FACTORS INFLUENCING HEALTH-RELATED QUALITY OF LIFE FOLLOWING CORONARY ARTERY BYPASS.

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at George Mason University

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Dedication

This work is dedicated to my husband, Colonel Michael D. Boyd, USMC (ret). Without his love and support, my dreams would never be a reality.

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I would like to express my deepest appreciation to the members of my dissertation committee. Jean Moore, Ph.D, (chair) guided the process with a unique balance of compassion and methodological certainty. Carol Urban, Ph.D. and Anastasia Kitsantas, Ph.D, provided a unique understanding of the needs of the critically ill, cardiovascular patient. Linda Henry, Ph.D., clinical nurse researcher provided the opportunity and direction to conduct a clinically focused, outcomes based study. A special thanks to Dr. James Vail, Ph.D, for securing funding for my research efforts. In addition to my committee, the members of the Cardiovascular Surgical Research Office, Inova Heart and Vascular Institute, Falls Church, VA for the willingness to support an academic-clinical collaborative effort. Without the permission of Dr. Niv Ad, MD. and the assistance of Lisa Martin, MA and Linda Halpin, RN, MSN, this dissertation would not have been possible. Recognizing the importance of mentors, Virginia Cassidy, Ed.D, Northern Illinois University, a stellar educator who set the standard to which I continue to strive. And to my students who became my teachers, Joan McLaughlin Rembacz, RN, MSN, and Michelle Clinton Sanabia, LT, United States Navy, Nurse Corps.

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Abstract

FACTORS INFLUENCING HEALTH-RELATED QUALITY OF LIFE FOLLOWING CORONARY ARTERY BYPASS

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George Mason University, 2011

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This non-experimental descriptive study examined the influence of preoperative health-related quality of life (HRQOL) and clinical risk factors on adults' postoperative HRQOL at 6 and 12 months after coronary artery bypass (CAB). Using the SF-12v2™ Health Survey (Standard Version 2.0) and the Society of Thoracic Surgeons (STS) Mortality and Morbidity risk assessment score, results indicate the overall model accounted for 21% (6 months) and 27% (12 months) of the variance in postoperative HRQOL. The greatest improvement in HRQOL was seen in the domains of physical function. No significant change in patients' wellbeing indicated by the mental health domains was seen after surgery.

Chapter 1

Introduction

Introduction and Background

Achieving the mandated, health-oriented goals identified by the Healthy People 2010 initiative rests with health care providers' ability to treat growing target populations with interventions that result in superior, measurable and cost-effective outcomes of care (Institute of Medicine, 1996; U.S. Department of Health and Human Services, 2000). As a result of increased life expectancies and advances in health care, Americans are living longer and requiring ongoing treatment for chronic illness at a substantial expense. One indication of this demographic change is the significant projected increase in the incidence of chronic cardiovascular disease (CVD) (Rosamond et al., 2007). In the United States, CVD is (1) the most prevalent chronic health problem reported by 47% of approximately 49 million adults over the age of 60; (2) the leading cause of death among adults; and (3) listed as the final discharge diagnosis in 13% of all hospital records (Agency for Health Care Research and Policy, 2006; Lloyd-Jones et al., 2009; U.S. Census Bureau, 2007) Although research has been directed at finding effective alternative treatments for CVD, coronary artery bypass grafting (CAB) remains the most frequent surgical intervention, at a significant expense to federal entitlement programs and health insurers. In 2005, 88,000 of the 469,000 cardiovascular surgical procedures performed were CAB, and averaged a cost of approximately $85,000 dollars per procedure (Hall & Owings, 2002; Mauldin, Becker, Phillips, & Weintraub, 2007).

In response to the projected increase in both the volume of surgical procedures and the cost burden associated with CAB, federal regulation and third party payers require cardiac surgeons and hospitals with heart surgery programs to provide evidence of comprehensive and measurable outcomes of care (Agency for Healthcare Research and Quality, 2006). Traditionally, the most universally accepted goal of CAB was survival, a clinically-focused outcome measure. If patients survived, the surgery was successful and the outcome of care was considered positive. Over time, survival after CAB implied a quality outcome.

