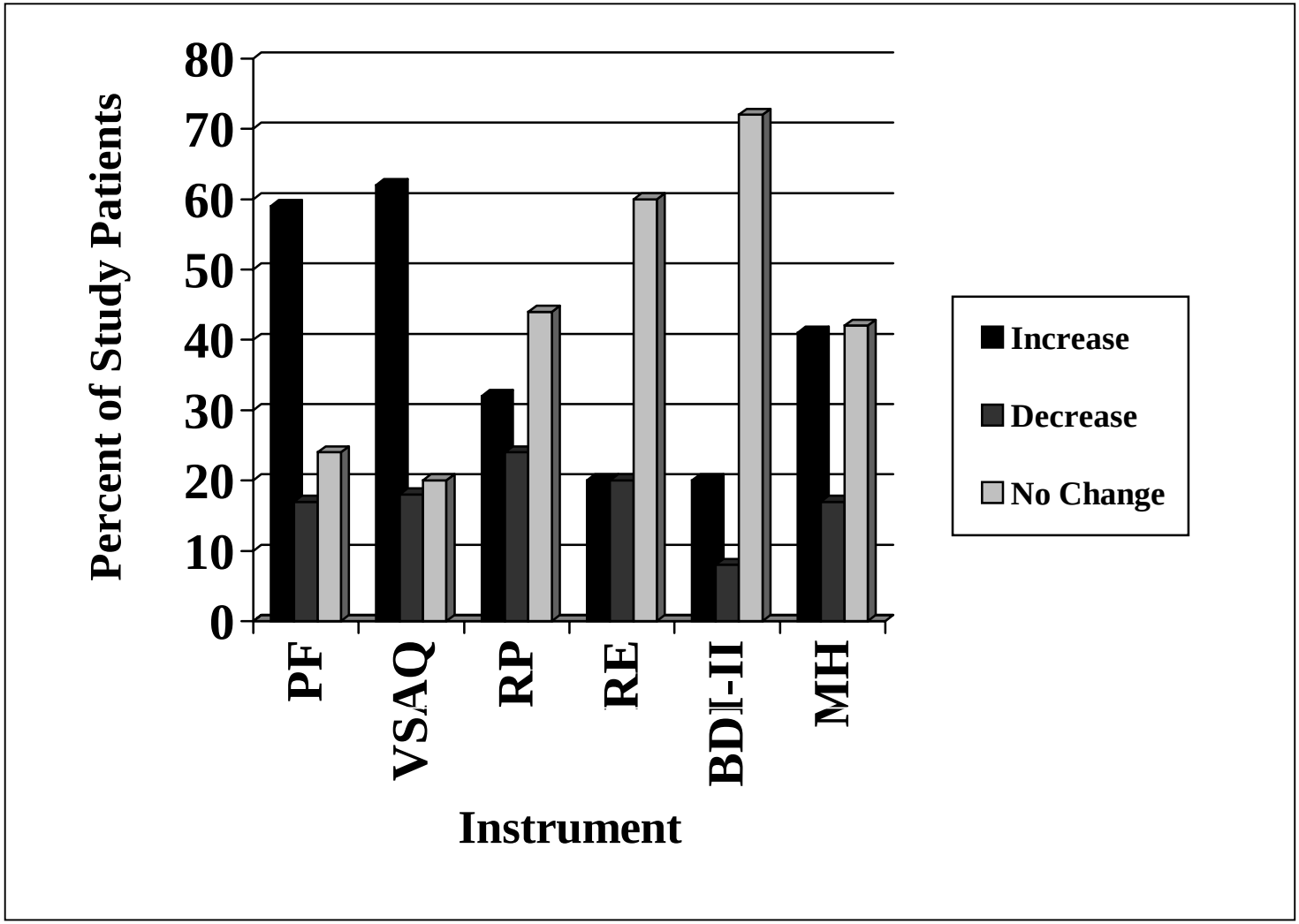

Figure II: Classification of Change (Pre- and 3 Mo Post-CABG) for MOS SF-36 Subscales, VSAQ, and BDI-II

Table III Chi-Square Analyses on Classifications of Change (and associated Kappa Values) for MOS SF-36 Subscales Versus VSAQ and BDI-II

Subscale vs Instrument	χ^2	κ-value
PF[a] vs VSAQ[b]	18.6*	.37
RP[c] vs VSAQ	11.8*	.22
MH[d] vs BDI-II[e]	25.1*	.32
RE[f] vs BDI-II	5.0	.12

[a] Physical Functioning
[b] Veteran's Specific Activity Questionnaire
[c] Role Physical
[d] Mental Health
[e] Beck Depression Inventory-2nd Edition
[f] Role Emotional
* Significant at $p < 0.05$

(The Kappa (κ) statistic is used along with χ^2 for measurement agreement in nominal scales. It corrects for agreement expected by chance. Here, only a slight-fair strength of agreement is observed.)

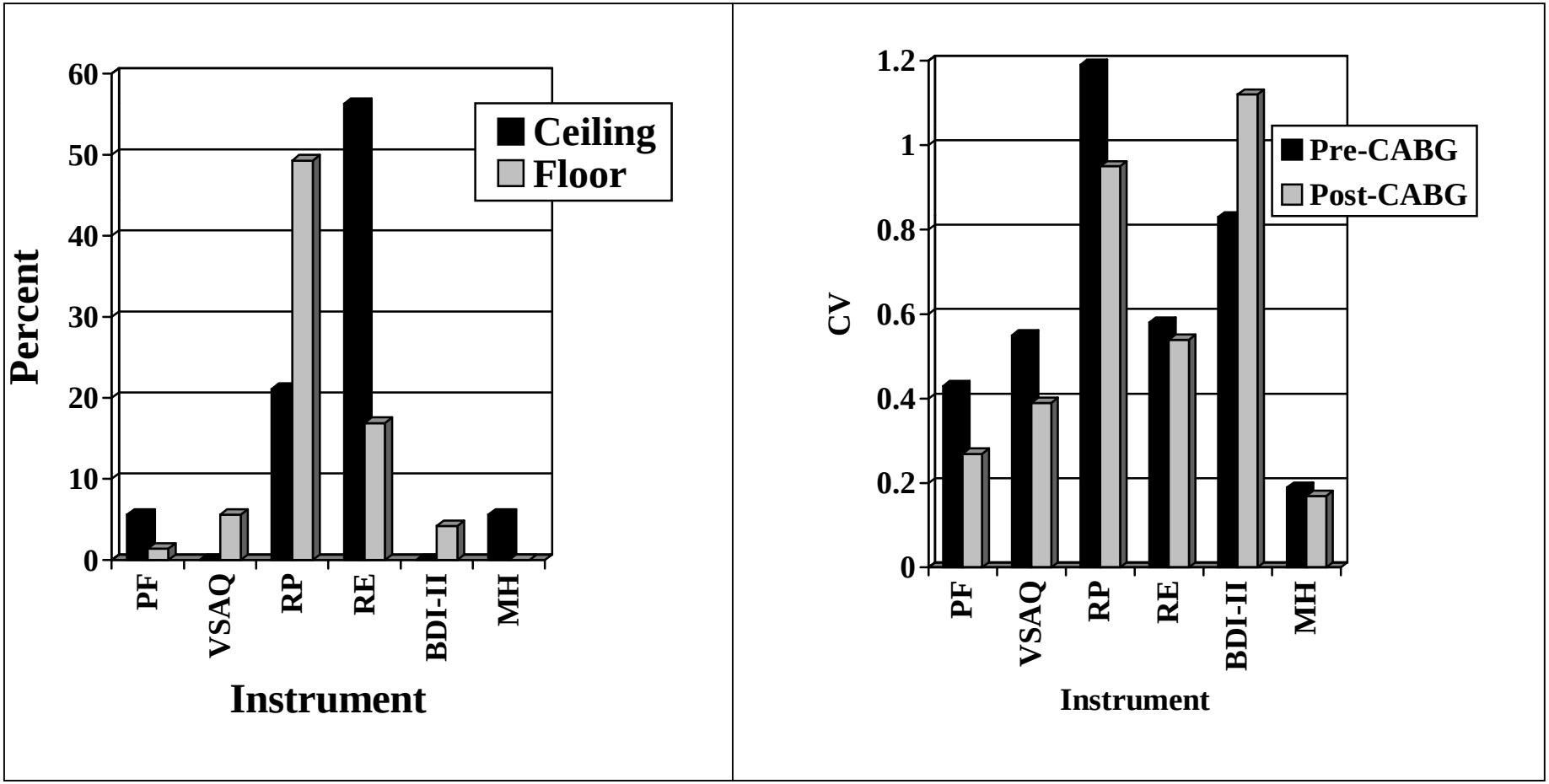

Figure III: Percent Ceiling and Floor Effects and Coefficients of Variation (CV) for MOS SF-36 Subscales, VSAQ, and BDI-II

Chapter IV

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS FOR FUTURE RESEARCH

SUMMARY

Health-related quality of life (HRQL) measures taken before and after coronary artery bypass grafting (CABG) aid in determining meaningful patient-perceived outcomes associated with alternative clinical interventions. More and more, since the advent of managed health care, clinicians are attending to measures of care that address patient opinions and values about the care they receive. The many HRQL scales that have been developed in recent years represent a response to this need. These HRQL evaluations serve to complement traditional outcome measures and serve as an integral component in optimizing clinical decision-making. Researchers advise clinicians to base their HRQL instrument selection on particular assessment needs, appropriateness for the specific population, and ability of an instrument to detect clinically significant changes over time.