International endeavors to understand, predict and mediate the potential risk of a poor surgical outcome led to the development of mortality and morbidity risk assessment models (O'Brien et al., 2007; Youn, Kwak, & Yoo, 2007).   The Society of Thoracic Surgeons (STS) designed the National Adult Cardiac Surgery Database (Edwards et al., 1997) to organize individual cardiovascular surgical patients' clinical and treatment data for the purposes of (1) determining preoperatively an individual's risk of dying within 30 days of surgery; (2) providing researchers with data to evaluate individual clinical risk factors and treatment variables that influence mortality and morbidity and; (3) facilitating standardized comparisons of therapeutic interventions between patients, among surgeons or across hospitals and communities (Ad, Barnett, & Speir, 2007). A risk assessment quantifies the contribution of individual clinical risk factors to an adverse surgical outcome. The value of the STS risk assessment model is that the preoperative risk score is a reliable and stable measure of patients' disease burden prior to surgery. The resulting body of knowledge empirically supported the accuracy of mortality and morbidity risk assessment models in predicting an adverse postoperative outcome (Ad, Barnett, & Speir, 2007; Grover et al., 2001; Rizzo & Sindelar, 1999).

The issue of health-related quality of life (HRQOL) as a measureable postoperative outcome of CAB gained momentum as the projected increase in life expectancy, consumer demand for provider accountability and pay for performance directives were addressed by changes in public policy. The Institute of Medicine Health Quality Initiative (1996) challenged the health services research community to redefine health care outcomes in holistic and individualist terms that refocus care beyond extending life to enhancing patients' lives. As a result, HRQOL became accepted as an appropriate, patient-centered outcome of care. Over time, HRQOL assessment became an established field of study within health services research and numerous studies have been undertaken to develop reliable measurements across diverse populations (Bowling, 2002; Krumholtz, et al., 2006; Power, Harper, & Bulinger, 1999; Tarlov et al., 1998; U.S Department of Health and Human Services, 2000).

Among the increasing numbers of chronically ill cardiovascular patients, international research efforts focused on the impact of medical treatments on individual patients and age and gender based differences in HRQOL outcomes. Supporting these research efforts were studies in which comparisons in HRQOL between the chronically ill and the general population were drawn (Stewart & Ware, 1992).

As the sophistication of HRQOL studies evolved, inconsistencies in research findings raised fundamental questions regarding (1) the essential nature of reliable HRQOL measures; (2) the empirical validation of proposed models; and (3) the variability in HRQOL among groups of patients based on diagnosis. In an attempt to reconcile inconsistent findings, the internationally-based Scientific Advisory Committee of the Medical Outcomes Trust, an independent working group of the Scientific Advisory Committee (2002), reviewed the state of HRQOL research and recommended a consistent and rigorous approach for empirically describing the phenomena and addressing the obvious gaps in knowledge relevant to adults following CAB. The purpose of this study was to explore the influence of preoperative HRQOL (baseline) and clinical risk factors on postoperative HRQOL at 6 and 12 months after coronary artery bypass (CAB).

Statement of the Problem

There remains a lack of consensus among researchers concerning which preoperative variables have the greatest influence on postoperative HRQOL in patients following CAB and when is the optimal time during the postoperative period to assess clinically significant changes in HRQOL (Al-Ruzzeh et al., 2005; Le Grande et al., 2006; Martin et al., 2008; Rumsfeld, 1999). Among CAB patients, individual clinical risk factors are associated with patients' HRQOL after CAB. Although the direct and indirect impact of these selected preoperative clinical risk factors on postoperative HRQOL has not been established, preliminary studies suggest that chronic neurological disease, hypertension, depression, psychiatric disorders, limited social networks (Rumsfeld, 1999; Sandau et al., 2008), diabetes, chronic renal disease, sleep disturbances (De Visser, Bilo, Groenier, De Visse, & Meyboom-de Jong, 2001; Le Grande et al., 2006;), preoperative gastrointestinal problems, preoperative congestive heart failure, and peripheral vascular disease (Al-Ruzzeh et al., 2005) may influence HRQOL after CAB (Ad, Barnett, & Speir, 2007; Grover et al., 2001; Nashef et al., 2002).

Other than selected clinical risk factors, El Baz, et al. (2008) demonstrated the value of a mortality and morbidity risk assessment score in predicting postoperative HRQOL. Using the European System for Cardiac Operative Risk Evaluation (EUROSCORE), the disease burden based on the contribution of clinical risk factors was found to predict postoperative HRQOL. Linking established and validated clinical risk assessment models with postoperative HRQOL outcomes would potentially allow health care providers and patients the opportunity to make treatment decisions before surgery, based on the projected long-term impact on quality of life.

In addition to the clinical risk factors included in the EUROSCORE, patients' preoperative HRQOL has also been found to predict postoperative HRQOL (Al-Ruzzeh et al., 2004). Preoperatively, CAB patients experiencing chronic pain and reporting a belief that the risks associated with surgery outweigh the potential benefits report poorer postoperative HRQOL, and experience increased mortality rates and longer hospital stays (Arthur, Daniels, McKelvie, Hirsh, & Rush, 2000; Hermele, Olivo, Namerow, & Oz, 2007). Although studies linking preoperative HRQOL to postoperative changes in HRQOL have been inconclusive, they do suggest that patients' subjective perception of their physical and mental health function captured by HRQOL measures may constitute preoperative clinical risk factors that predict patients' HRQOL following surgery (Martin et al., 2008).

In an effort to better understand the influence of preoperative clinical risk factors, risk assessments and HRQOL on postoperative HRQOL, researchers have used several reliable and valid, general and disease-specific tools including the SF-12v2™ Health Survey Standard Version (SF-12v2™) (Höfer, Lim, Guyatt, & Oldridge, 2004; Ware, 2008). The 12-item, SF-12v2™ is one of several Short Form Health Surveys (SF-36™, SF-20™, SF-8™) constructed from a subset of 149 core items developed during the Medical Outcome Study (MOS) (Scientific Advisory Committee of the Medical Outcomes Trust, 2002; Stewart & Ware, 1993). In longitudinal studies with large sample sizes, the scales of the SF-12v2™, a subset of the longer 36-item, SF-36™ survey, have demonstrated equivalent means scores for total HRQOL and the physical (PCS) and mental (MCS) component subscales of HRQOL among general and disease-specific populations at 3, 6, and 12 months (Hahn et al., 2007; Scientific Advisory Committee of the Medical Outcomes Trust, 2002). Used extensively in HRQOL research to measure changes in the general population, the SF-12v2™ survey is convenient, may be completed in less than 2 minutes, and is sensitive to modest changes in HRQOL among the chronically ill.

Conceptual Framework

Wilson and Cleary's (1995) comprehensive conceptual framework of HRQOL guided the study. Extensive testing among cardiovascular surgical patients has shown that the framework consistently supports a causal relationship between clinical variables and HRQOL (Höfer et al., 2005; Rosen, Contrada, Gorkin, & Kostis, 1997). The Wilson and Cleary model is presented in Figure 1.