The Medical Outcomes Study Short Form (MOS SF-36), Veteran's Specific Activity Questionnaire (VSAQ), and Beck Depression Inventory (BDI-II) were selected for the current investigation to measure physical and mental health status in patients undergoing CABG. The MOS SF-36, was designed as a generic HRQL instrument and psychometric studies to establish its validity and reliability were performed on large groups of patients with specific chronic diseases and other medical conditions. The VSAQ and BDI-II, two simple measures, have been validated and assessed for reliability under specific conditions and for specific purposes. The BDI-II has been evaluated for detection of clinically depressive symptoms in patients, but not necessarily for validation of assessing changes in the mental-emotional status of patients undergoing physical treatments for non-psychological conditions (i.e. CABG). The VSAQ, however, has been studied in similar cardiac patient groups for the reliability of assessing patient-perceived physical functioning before and after treatment procedures. Investigations using the VSAQ and BDI-II provide evidence for their clinical use in evaluating treatment outcomes.

The research reported in this thesis compared performance of four MOS SF-36 subscales (Physical Functioning: PF; Role Physical: RP; Mental Health: MH; and Role

Emotional: RE) of physical and mental-emotional functioning against the VSAQ and BDI-II in patients just before and 3 months following CABG surgery. A sample of 71 patients who met the inclusion criteria and completed the pre-surgical and 3-month post-surgical battery of questionnaires were selected from the subject pool consisting of 200 consecutive patients. These patients were found to be typical of other patients undergoing first time CABG.

Mean values for the MOS SF-36 subscales demonstrated highest pre- and post-surgery scores for MH (77.3 and 80.6, respectively) and lowest scores for RP (34.5 and 42.6, respectively). Patient-perceived MET levels, as measured by the VSAQ, were relatively low for pre- and post-surgery (4.4 and 5.9, respectively). The BDI-II scores demonstrated a minimal degree of depressive symptoms in patients before and after CABG. The PF and MH subscales, as well as, the VSAQ and BDI-II, demonstrated statistically significant mean change scores ($p < 0.05$). However, for comparisons of pre- to post-CABG mean change scores, there was a great deal of unexplained variance (i.e. $1 - r^2 = .66$ for change MH vs change BDI-II). Similarly, pre-surgery means for VSAQ vs pre-surgery means for PF revealed 63% of unexplained variance.

Post-surgery VO_2 peak values were correlated with post-surgery VSAQ, PF, and RP scores in a subset of 51 patients. The VSAQ was found to be more accurate in estimating VO_2 peak ($r = 0.64$) in comparison to PF ($r = 0.53$) and RP ($r = 0.2$). These findings may differ slightly from Myers et al. (VSAQ vs VO_2 peak; $r = 0.79$)[12] due to factors such as differences in the populations. For instance, the sample size for the current investigation was much smaller. Patients recruited by Myers et al. were healthier in that they were Veterans referred for diagnostic testing. Only 19% of the patients evaluated in Myers et al. had undergone previous CABG, they demonstrated fewer comorbidities, and were functionally better off with VSAQ scores averaging 6.3 METs. The RP and RE subscales displayed moderately high floor effects (49.3 and 16.9%, respectively), as well as ceiling effects (21.1 and 56.3%, respectively) which were consistent with previous literature, while the VSAQ and BDI-II showed no ceiling and only modest floor effects. In conjunction with these floor and ceiling effects, Coefficient of Variation (CV) was

determined for each pre- and post-CABG mean score. The VSAQ demonstrated high pre-surgical variability and a low pre-surgical mean; therefore CV was high (0.55). Subsequently, the RP and RE subscales did not display a true representation of the patients potential to improve their HRQL and may be due to flaws with item development.

Statistically significant correlations were established between change scores for each of the MOS SF-36 subscales vs the VSAQ and BDI-II ($p < 0.05$). A majority of the subjects demonstrated pre- to post-surgery improvements in PF and VSAQ (59 and 62%, respectively) while a high percentage of patients neither increased nor decreased in MH and BDI-II (60 and 72%). Finally, chi-square analysis revealed significant differences among the distribution of classifications of change for PF vs VSAQ ($p < 0.001$); RP vs VSAQ ($p < 0.02$); and MH vs BDI-II ($p < 0.0001$). Rationale for determining a clinically meaningful change for each MOS SF-36 subscale, VSAQ, and BDI-II were discussed in brief.

CONCLUSION

This investigation illustrated the limitations in performance of the MOS SF-36 (i.e. floor and ceiling effects) for assessing changes of clinical importance in HRQL after CABG. Suggested rationale for what constitutes a clinically meaningful change, given the selected instruments, was also presented in this study. The VSAQ and BDI-II were found to be two simple measures that assess HRQL constructs which are fundamentally similar to MOS SF-36 subscales for physical functioning, role physical, mental health, and role emotional. In this particular subject group, the BDI-II appeared to perform better than the definitionally similar MOS SF-36 subscales (mental health and role emotional). However, whether or not the BDI-II is the choice instrument for assessing mental-emotional functioning, in this subset of CABG patients, can not be determined since the subjects displayed very little mental-emotional distress prior to surgery. Pre-and post-surgery BDI-II mean scores revealed only a minimal degree of depressive symptoms with 72% demonstrating no change from pre-to post-surgery. The VSAQ, however, appears to be a very useful marker for assessing patient-perceived physical functioning outcomes

following CABG surgery. The VSAQ demonstrated significant pre- to post-CABG mean change scores. A majority of improvements in perceived physical functioning was measured by the VSAQ (62%), as compared to the MOS SF-36 subscales (physical functioning and role physical). The VSAQ demonstrated greater sensitivity to change, than the MOS SF-36 subscales, as is revealed no ceiling and only modest floor effects. Therefore, results of the VSAQ, under this investigation, greatly supports its superiority in assessing patient-perceived physical functioning before and after CABG.

These findings stemmed from a considerable sample size that was typical of other patients undergoing CABG. Researchers and clinicians are, therefore, encouraged to generalize these results to patients who may be undergoing other coronary revascularization procedures. Likewise, the results provide clinicians with valuable information in regards to specific HRQL instruments that exhibit greater performance in evaluating patient-perceived treatment outcomes.

RECOMMENDATIONS FOR FUTURE RESEARCH

Future research is needed for developing methods for the elimination of selection biases. Recall that the results herein were derived from a more broad-based investigation conducted under the supervision of Dr. Joseph Cook. Since the overall study consisted of fitness testing such as maximal grip strength, maximal arm and leg flexion, and graded exercise testing, patient selection was biased so as to not place very ill or frail patients at any unnecessary risk by ambulating and performing strength measurements on them. Therefore, the results of the current study may have been limited as patients were excluded if they had an MI < 5 days prior to surgery, were < 45 years-of-age, demonstrated very low functional capacity, or were undergoing any other concomitant cardiovascular surgery. In light of the current investigation, such exclusion criteria would not have been necessary if the subjects were recruited independently. Of the 200 patients represented in the subject pool, only the results for 71 were satisfactory for inclusion and therefore, were selected for the study sample. Any patient who suffered from post-operative complications and was unable to complete the 3-month battery of tests were excluded from the study. This, too, may have contributed to biased results.

In contrast, 3 months following CABG may be too soon to evaluate and determine differences in HRQL in these patients. A majority of patients are still sore from incisions, fatigued from doctor visits, loaded on excess medications, and anxious about their overall recovery. Many HRQL investigations demonstrate substantial differences in CABG patients at 6, 8, and 12 months following surgery. Therefore, it may benefit future investigators to reconsider time frame selections in the evaluation of post-surgery HRQL outcomes so as to increase sensitivity of the measures. Another issue relating to sensitivity of the measures is the percentage of patients suffering from angina prior to surgery. In the current study, 87% of the subjects demonstrated symptoms associated with angina. Therefore, it would be of great interest to clinicians to investigate the unknown influence of angina on the assessment of physical functioning as measured by the VSAQ and MOS SF-36 subscales (PF and RP). A study designed similar to the current investigation would adequately compare the overall performance of a patient-perceived angina scale to other physical functioning scales.

Determining what constitutes a clinically significant change in HRQL measures is difficult. Use of statistical methods such as the standardized response mean (SRM) does not give way to what is clinically meaningful. The cut-off points that were determined for this investigation by a small group of clinicians, although clinically reasonable, were arbitrary. Therefore, a reliability or precision study using an independent sample of patients would aid clinicians towards a better understanding of how individual responses to the instruments may change over time, possibly due to chance alone. These results could then be factored into the determination of clinically meaningful changes for the MOS SF-36 subscales, VSAQ, and BDI-II.