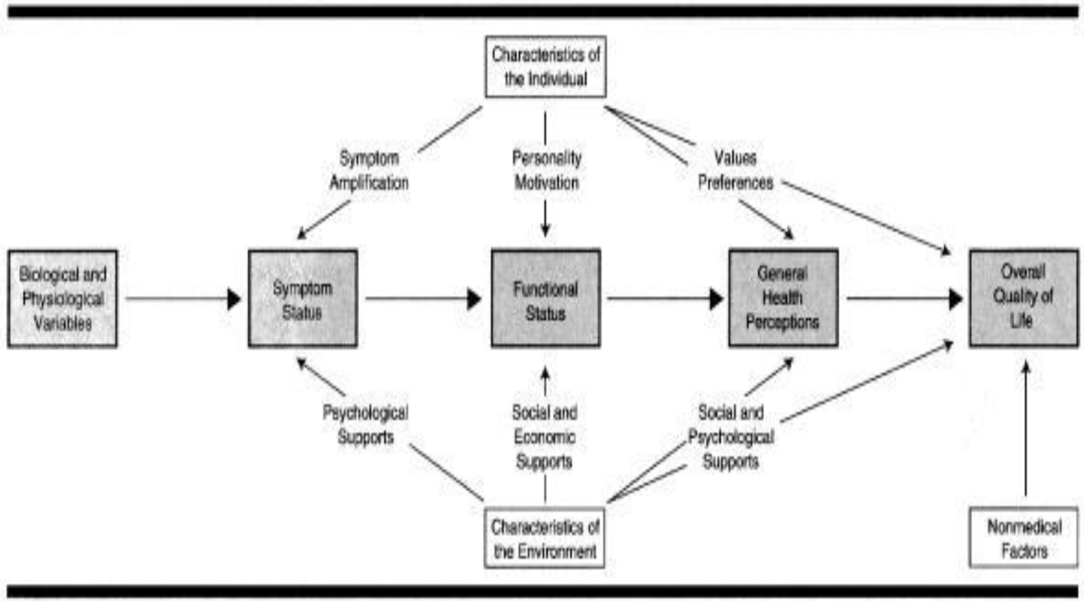

Figure 1: Wilson I. & Cleary, P. Linking clinical variables with health-related quality of life: a conceptual model of patient outcomes. JAMA 1995; 273 (1), 59–65.

Components of the model include a total of 8 latent factors, with 5 factors arranged in a linear fashion and a causal flow from biological factors on the left to psychological factors on the right. Four endogenous factors (symptom status, functional status, general health perception and overall quality of life) are influenced by four exogenous factors (biological and physiological variables, characteristics of the individual, characteristics of the environment and nonmedical factors). In a linear fashion, the effects of biological and physiological variables or factors on general health perception are mediated by patients' symptoms and functional status. General health perception, influenced by symptoms and functional status, has a direct effect on overall quality of life.

Individual and environmental characteristics directly influence symptom status, functional status, general health perceptions, and overall quality of life. The transition between latent factors and empirical data can be verified by previous studies in which the variables or factors included in the model have been successfully operationalized (Ferrans, Zerwic, Wilbur, & Larson, 2004; Hahn et al., 2007; Höfer et al., 2005). Based on the comprehensiveness of the Wilson and Cleary model (1995), the current study was undertaken to investigate the hypotheses that (1) the HRQOL for patients following CAB is influenced by clinical biological and physiological variables; (2) the influence of clinical variables on HRQOL is unidirectional and linear; (3) the effect of clinical variables on HRQOL is mediated by symptom and functional status, and (4) general health perception is a subjective assessment of the impact of the previous factors on overall quality of life. Previous studies that have attempted to identify clinical variables that predict postoperative HRQOL after CAB have been inconsistent (El Baz et al., 2008; Janse et al., 2004; Komorovsky et al., 2008; Sandau et al., 2008). The information derived from the study will provide empirical support for a theoretical biopsychosocial model of HRQOL, which can then be applied to subgroups or clusters of CAB patients, in an effort to tailor postoperative care for patients with higher probabilities of declining HRQOL (Bridgewater, Neve, Moat, Hooper, & Jones, 1998; Edwards et al., 2005; Scientific Advisory Committee of the Medical Outcomes Trust, 2002).

Adapted from the Wilson and Cleary (1995) model, the following framework guided the study of the influence of preoperative HRQOL (baseline) and clinical risk factors on postoperative HRQOL at 6 and 12 months after CAB.