As discussed previously, the VSAQ has been found to be quite accurate in estimating MET levels in CAD patients. Likewise, the VSAQ portrays confidence in measuring patient-perceived physical health outcomes in those undergoing CABG surgery. Reliability of the VSAQ, however, has yet to be determined. In order to consider the VSAQ as a true assessment of self-efficacy for physical activity in patients before and after CABG, a study determining the consistency, or repeatability, is deemed necessary.

RECOMMENDATIONS FOR CLINICAL PRACTICE

The purpose of the current investigation was to compare the results of the MOS SF-36 subscales against the VSAQ and BDI-II. More specifically, the aim of the study was to demonstrate to clinicians that limitations to the MOS SF-36 do indeed exist. Even with its known limitations, many institutions continue to purchase and adopt the MOS SF-36 clinical questionnaire because it is easily administered, scored, and interpreted. Clinicians, therefore, may be making purchase decisions before they are well informed of the instrument's overall performance ability. A word of caution need go out to clinicians involved with interventions such as cardiac rehabilitation. The results of this investigation demonstrated that even without undergoing cardiac rehabilitation, spontaneous increases in the MOS SF-36 subscales were noted in patients following CABG. The hope is that clinicians review the current investigation and take note of other instruments that are just as easy to administer, score, and interpret, yet are not subject to the same shortcomings of the MOS SF-36.

Recall that the sample of subjects selected for the current investigation was found to be consistent with the overall population of patients undergoing CABG at that institution and time. Therefore, when determining whether or not a patient is a good candidate for CABG, surgeons may utilize the results of this investigation, along with traditional measures, to help predict HRQL outcomes following surgery. To guide surgeons down this path, an investigation that would seek to develop prediction equations in conjunction with the current results would be of added benefit to clinical decision making.

BIBLIOGRAPHY

Alderman E. Angiographic Correlates of Graft Patency and Relationship to Clinical Outcomes. *Ann Thorac Surg* 1996; 62(5): S22-5.

Allen J, Fitzgerald S, Swank R, Becker D. Functional Status After Coronary Artery Bypass Grafting and PTCA. *Am J Cardiol* 1990; 65: 921-925.

American Heart Association: *Cardiovascular Disease Statistics.* On the World Wide Web at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/cvds.html, 1997.

Andresen E, Patrick D, Carter W, Malmgren J. Comparing the Performance of Health Status Measures for Healthy Older Adults. *J Am Geriatr Soc* 1995; 43: 1030-1034.

Ayanian J, Guadagnoli E, Cleary P. Physical and Psychological Functioning of Women and Men After Coronary Artery Bypass Surgery. *JAMA* 1995; 274: 1767-1770.

Beck A, Steer R, Brown, G. *BDI-II Manual*. San Antonio: The Psych Corp., 1996: 1-6.

Chocron S, Etievent J, Viel J, Dussaucy A, Clement F, Alwan K, Neidhardt M, Schipman N. Prospective Study of Quality of Life Before and After Open Heart Operations. *Ann Thorac Surg* 1996; 61: 153-157.

Cleary P, Greenfield S, McNeil B. Assessing Quality of Life after Surgery. *Control Clin Trials* 1991; 12: 189S-203S.

Codman E.. The Product of a Hospital. *Surg Gynecol Obstetr* 1914; 491-496.

Donabedian A. The Methods and Findings of Quality, Assessment and Monitroing: An Illustrated Analysis. Ann Arbor, Mich.: Health Administration Press 1985; 256.

Duits A, Boeke S, Taams M, Passchier J, Erdman A. Prediction of Quality of Life After Coronary Artery Bypass Graft Surgery: A Review and Evaluation of Multiple, Recent Studies. *Psychosomatic Medicine* 1997; 59: 257-268.

Engblom E, Korpilahi K, Hamalainen H, Ronnemaa T, Puukka P. Quality of Life and Return to Work 5 Years After Coronary Artery Bypass Surgery: Long Term Results of Cardiac Rehabilitation. *J Cardiopulmonary Rehabil* 1997; 17: 29-36.

Freedland K, Lustman, P, Carney, R, Hong, B. Underdiagnosis of Depression in Patients with Coronary Artery Disease: The Role of Nonspecific Symptoms. *Int'l J. Psychiatry in Medicine* 1992; 22: 221-229.

Glower D, Christopher T, Milano C, White W, Smith L, Jones R, Sabiston D. Performance Status and Outcome After Coronary Artery Bypass Grafting in Persons Aged 80-93 Years. *Am J Cardiol* 1992; 70: 567-571.

Green L, Kreuter M, Deeds S. Health Education Planning: A Diagnostic Approach. Palo Alto, CA: Mayfield Publishing Co; 1980: 306.

Guadagnoli E, Ayanian J, Cleary P. Comparison of Patient-Reported Outcomes After Elective Coronary Artery Bypass Grafting in Patients Aged $\geq$ and < 65 Years. *Am J Cardiol* 1992; 70: 60-64.

Guyatt G, Feeny D, Patrick D. Measuring Health-Related Quality of Life. *Annals of Internal Medicine* 1993; 118: 622-629.

Haley S, McHorney C, Ware, J. Evaluation of the MOS SF-36 Physical Functioning Scale (PF-10): I. Unidemsionality and Reproducibility of the Rasch Item Scale. *J Clin Epidemiol* 1994: 47: 671-684.

Herbert W. Current Issues: Patient Outcome Monitoring in Cardiac Rehab. Presented at *Symposium on Heart Disease and Rehab*; Glasgow, Scotland, UK; August 1996.

Hoad N, Crawford I. Rehabilitation After Coronary Artery By-Pass Grafting and Improved Quality of Life. *Br J Sports Med* 1990; 24(2): 120-122.

Jaarsma T, Kastermans M. Recovery and Quality of Life One Year After Coronary Artery Bypass Grafting. *Scand J Caring Sci* 1997; 11(2): 67-72.

Jaeger A, Hlatky M, Paul S, Gortner S. Functional Capacity After Cardiac Surgery in Elderly Patients. *J Am Coll Cardiol* 1994; 24: 104-108.

Jenkins C, Stanton B, Savageau J Denlinger P, Klein M. Coronary Artery Bypass Surgery: Physical, Psychological, Social, and Economic Outcomes Six Months Later. *JAMA* 1983; 250: 782-788.

Jette D, Downing J. Health Status of Individuals Entering a Cardiac Rehabilitation Program as Measured by the Medical Outcomes Study 36-Item Short-Form Survey (SF-36). *Physcial Therapy* 1994; 74: 521-527.

Jette D, Downing J. The Relationship of Cardiovascular and Psychological Impairments to the Health Status of Patients Enrolled in Cardiac Rehabilitation Programs. *Physical Therapy* 1996; 76: 130-139.

Johnson P, Goldman L, Orav J, Garcia, Pearson S, Lee T. Comparison of the Medical Outcomes Study Short-Form 36-Item Health Survey in Black Patients and White Patients with Acute Chest Pain. *Med Care* 1995; 33: 145-160.

Juniper E, Guyatt G, Willan A, Griffith L. Determining a Minimal Important Change in a Disease Specific Quality of Life Questionnaire. *J Clin Epidemiol* 1994; 47: 81-87.

Katz J, Larson M, Phillips C, Fossel A, Liang M. Comparative Measurement Sensitivity of Short and Longer Health Status Instruments. *Med Care* 1992; 30: 917-925.

Kiebzak G, Vain P, Gregory A, Mokris J, Mauerhan D. SF-36 General Health Status Survey to Determine Patient Satisfaction at Short-Term Follow-up After Total Hip and Knee Arthroplasty. *J Southern Orthopaedic Assoc* 1997; 6: 169-173.

Kramer M, Feinstein A. Clinical Biostatistics LIV. The Biostatistics of Concordance. *Clin Pharmacol Ther* 1981; 111-123.

Landis R, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics* 1977; 33: 159-174.

Lavie C, Milani R. Effects of Cardiac Rehabilitation and Exercise Training on Exercise Capacity, Coronary Risk Factors, Behavioral Characteristics, and Quality of Life in Women. *Am J Cardiol* 1995; 75: 340-343

Lesperance F, Frasure-Smith N, Talajic M. Major Depression Before and After Myocardial Infarction: Its Nature and Consequences. *Psychosomatic Medicine* 1996; 58: 99-110.

Levinson M. The Learning Center Preserve: Coronary Artery Bypass Surgery; November 1995; On the World Wide Web at http://www.hsforum.com/HeartSurgery/TLC/CABG/CABGTLC.hst

McHorney C, Ware J, Rogers W, Racaek A, Lu R. The Validity and Relative Precision of MOS Short- and Long-Form Health Status Scales and Dartmouth COOP Charts. *Med Care* 1992; 30: MS253-MS265.

McHorney C, Ware J, Raczek A. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and Clinical Tests of Validity in Measuring Physical and Mental Health Constructs. *Med Care* 1993; 31: 247-263.