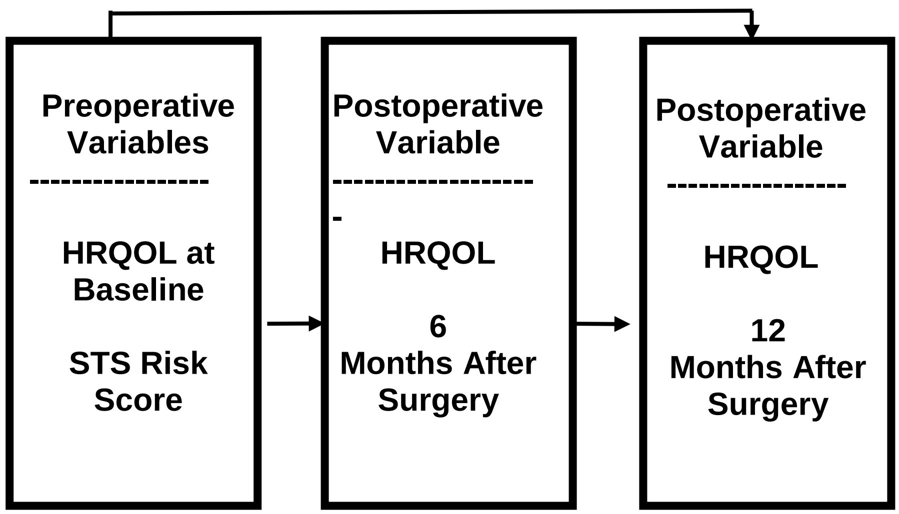

Figure 2: Factors influencing health-related quality of life following coronary artery bypass: A proposed conceptual framework.

Definition of Terms

Health-related quality of life.

Health-related quality of life (HRQOL) is a self-reported, personal perception of functioning and well-being impacted by disease, disability or medical treatment (Appendix A) (Crosby, Kolotkin, & Williams, 2003; Höfer et al., 2005; Wilson & Cleary, 1995). A patient with severe chronic disease, for example, may have a positive self-reported HRQOL if they are able to participate in a favorite activity or attend a social function. Consisting of both physical and mental health dimensions, HRQOL is influence by bodily pain, vitality, social networks, general health perspective, and the ability to physically and mentally meet day to day responsibilities. Patients' general health perception is a measure of an individual's view of their current overall health in reference to previous health status and future concerns. Subjective assessment reflects a global perspective of overall health influenced by multiple experiences including number of physician visits, compliance with medical plan of care, and future health outlook (Elliott, Lazarus, & Leeder, 2006; Mandzuk & McMillan, 2005).

Preoperative clinical risk factors.

Biological and physiological variables included in Society for Thoracic Surgeons (STS) Mortality and Morbidity Risk Assessment Model. Each risk factor is weighted and the probability of mortality or morbidity within 30 days of surgery calculated. For example, a patient with a score of 0.50 has a 50% chance of dying or having chronic disability after surgery. Alterations in health leading to disability may include pain, chronic renal insufficiency, renal failure, or altered pulmonary and neurological function. Operational definitions of individual risk factors included in the STS model, are provided (Appendix B).

Coronary artery bypass (CAB).

Operative procedure in which blood flow to the heart muscle is re-established by surgically attaching an alternate vessel to redirect blood flow around an occlusion in the coronary artery or arteries. The new route delivers oxygen rich blood flow to the heart muscle (myocardium). Surgery is limited to coronary arteries only and does not include other cardiac structures including the atria, ventricles, or valves.

Summary

Increased numbers of older adults are living longer with chronic cardiovascular or coronary artery disease. Increased life expectancy parallels the increased utilization of CAB, which is the most frequently performed surgical intervention for coronary artery disease. Preliminary studies have been inconclusive, but suggest that the variables influencing surgical risk may predict changes in HRQOL following surgery. This study would (1) explore the influence of selected variables on changes in HRQOL after CAB; and (2) identify whether significant HRQOL changes may occur at 6 and 12 months after surgery. Identifying preoperatively subgroups of patients at risk for suboptimal postoperative HRQOL outcomes would allow health care providers to (1) provide patients with realistic expectations during the informed consenting process; and (2) extend postoperative care to include additional screenings for patients at risk for declining HRQOL, re-hospitalization and early death.