McHorney C, Ware J, Lu R, Sherbourne C. The MOS 36-Item Short-Form Health Survey (SF-36): III. Tests of Data Quality, Scaling Assumptions, and Reliability Across Diverse Patient Groups. *Med Care* 1994; 32: 40-66.

Merrill W, Sterwart J, Frist W, Hammon J, Bender H. Cardiac Surgery in Patients Age 80 Years or Older. *Ann. Surg* 1990; 772-776.

Mick M, Simpfendorfer C, Arnold A, Piedmonte M, Lytle B. Early and Late Results of Angioplasty and Bypass in Octogenarians. *Am J Cardiol* 1991; 68:1316-1320.

Milani R, Lavie C, Cassidy M. Effects of Cardiac Rehab and Exercise Training Programs on Depression in Patients After Major Coronary Events. *Am Heart J* 1996; 132: 726-732.

Myers J, Herbert W, Ribisl P, Froelicher V. A Nomogram to Predict Exercise Capacity from a Specific Activity Questionnaire and Clinical Data. *Am J Cardiol* 1994; 73: 591-596.

Nelson E, Wasson J, Krik J. Assessment of Function in Routine Clinical Practice: Description of the COOP Chart Method and Preliminary Findings. *J Chronic Dis* 1987; 40: 55S-63S.

Oldridge N. Outcome Assessment in Cardiac Rehabilitation. *J Cardiopulmonary Rehab* 1997; 17:179-194.

Oldridge N, Gotlieb M, Guyatt G, Jones N, Streiner D, Feeny D. Predictors of Heatlh-Related Quality of Life With Cardiac Rehabilitation After Acute Myocardial Infarction. 1998; 18: 95-103.

Pashkow P, Ades P, Emery C, Frid D, Miller N, Peske G, Reardon J, Schiffert J, Southard D, ZuWallack R. Outcome Measurement in Cardiac and Pulmonary Rehabilitation. *J Cardiopulmonary Rehabil* 1995; 15: 394-405.

Patrick D, Erickson P. Health Status and Health Policy. Quality of Life in Health Care Evaluation and Resource Allocation. New York: Oxford University Press, 1993: 1-478.

Pierson L, Callaghan C, Cook J, Herbert W. A New Application of the Specific Activity Questionnaire for Pre-Surgical Assessment of CABG Patients. *Med Sci Sport & Exer* 1998; Supplement 30: S249.

Pitbladdo M, Brubaker P, Johnston R, Collier B, Miller H, Rejeski W. Use of Activity Questionnaires to Predict Functional Capacity in Outpatient Cardiac Rehabilitation Participants. Presented at *AACVPR's 1996 Annual Meeting* in Baltimore, MD.

Rejeski J, Brawley L, Shumaker S. Physical Activity and Health-Related Quality of Life. *Exercise & Sports Science Review* 1996; 24: 71-108.

Schipper H, Clinch J, Olweny C. Quality of Life Studies: Definitions and Conceptual Issues. In: Spilker B, ed. *Quality of Life and Pharmacoeconomics in Clinical Trials*. Philadelphia: Lippincott-Raven, 1996: 11-23.

Shapira I, Isakov A, Yakirevich V, Topilsky M. Long-Term Results of Coronary Artery Bypass Surgery in Patients With Severely Depressed Left Ventricular Function. *Chest* 1995; 108: 1546-1550.

Sjoland H, Hartford M, Caidahl K, Karlson B, Wiklund I, Karlsson T, Herlitz J. Improvement in Various Estimates of Quality of Life After Coronary Artery Bypass Grafting in Patients With and Without a History of Hypertension. *J Hypertension* 1997; 15: 1033-1039.

Stewart A, Hays R, Ware J. The MOS Short-Form General Health Survey: Reliability and Validity in a Patient Population. *Med Care* 1988; 26: 724-732.

Stewart A, Ware J. Measuring Functioning and Well-Being. Durham, NC: Duke University Press; 1992.

Tarlov R, Ware J, Greenfield S, Nelson E, Perrin W, Zubkoff M. An Application of Methods for Monitoring the Results of Medical Care. *JAMA* 1989; 262: 925-930.

Testa M, Simonson D. Assessment of Quality of Life Outcomes. *New England J Med* 1996; 334: 835-840.

Timberlake N, Klinger L, Smith P, Venn G, Treasure T, Harrison M, Newman P. Incidence And Patterns of Depression Following Coronary Artery Bypass Graft Surgery. *J Psychosomatic Res* 1997; 43: 197-207.

U.S. Department of Health and Human Services: Health, United States, 1994. Hyattsville, MD: Public Health Service. DHHS Pub # (PHS) 1995; 95-1232.

Ware J and Sherbourne C. The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection. *Med Care* 1992; 30:473-483.

Ware J, Snow K, Kosinki M, Gandek B. *SF-36 Health Survey: Manual and Interpretation Guide* Boston: The Health Institute, 1993: 2:2-3:3.

Wilson I, Cleary P. Linking Clinical Variables With Health Related Quality of Life: A Conceptual Model of Patient Outcomes. *JAMA* 1995; 273: 59-67.

Appendix A

Detailed Methodology

Study Patients

The pool of potential subjects consisted of all patients admitted to Carolinas Medical Center in Charlotte, NC for first CABG between November 1996 and December 1997 (N = 904). Recruitment took place between 1 and 7 days prior to surgery. To be included, patients must have been undergoing first time CABG, must have been >45 years of age, not undergoing any other concomitant cardiovascular surgery, and not presenting with evidence of cognitive-emotive disorder that would preclude completion of HRQL instruments. Patients who consecutively met the above criteria and agreed to participate in the study made up the subject pool (N = 200). A subset of 71 patients (59 males; 12 females; mean age = 63 ± 8.6 years) who completed the pre-surgical and 3 month post-surgical battery of HRQL questionnaires were selected from the pool for this investigation. Clinical characteristics of the sample can be found in Chapter III. Clinical characteristics of the same versus all other patients undergoing CABG (N =904) at the same institution and during the same time frame can be found in Appendix B.

HRQL Questionnaires

The following instruments were used to assess the physical and/or mental health constructs of HRQL. The MOS SF-36 is a generic instrument used to measure 8 concepts of HRQL (Ware & Sherbourne, 1992). For the purpose of this investigation, however, only the two physical health (PF and RP) and two mental health (MH and RE) subscales were evaluated. Each of these subscales consists of 3-10 items. When computed independently, the subscales result in total scores ranging from 0-100. The lower the total scores, the more suggestive of a diminished HRQL; the higher the total scores, the more suggestive of an enhanced HRQL. The BDI-II is a 21-item instrument designed to assess the presence and degree of depressive in patient populations. All items are rated on a four-point scale (0-3) with total scores ranging from 0-63 points. According to Beck et al.

(1996) total scores ranging from 0-13 suggest minimal depression; 14-19 mild depression; 20-28 moderate depression; and 29-63 severe depression. The VSAQ was designed to gauge which daily activities may be limited in patients with CAD (Myers et al., 1994) These activities range from recreational to competitive activities and from self-care to house/yard work activities. Each activity level is organized by increasing difficulty in terms of metabolic equivalents (METs). The activities range from 1-13 METs. Patients limited by symptoms of CAD are expected to score within 3-7 METs.

Statistical Analyses

All statistical analyses were performed with JMP Start Statistics software (SAS Institute Inc.; Cary, NC; 1996). Once scaling characteristics, measures of central tendency and variability were determined, Spearman Rho correlations were performed on pre-surgery, post-surgery, and change scores to establish levels of agreement between the MOS SF-36 subscales, and the VSAQ or BDI-II. All change scores were also tested for significance using Wilcoxon Signed-Rank test for related samples. Finally, Chi-Square analyses were performed on the distributions of patient's classifications of change (determination of these classifications will be discussed later) to test the significance of the agreement between the MOS SF-36 subscales and the VSAQ or BDI-II. To determine the level of agreement above that of chance, Kappa values were established. The level of statistical significance was set at $p<0.05$.

Determination of Classifications of Change

Individual change scores were classified as being a clinically meaningful increase, decrease, or no change. To aid in determining clinical rationale for classifying these changes, a small group of clinical exercise physiologists were asked to review each MOS SF-36 subscale, VSAQ, and BDI-II and to determine the number of points that reflected a change, they believed, would be considered clinically important. The group consisted of five Master's level exercise physiologists working in either cardiac rehabilitation or cardiac diagnostics.

Specifically, the clinicians were asked to review each MOS SF-36 subscale, VSAQ, and BDI-II independently. Each clinician was instructed to first read each item, or question, pertaining to the specific subscale or questionnaire at hand, as well as it's respective responses, in order to gain a better understanding of item definition and meaning. Clinicians were then given the breakdown of scoring for the subscale or questionnaire at hand. For instance, each of the 10 items representing the Physical Functioning (PF) subscale has three possible responses. Each response to an item may be worth 0 points ("limited a lot"), 5 points ("limited a little"), or 10 points ("not limited at all"). It was then suggested to the clinician that he/she consider issues related to the patient's being evaluated. For example, the subjects were undergoing first time bypass surgery, therefore, may display various physical and mental symptoms (angina, chest wall pain, incision pain, anxiety, depression, and fear) before and after surgery. It was also suggested that the clinicians consider responses that may simply be a result of day-to-day chance. In other words, a patient's response to a particular item one day may differ from the same patient's response to the same item on a different day.

Given the factors previously mentioned (item definition and meaning, scoring, patient attributes, and response precision), the clinicians were then asked to determine how much change in point values from the item responses would signify a clinically meaningful change in the patient's HRQL for the particular subscale or questionnaire at hand. To help get at this answer clinicians were asked, for instance, if a change of 5, 10, 15 or 20 points for PF would be considered a clinically significant change in their mind. Also, what would a change of 5, 10, 15 or 20 points mean for a particular patient responding to the PF subscale?

Keeping with PF as an example if a particular patient scores 50 points before surgery and 60 points after surgery that is a change of 10 points. A change of 10 points for PF might represent a patient who before surgery perceived him/herself as being limited a lot in his/her ability to climb several flights of stairs (0 points) and limited a little in his/her ability to lift or carry groceries (5 points). After surgery, however, this patient may perceive his/herself as being limited only a little in his/her ability to climb

several flights of stairs (5 points) and not limited at all in his/her ability to lift or carry groceries (10 points). To a clinician, this amount of change may demonstrate a meaningful increase in a patient's quality of life as a result of CABG surgery.

The above rationale was used for each MOS SF-36 subscale, VSAQ, and BDI-II. Once each exercise physiologist reviewed all items, the following classifications of change were determined based on consensus among the group. For PF there were 10 items with 0, 5, or 10 points possible for each item. The group agreed that a change of ±10 points for PF was acceptable as an increase or decrease of clinical importance, whereas a change of $< \pm 10$ points would indicate no clinically significant change. For RP, there were 4 items, with 0 or 25 points possible for each item. The group agreed that a change of ± 25 points for RP was acceptable as an increase or decrease of clinical importance, whereas a change of $< \pm 25$ would indicate no clinically significant change. For RE there were 3 items with 0 or 33.3 points possible for each item. The group agreed that a change of ±33.3 points for RE was acceptable as an increase or decrease of clinical importance, whereas a change of $< \pm 33.3$ points would indicate no clinically significant change. For MH there were 5 items with 0, 4, 8, 12, 16, or 20 points possible for each item. The group agreed that a change of ± 8 points for MH was acceptable as an increase or decrease of clinical importance, whereas a change of $< \pm 8$ points would indicate no clinically significant change. For VSAQ there were 1-13 METs possible and a change of ± 1 MET was accepted as an increase or decrease of clinical importance, whereas a change of $< \pm 1$ MET would indicate no clinically significant change. Finally, for BDI-II there were 21 items with 0, 1, 2, or 3 points possible for each item. The group agreed that a change of ±6 points for the BDI-II was acceptable as an increase or decrease of clinical importance, whereas a change of $< \pm 6$ points would indicate no clinically meaningful change.

Appendix B

Clinical Characteristics of Research vs Non-Research Group

Clinical Characteristics in Research Patients Versus Non-Research Patients

Risk Factors	Research Patients (n=71)[a] Occurrence (%)	Non-Research Patients (n=904)[b] Occurrence (%)
Male	83	67
Female	17	33
Family History	65	64
Hypercholesterolemia	65	65
PVD [c]	14	17
Diabetes	28	35
COPD[d]	11	15
Myocardial Infarction	49	49
CHF [e]	8	13
Smoking History	75	65
Current Smoker	25	25

[a] Mean Age ± SD (62.7 ± 8.57)
[b] Mean Age ± SD (63.24 ± 10.12)
[c] Peripheral Vascular Disease
[d] Chronic Obstructive Pulmonary Disease
[e] Congestive Heart Failure

Appendix C

Informed Consent

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Clinical, Physical, and Quality of Life Variables in Patients after
Coronary Artery Bypass Graft Surgery

INTRODUCTION
You are being asked to participate in a research study to be conducted by Joseph Cook, M.D. at the Carolinas Heart Institute (CHI). The purpose of this study is to determine if physical, psychological, and nutritional status are important factors in determining how well patients do after coronary artery bypass surgery. This will involve completing questionnaires and having non-invasive measurements made before and after your surgery. You will be one of approximately 200 people involved in this research at CHI, and your participation will last approximately 1 year.

PROCEDURE
Two types of tests will be used. Some will involve answering questions about yourself and will include evaluation of how you feel about your ability to tolerate activities involving exercise, your ability to perform self care and daily living activities at home, your feelings of well being, your health, your quality of life, and your diet. Other non-invasive tests will include determining your body composition by measuring the thickness of a skin fold, grip strength by squeezing a hand-held device and upper body strength by pushing against or pulling on a small machine with your hands.

These tests will be done at the time of your surgery and/or at 3 and 12 months after surgery. Also at 3 months after your surgery and again at 12 months, you will be tested to maximum effort on a treadmill, and your ECG, heart rate, and blood pressure will be evaluated by a physician. In addition, at surgery and at 12 months, you will receive a non-invasive low-energy x-ray scan (DEXA) to determine the percentage of your body that is fat or muscle and to determine the quality of your bones.

RISKS
None of the tests should cause any foreseeable risks or discomfort. The strength tests are of low intensity and the treadmill test will be the same maximal effort evaluation you took before your surgery. These tests will be closely monitored during their administration. The amount of x-ray exposure from the DEXA scan will be very low.

_____
Patient/Guardian
Initials

EXCLUSION CRITERIA
You should not participate in this study if:

You have any circulatory, joint, nerve, or emotional disorders that would not allow completion of the items being tested.

You are taller than 6' or you weigh more than 220 lb.

BENEFIT
There may be no direct benefit to you for participating in this study, but the information gained may benefit others with your condition. Being able to better predict who will benefit most from coronary artery bypass surgery would result in better treatment and rehabilitation planning for future patients. At the conclusion of participation in the study, your results will be forwarded to your personal physician and may be used in planning your future health care.

ADDITIONAL COST
There will be no additional cost to you for participating in this study.

COMPENSATION
In the event that physical injury occurs as a result of this research project, medical treatment will be available. This treatment, as well as other medical care expenses, will be your responsibility or may, in some instances, be paid for you by your health insurance. No compensation or reimbursement will be available from the Carolinas HealthCare System, or from Joseph Cook, M.D., John Fedor, M.D., Parks Griffith, M.A., William Herbert, Ph. D., Warren Ramp, Ph. D., Gary Kiebzak, Ph. D., or James Norton, Ph. D.

WITHDRAWL
Participation in this study is voluntary. You may refuse to participate or you may with withdraw from the study at any time. This will result in no penalty or loss of benefits to which you are otherwise entitled. You will be notified of significant new findings that may affect your treatment or your willingness to continue in the study.

CONFIDENTIALITY
The record of your visits will be in our medical record and is accordingly confidential. Other study results will be maintained by the investigator in a likewise confidential manner. Records pertaining to this study may be examined and/or copied by Joseph Cook, M.D. This research may result in scientific presentations and publications, but precautions will be taken to make sure that you are not identified by name.

_____
Patient/Guardian
Initials

FINANCIAL INTEREST OF THE INVESTIGATOR
As the primary investigator, I, (Joseph Cook, M.D.), as well as the co-investigators (John Fedor, M.D., Parks Griffith, M.A., William Herbert, Ph. D., Warren Ramp, Ph. D., Gary Kiebzak, Ph. D., or James Norton, Ph. D.), will not receive compensation for your involvement in this study.

QUESTIONS
For more information concerning the research and research-related risks or injuries, you may contact the principal investigator, Dr. Joseph Cook at (704) 373-1500. In addition, you may contact the chairman of the Institutional Review Board of the Carolinas HealthCare System for information regarding patient rights in a research study. You can obtain the name and number of this person by calling (704) 355-3158.

CONSENT
I hereby give my consent to participate in this study. I have read all of the above or have heard it read to me. I have had the opportunity to ask questions about this study, and my questions have been answered. A copy of this consent form has been provided to me.

_____
Patient Printed Name

_____ _____
Patient/Guardian Signature Date

_____ _____
Witness Signature Date

_____ _____
Investigator Signature Date

Appendix D

HRQL Questionnaires

MEDICAL OUTCOMES STUDY SHORT FORM HEALTH SURVEY (MOS-SF 36)

PHYSICAL FUNCTIONING SUBSCALE

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

c. Lifting or carrrying groceries

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

d. Climbing *several* flights of stairs

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

e. Climbing *one* flight of stairs

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

f. Bending, kneeling or stooping

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

g. Walking *more than a mile*

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

h. Walking *several* blocks

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

i. **Walking *one block***

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

j. Bathing or dressing yourself

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

ROLE PHYSICAL SUBSCALE

Have you had any of the following problems with your regular daily activities lately, as a result of your physical health?

a. Cut down on the amount of time you spent on work or other activities

1. Yes
2. No

b. Accomplished less than you like

1. Yes
2. No

c. Were limited in the *kind of work* or other activities

1. Yes
2. No

d. Had difficulty performing your work or other activities (it took extra effort)

1. Yes
2. No

ROLE EMOTIONAL SUBSCALE

Have you had any of the following problems with your work or other regular daily activities lately, as a result of any emotional problems (such as feeling depressed or anxious)?

a. Cut down on the amount of time you spent on work or other activities

1. Yes
2. No

b. Accomplished less than you would like

1. Yes
2. No

c. Didn't do work or other activities as carefully as usual

1. Yes
2. No

MENTAL HEALTH SUBSCALE

The following questions are about how you feel and how things have been with you lately. For each question, please give the one answer that comes the closest to the way you have been feeling.

Lately, how much of the time:

a. Have you been a very nervous person?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

b. Have you felt so far down in the dumps that nothing could cheer you up?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

c. Have you felt calm and peaceful?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

d. Have you felt downhearted and blue?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

e. Have you been a happy person?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

VETERAN'S SPECIFIC ACTIVITY QUESTIONNAIRE
(VSAQ)

Draw one line below the activities you are able to do routinely with minimal or no symptoms, such as shortness of breath, chest discomfort or fatigue

1 MET**:**	- Eating, getting dressed, working at a desk
2 METs:	- Taking a shower - Walking down eight steps
3 METs:	- Walking slowly on a flat surface for one two blocks - A moderate amount of work around the house, like vacuumming, sweeping the floors or carrying groceries
4 METs:	- Light yard work, i.e. raking leaves, weeding or pushing a power mower - Painting or light carpentry
5 METs:	- Walking briskly, i.e. four miles in one hour - Social dancing, washing the car
6 METs:	- Play nine holes of golf carrying your own clubs, heavy carpentry, mow lawn with push mower
7 METs:	- Perform heavy outdoor work (digging, spading soil,etc.) - Play tennis (singles), carry 60 pounds
8 METs:	- Move heavy furniture - Jog slowly, climb stairs quickly, carry 20 pounds upstairs
9 METs:	- Bicycling at a moderate pace, sawing wood, jumping rope
10 METs:	- Brisk swimming, bicycle up a hill, walking briskly up a hill, jog 6 miles per hour
11 METs:	- Cross country ski - Play basketball (full court)
12 METs:	- Running briskly, continuously (level ground, 8 min per mile)
13 METs:	- Any competitive activity, including those which involve intermittent sprinting - Running competitively, rowing, backpacking

BECK DEPRESSION INVENTORY-SECOND EDITION (BDI-II)

Name:_____ Marital Status:_____

Age:_____ Sex:_____

Occupation:_____Education:_____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** that best describes the way you have been feeling during the **past two weeks including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleep Pattern) or Item 18 (Changes in Appetite).

1. Sadness
- 0 I do not feel sad.
- 1 I feel sad much of the time.
- 2 I am sad all the time.
- 3 I am so sad or unhappy that I can't stand it.

2. Pessimism
- 0 I am not discourages about my future.
- 1 I feel more discouraged about my future than I used to be.
- 2 I do not expect things to work out for me.
- 3 I feel my future is hopeless and will only get worse.

3. Past Failure
- 0 I do not feel like a failure.
- 1 I have failed more than I should have.
- 2 As I look back, I see a lot of failures.
- 3 I feel I am a total failure as a person

4. Loss of Pleasure
- 0 I get as much pleasure as I ever did from the things I enjoy.
- 1 I don’t enjoy things as much as I used to.
- 2 I get very little pleasure from the things I used to enjoy.
- 3 I can’t get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thought of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I wold kill myself if I have the chance.

10. Crying

0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am not more restless or wound up than usual.
1 I feel more restless or would up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making decisions.

14. Worthlessness

0 I do not feel I am worthless
1 I don't consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.
1a I sleep somewhat more than usual.
1b I sleep somewhat less than usual.
2a I sleep a lot more than usual.
2b I sleep a lot less than usual.
3a I sleep most of the day.
3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.
1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.
2a My appetite is much less than before
2b My appetite is much greater than usual.
3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

Appendix E

KEY FOR RAW DATA VARIABLES

ID- patient identification number

Gender- 1= Male 0= Female

For the following 12 variables: 1= Yes, 0= No

Smoking Hx- history of smoking tobacco (Yes/No)

Current Smoker- currently smoking tobacco (Yes/No)

Family Hx- positive family history of heart disease (Yes/No)

Diabetes- diagnosed with Type I or Type II diabetes (Yes/No)

Hyperchol- diagnosed with hypercholesterolemia (Yes/No)

HTN- diagnosed with hypertension (Yes/No)

CVA- history of cerebrovasculur accident (Yes/No)

COPD- diagnosed with chronic obstructive pulmonary disease (Yes/No)

PVD- diagnosed with peripheral vascular disease (Yes/No)

Recent MI- suffered a recent (in relation to CABG) myocardial infarction (Yes/No)

CHF- diagnosed with congestive heart failure (Yes/No)

Angina-	suffers from symptoms of angina (Yes/No)
Pre-VSAQ-	VSAQ score prior to CABG
Post-VSAQ-	VSAQ score 3 months after CABG
Change VSAQ-	difference between pre- and post- VSAQ scores
Class VSAQ-	classification of VSAQ change score (1= increase; 0= no change; -1= decrease)
Pre-BDI-	BDI-II score prior to CABG
Post-BDI-	BDI-II score 3 months after CABG
Change BDI-	difference between pre- and post-BDI-II scores
Class BDI-	classification of BDI-II change score (1= increase; 0= no change; --1= decrease)
Pre-PF-	MOS SF-36 Physical Functioning score prior to CABG
Post-PF-	MOS SF-36 Physical Functioning score 3 months after CABG
Change PF-	difference between pre- and post- MOS SF-36 Physical Functioning scores
Class PF-	classification of MOS SF-36 Physical Functioning change score (1= increase; 0= no change; -1= decrease)

Pre-RP-	MOS SF-36 Role Physical score prior to CABG
Post-RP-	MOS SF-36 Role Physical score 3 months after CABG
Change RP-	difference between pre- and post- MOS SF-36 Role Physical scores
Class RP-	classification of MOS SF-36 Role Physical change score (1= increase; 0= no change; -1= decrease)
Pre-MH-	MOS SF-36 Mental Health score prior to CABG
Post-MH-	MOS SF-36 Mental Health score 3 months after CABG
Change MH-	difference between pre- and post- MOS SF-36 Mental Health scores
Class MH-	classification of MOS SF-36 Mental Health change score (1= increase; 0= no change; -1= decrease)
Pre-RE-	MOS SF-36 Role Emotional score prior to CABG
Post-RE-	MOS SF-36 Role Emotional score 3 months after CABG
Change RE-	difference between pre- and post- MOS SF-36 Role Emotional scores
Class RE-	classification of MOS SF-36 Role Emotional change score (1= increase; 0= no change; -1= decrease)
Post-VO_2 pk-	peak oxygen uptake collected during GXT 3 months after CABG

Appendix F: RAW DATA

PATIENT	ID#	AGE	GENDER	SMOKING HX	CURRENT SMOKER	FAM HX	DIABETES	HYPERCHOL	HTN	CVA	COPD
1	4	68	1	1	0	1	0	0	1	0	0
2	6	55	1	1	0	1	0	1	0	0	0
3	8	53	1	1	0	1	1	1	1	0	0
4	9	62	0	0	0	1	0	0	0	0	0
5	11	58	1	1	1	1	0	1	1	0	0
6	12	72	1	1	0	1	0	0	1	0	0
7	14	64	0	0	0	1	0	1	1	0	0
8	15	66	1	1	0	1	1	0	0	0	0
9	16	67	0	0	0	0	0	1	1	0	0
10	21	50	1	1	0	1	0	1	1	0	0
11	22	50	1	0	0	1	0	1	1	0	0
12	25	57	1	1	0	1	1	0	1	0	0
13	26	60	0	0	0	1	0	0	0	0	0
14	27	68	1	1	0	0	1	0	1	0	0
15	38	65	1	1	1	1	0	0	0	0	1
16	39	66	1	1	0	0	1	1	1	0	0
17	40	53	1	0	0	0	0	1	0	0	0
18	44	59	1	1	0	1	0	1	0	0	0
19	46	67	0	0	0	1	0	1	1	0	0
20	47	73	1	0	0	1	0	1	0	0	0
21	49	63	1	1	0	1	0	1	0	0	0
22	50	79	1	1	0	1	1	1	1	0	0
23	55	52	1	1	0	1	1	1	0	0	0
24	56	66	1	1	1	0	0	1	0	0	0
25	61	60	0	0	0	0	1	0	1	1	0
26	63	56	0	1	1	1	0	1	0	0	0
27	66	53	1	1	0	0	0	1	1	0	1
28	67	62	1	1	1	1	0	1	1	0	0
29	69	81	0	0	0	1	0	1	0	0	1
30	70	69	1	1	0	1	1	0	1	1	0
31	72	53	1	1	0	1	0	1	1	0	0
32	74	54	1	0	0	1	0	0	1	0	0
33	76	56	1	1	0	1	1	1	1	0	0
34	78	52	1	1	0	1	1	0	1	0	0
35	79	63	1	1	1	0	0	0	1	0	0
36	81	57	1	1	1	0	0	1	1	0	0
37	83	65	1	1	1	1	0	1	1	0	0
38	85	69	1	1	0	0	1	1	1	0	0
39	86	52	1	1	1	0	0	0	1	0	0

PATIENT	ID#	AGE	GENDER	SMOKING HX	CURRENT SMOKER	FAM HX	DIABETES	HYPERCHOL	HTN	CVA	COPD
40	89	75	1	1	1	0	1	1	0	0	0
41	91	68	1	0	0	1	1	0	0	0	0
42	92	76	1	1	0	0	0	1	1	0	0
43	100	70	1	1	0	1	0	1	0	0	0
44	103	56	1	1	0	0	1	1	1	1	0
45	106	68	1	1	0	0	0	1	1	0	0
46	110	55	1	0	0	1	0	1	1	1	0
47	112	59	1	1	0	0	0	1	1	0	0
48	113	63	1	1	1	1	0	0	0	0	1
49	119	60	0	1	0	0	1	0	1	0	0
50	130	56	0	1	0	0	1	1	1	0	0
51	135	46	1	1	0	1	0	1	0	0	0
52	139	58	1	1	1	1	1	1	0	0	1
53	144	77	1	1	0	0	0	1	0	0	0
54	146	60	1	1	1	1	0	1	0	0	0
55	154	77	1	1	0	1	0	1	1	0	0
56	156	76	1	1	0	1	0	1	0	0	0
57	157	71	1	1	0	0	0	0	1	0	0
58	162	53	1	1	1	1	0	0	0	0	0
59	168	52	0	0	0	1	1	0	0	0	0
60	171	54	1	1	0	1	0	1	1	0	0
61	173	57	1	1	1	1	0	1	0	0	1
62	175	67	1	1	1	1	0	1	0	0	0
63	178	66	0	1	0	0	0	0	1	0	0
64	179	55	1	1	1	0	0	0	0	0	1
65	181	70	1	1	0	0	0	1	1	0	1
66	183	50	1	1	1	0	0	1	1	0	0
67	186	71	1	0	0	0	0	1	1	0	0
68	188	71	1	0	0	1	1	0	1	0	0
69	190	75	1	1	0	1	0	0	1	0	0
70	192	77	1	0	0	1	0	0	1	0	0
71	193	71	1	0	0	1	0	1	1	0	0

PATIENT	PVD	RECENT MI	CHF	ANGINA	PRE-VSAQ	POST-VSAQ	CHANGE VSAQ	CLASS VSAQ	PRE-BDI	POST-BDI	CHANGE BDI
1	0	1	0	1	6	6	0	0	8	10	-2
2	0	0	0	1	5	10	5	1	4	1	3
3	0	1	1	1	3	6	3	1	3	3	0
4	0	0	0	1	4	6	2	1	1	0	1
5	0	1	0	1	1	8	7	1	4	3	1
6	0	0	0	0	9	8	-1	-1	4	1	3
7	1	0	0	1	4	9	5	1	9	12	-3
8	0	1	0	1	2	5	3	1	8	4	4
9	0	0	0	1	3	5	2	1	9	1	8
10	0	0	0	1	6	8	2	1	9	1	8
11	0	0	0	1	2	8	6	1	11	7	4
12	0	0	0	1	3	8	5	1	11	9	2
13	0	1	0	1	6	4	-2	-1	9	5	4
14	0	1	0	1	9	5	-4	-1	0	1	-1
15	0	1	0	1	8	9	1	1	6	2	4
16	1	0	0	1	4	6	2	1	0	0	0
17	0	1	0	1	10	10	0	0	7	1	6
18	0	1	0	1	6	7	1	1	14	0	14
19	0	0	0	1	4	9	5	1	5	2	3
20	0	0	0	1	4	6	2	1	10	8	2
21	0	0	0	1	3	8	5	1	6	3	3
22	0	1	1	1	1	4	3	1	6	1	5
23	0	0	0	1	7	7	0	0	12	6	6
24	0	1	0	0	4	4	0	0	5	3	2
25	0	1	0	1	1	5	4	1	7	23	-16
26	0	0	0	1	1	0	-1	-1	6	15	-9
27	0	1	0	0	4	4	0	0	8	14	-6
28	0	0	0	1	4	9	5	1	2	1	1
29	1	0	0	1	5	5	0	0	3	7	-4
30	0	1	1	1	2	3	1	1	17	7	10
31	0	0	0	1	4	6	2	1	16	7	9
32	0	0	0	1	4	7	3	1	2	0	2
33	0	0	0	1	3	6	3	1	2	0	2
34	0	1	0	1	3	10	7	1	8	4	4
35	0	1	0	1	3	5	2	1	8	4	4
36	0	1	0	1	6	9	3	1	4	0	4
37	1	0	0	1	4	4	0	0	11	6	5
38	0	0	0	1	3	3	0	0	8	6	2

PATIENT	PVD	RECENT MI	CHF	ANGINA	PRE-VSAQ	POST-VSAQ	CHANGE VSAQ	CLASS VSAQ	PRE-BDI	POST-BDI	CHANGE BDI
39	0	0	0	1	3	7	4	1	9	8	1
40	0	0	0	0	3	3	0	0	2	3	-1
41	0	0	0	1	8	7	-1	-1	3	7	-4
42	0	0	0	1	4	7	3	1	1	0	1
43	0	0	0	0	4	4	0	0	4	3	1
44	1	0	0	1	3	3	0	0	26	6	20
45	0	1	0	1	7	5	-2	-1	9	8	1
46	0	0	0	1	3	9	6	1	7	5	2
47	0	0	0	1	4	9	5	1	12	13	-1
48	1	1	0	1	2	3	1	1	6	6	0
49	0	1	0	1	2	4	2	1	4	2	2
50	0	1	0	1	2	4	2	1	30	4	26
51	0	1	0	1	6	6	0	0	12	1	11
52	0	1	0	1	2	3	1	1	34	27	7
53	0	0	0	1	4	3	-1	-1	18	7	11
54	0	1	0	1	4	5	1	1	8	6	2
55	0	0	0	1	4	5	1	1	10	9	1
56	0	0	0	1	10	9	-1	-1	12	3	9
57	0	1	0	0	6	5	-1	-1	6	8	-2
58	0	1	0	0	12	11	-1	-1	1	1	0
59	0	0	0	1	3	3	0	0	6	2	4
60	0	1	0	1	5	9	4	1	1	2	-1
61	1	1	0	1	3	4	1	1	16	7	9
62	1	1	1	1	3	3	0	0	3	5	-2
63	1	0	0	0	7	6	-1	-1	0	0	0
64	0	1	0	1	7	9	2	1	1	6	-5
65	0	1	0	1	4	6	2	1	2	0	2
66	0	1	0	1	9	4	-5	-1	22	39	-17
67	0	0	1	1	2	8	6	1	6	9	-3
68	0	1	0	1	2	3	1	1	12	10	2
69	1	0	0	0	5	3	-2	-1	4	11	-7
70	0	1	0	1	3	4	1	1	3	12	-9
71	0	1	1	1	3	6	3	1	8	3	5

PATIENT	CLASS BDI	PRE-PF	POST-PF	CHANGE PF	CLASS PF	PRE-RP	POST-RP	CHANGE RP	CLASS RP	PRE-MH	POST-MH
1	0	80	85	5	0	0	0	0	0	92	88
2	0	50	70	20	1	25	0	-25	-1	64	84
3	0	65	45	-20	-1	25	0	-25	-1	84	64
4	0	85	95	10	1	0	25	25	1	96	92
5	0	20	90	70	1	0	0	0	0	100	96
6	0	100	100	0	0	100	100	0	0	92	92
7	0	40	75	35	1	0	0	0	0	84	76
8	0	75	70	-5	0	0	50	50	1	80	80
9	1	65	70	5	0	0	75	75	1	84	84
10	1	95	95	0	0	0	100	100	1	60	84
11	0	65	100	35	1	25	100	75	1	68	80
12	0	50	90	40	1	25	75	50	1	60	60
13	0	75	70	-5	0	100	50	-50	-1	80	92
14	0	85	70	-15	-1	100	50	-50	-1	100	100
15	0	75	90	15	1	0	75	75	1	68	64
16	0	65	95	30	1	25	100	75	1	84	92
17	1	100	95	-5	0	75	50	-25	-1	64	72
18	1	75	90	15	1	100	50	-50	-1	68	88
19	0	65	95	30	1	50	100	50	1	92	96
20	0	50	80	30	1	0	0	0	0	88	88
21	0	40	95	55	1	0	50	50	1	76	88
22	0	30	25	-5	0	0	0	0	0	60	60
23	1	80	75	-5	0	75	25	-50	-1	64	72
24	0	65	95	30	1	100	100	0	0	100	100
25	-1	20	80	60	1	25	0	-25	-1	84	52
26	-1	30	10	-20	-1	0	0	0	0	84	72
27	-1	65	50	-15	-1	0	0	0	0	68	68
28	0	80	95	15	1	25	75	50	1	84	72
29	0	85	100	15	1	75	75	0	0	92	84
30	1	35	75	40	1	0	75	75	1	64	76
31	1	80	90	10	1	25	50	25	1	56	64
32	0	90	95	5	0	75	100	25	1	100	92
33	0	90	90	0	0	100	100	0	0	80	76
34	0	55	85	30	1	0	100	100	1	76	96
35	0	65	70	5	0	0	0	0	0	44	80
36	0	95	95	0	0	100	100	0	0	92	96
37	0	70	75	5	0	50	75	25	1	84	96
38	0	35	50	15	1	0	0	0	0	72	68

PATIENT	CLASS BDI	PRE-PF	POST-PF	CHANGE PF	CLASS PF	PRE-RP	POST-RP	CHANGE RP	CLASS RP	PRE-MH	POST-MH
39	0	75	90	15	1	100	25	-75	-1	64	68
40	0	55	55	0	0	0	0	0	0	80	96
41	0	80	85	5	0	50	25	-25	-1	88	92
42	0	100	75	-25	-1	100	50	-50	-1	80	92
43	0	70	65	-5	0	25	0	-25	-1	92	92
44	1	20	50	30	1	0	25	25	1	68	88
45	0	90	60	-30	-1	100	0	-100	-1	80	80
46	0	30	90	60	1	0	75	75	1	84	80
47	0	85	95	10	1	50	50	0	0	60	48
48	0	35	55	20	1	0	25	25	1	52	60
49	0	50	75	25	1	0	100	100	1	80	84
50	1	5	95	90	1	0	75	75	1	52	92
51	1	65	90	25	1	50	50	0	0	80	80
52	1	30	50	20	1	0	0	0	0	40	52
53	1	55	65	10	1	0	0	0	0	76	84
54	0	45	65	20	1	0	0	0	0	92	84
55	0	50	65	15	1	0	0	0	0	84	92
56	1	85	60	-25	-1	100	50	-50	-1	48	72
57	0	90	60	-30	-1	75	0	-75	-1	80	84
58	0	0	95	95	1	0	100	100	1	72	72
59	0	5	55	50	1	0	0	0	0	96	88
60	0	80	95	15	1	75	100	25	1	84	96
61	1	25	70	45	1	0	0	0	0	56	80
62	0	45	35	-10	-1	25	0	-25	-1	80	88
63	0	95	85	-10	-1	100	100	0	0	84	80
64	0	75	90	15	1	100	100	0	0	88	92
65	0	80	95	15	1	100	100	0	0	84	92
66	-1	90	60	-30	-1	0	0	0	0	52	28
67	0	15	50	35	1	0	0	0	0	76	60
68	0	35	50	15	1	0	0	0	0	76	72
69	-1	20	30	10	1	0	0	0	0	92	92
70	-1	100	75	-25	-1	100	50	-50	-1	96	84
71	0	60	85	25	1	0	0	0	0	84	92

PATIENT	CHANGE MH	CLASS MH	PRE-RE	POST-RE	CHANGE RE	CLASS RE		PATIENT	ID#	POST-VO2 PK
1	-4	0	100	0	-100	-1		1	4	23.7
2	20	1	33.33	0	-33.33	-1		2	8	15
3	-20	-1	66.67	33.33	-33.33	-1		3	9	15.6
4	-4	0	0	100	100	1		4	11	25
5	-4	0	100	100	0	0		5	12	25.1
6	0	0	100	100	0	0		6	14	17.6
7	-8	-1	100	100	0	0		7	15	19.8
8	0	0	0	33.33	33.33	1		8	16	17.8
9	0	0	100	100	0	0		9	21	24.6
10	24	1	0	100	100	1		10	22	23
11	12	1	100	100	0	0		11	25	22.8
12	0	0	100	100	0	0		12	26	10.4
13	12	1	100	100	0	0		13	27	15.4
14	0	0	100	100	0	0		14	38	18.2
15	-4	0	100	100	0	0		15	39	21
16	8	1	100	100	0	0		16	40	34.6
17	8	1	33.33	33.33	0	0		17	44	20.3
18	20	1	100	100	0	0		18	46	19.3
19	4	0	100	100	0	0		19	47	23.7
20	0	0	100	100	0	0		20	49	27
21	12	1	100	100	0	0		21	55	23.2
22	0	0	0	0	0	0		22	56	14.1
23	8	1	66.67	66.67	0	0		23	61	17.1
24	0	0	100	100	0	0		24	66	13.4
25	-32	-1	100	0	-100	-1		25	67	20.6
26	-12	-1	100	0	-100	-1		26	72	21.5
27	0	0	0	0	0	0		27	74	26.9
28	-12	-1	66.67	66.67	0	0		28	76	20.9
29	-8	-1	100	66.67	-33.33	-1		29	78	19.6
30	12	1	100	66.67	-33.33	-1		30	79	20.5
31	8	1	33.33	33.33	0	0		31	81	18.9
32	-8	-1	100	100	0	0		32	83	11.5
33	-4	0	100	100	0	0		33	85	18
34	20	1	33.33	100	66.67	1		34	86	23.6
35	36	1	66.67	33.33	-33.33	-1		35	91	21.6
36	4	0	100	100	0	0		36	92	23.6
37	12	1	100	100	0	0		37	100	12.7
38	-4	0	100	33.33	-66.67	-1		38	106	16

PATIENT	CHANGE MH	CLASS MH	PRE-RE	POST-RE	CHANGE RE	CLASS RE		PATIENT	ID#	POST-VO2 PK
39	4	0	33.33	33.33	0	0		39	110	19.3
40	16	1	100	100	0	0		40	112	25.2
41	4	0	100	100	0	0		41	119	13.1
42	12	1	100	100	0	0		42	130	12.1
43	0	0	100	33.33	-66.67	-1		43	139	15
44	20	1	0	66.67	66.67	1		44	154	22.5
45	0	0	100	0	-100	-1		45	156	15.9
46	-4	0	0	100	100	1		46	162	27.5
47	-12	-1	33.33	66.67	33.33	1		47	168	18.5
48	8	1	0	66.67	66.67	1		48	181	18.5
49	4	0	33.33	100	66.67	1		49	188	12.7
50	40	1	0	33.33	33.33	1		50	192	16.7
51	0	0	66.67	66.67	0	0		51	193	17.1
52	12	1	33.33	33.33	0	0				
53	8	1	100	100	0	0				
54	8	1	100	100	0	0				
55	8	1	0	100	100	1				
56	24	1	100	100	0	0				
57	4	0	100	66.67	-33.33	-1				
58	0	0	100	100	0	0				
59	-8	-1	100	100	0	0				
60	12	1	100	100	0	0				
61	24	1	0	33.33	33.33	1				
62	8	1	33.33	33.33	0	0				
63	-4	0	66.67	100	33.33	1				
64	4	0	100	100	0	0				
65	8	1	100	100	0	0				
66	-24	-1	0	0	0	0				
67	-16	-1	33.33	33.33	0	0				
68	-4	0	33.33	0	-33.33	-1				
69	0	0	66.67	100	33.33	1				
70	-12	-1	100	66.67	-33.33	-1				
71	8	1	33.33	33.33	0	0				

VITA

Sharon Yvonne Malo was born December 15, 1973 in Fort Belvoir, Virginia. She grew up in Northern Virginia with her parents Armand and Lin Malo, older brother Steve and younger brother Doug. She participated in organized soccer, and enjoyed playing softball and volleyball as well. While at Lake Braddock High School she joined the Varsity Dance Team, served as sports editor of the yearbook staff, and received many creative and technical writing awards. She graduated from high school in 1992 and set off for Virginia Tech in the fall of that year.

Sharon completed her first three semesters as a communications major, but soon realized that was not where she belonged. Early into her sophomore year she was accepted into the Exercise Science department with the intentions of pursuing a career in physical rehabilitation services. As an undergraduate, she was involved in intramural sports, performed volunteer services, held part-time jobs, and served as an active member of Delta Zeta Sorority. Sharon received the degree of Bachelor of Science in Human Nutrition, Foods, and Exercise in May of 1996.

Sharon entered the graduate Clinical Exercise Physiology program at Virginia Tech in the fall of 1996. While completing her graduate requirements, she worked with the cardiac rehabilitation program and served as a graduate teaching assistant. Sharon spent her last semester in Charlotte, NC and completed an internship in cardiac rehabilitation and assisted with a research study while collecting her thesis data.

Currently, Sharon works as a clinical supervisor of diagnostic testing, as well as an enhanced external counter-pulsation (EECP) technician, for a large cardiology group in Charlotte, NC. She plans to pursue future jobs in cardiovascular health promotion or rehabilitation.