Chapter 2

Literature Review

Introduction

The purpose of this literature review is to establish theoretical and empirical support for the planned study to explore the influence of preoperative HRQOL (baseline) and clinical risk factors on postoperative HRQOL at 6 and 12 months after coronary artery bypass (CAB) (Bootee & Beile, 2005). To achieve this purpose, a literature review was organized based on relevant and reliable primary studies analyzed for validity, and meaningful clinical comparisons. Using inclusion and exclusion criteria, a search strategy based on the variables of interest - clinical variables included in a mortality and morbidity risk assessment and health-related quality of life (HRQOL) were selected for review. Research methodologies and techniques were also considered when answering the research questions.

Inclusion and exclusion criteria.

Empirical studies included in the review were written in English and addressed the theoretical and empirical relationship between clinical risk factors and HRQOL. A review of methodological approaches focused on studies published between 1999 and 2009 in which HRQOL outcomes were measured in large datasets of CAB patients using the MOS 12v2™ Health Survey Standard Version (SF-12v2™), a revision of the extensively tested SF-36™ (Ware, 2008). Research studies were retained for further analysis if the variables - HRQOL and clinical risk factors included in the mortality and morbidity risk assessment - were the primary study variables and an adequate sample size yielded meaningful clinical comparisons.

Search strategy.

Using the inclusion and exclusion criteria, a review of the literature was undertaken in three sections, including (1) HRQOL among CAB patients; (2) clinical risk factors influencing HRQOL following CAB; and (3) empirical support linking clinical risk factors to changes in HRQOL over time. Search strategies included a review of electronic and print resources, in English, using the following key words: coronary bypass surgery, cardiovascular surgery, risk factors, risk of mortality, prognosis, Wilson and Cleary, quality of life, health-related quality of life, measurement, outcomes assessment, Medical Outcomes Study, Short-form 36, Short-form 12, Short-form 8, and mortality risk assessment. Searches were conducted using the following electronic databases: The Cumulative Index to Nursing and Allied Health (CINAHL), 1995 to present; U.S. National Library of Medicine, MEDLINE, 1995 to present; Evidence Based Medicine Reviews (EBMR), Cochrane Database of Systematic Reviews (DSR), Health and Psychological Instruments and Mental Measurements Yearbook, 1999-present, and Digital Dissertations, 1999-present. Additionally, a manual search of these selected journals: Circulation, European Society of Cardiology, Health Psychology, Quality of Life Research, and Heart & Lung: Journal of Acute & Critical Care Nursing provided significant research studies not found in the previously identified electronic databases.

Postoperative Health-related Quality of Life (HRQOL)

Cardiovascular surgical outcomes researchers agree that HRQOL is a multidimensional, valid and measureable outcome of care in which overall quality of life is viewed from a health perspective (Hahn et al., 2007). Conventional measures of HRQOL reflect patients' self-reported impact of illness or medical treatments on their physical and mental functioning (Elliot, Lazarus, & Leeder, 2006; Ferrans et al., 2005; Höfer, Doering, Rumpold, Oldridge, & Benzer, 2006; Naughton & Shumaker, 2003; Wilson & Cleary, 1995).

Patients' perception of their function and well-being (HRQOL) has gained acceptance as an outcome measure of care because (1) changes in health policy support more patient-centered outcomes; (2) surgery reduces mortality but increases morbidity; and (3) patients' and physicians' assessments of HRQOL after CAB diverge, raising the issue of what constitutes a realistic outcome of care from the patients' perspective (Janse et al., 2004). Supporting HRQOL research has been the development of several reliable tools that have been internationally validated across general and disease-specific patient populations resulting in an extensive collection of outcomes research. However, there remains a lack of consensus among researchers on the most accurate and efficient measure of HRQOL following CAB. Methodologically, researchers weigh the advantages and disadvantages of using a shorter, generic HRQOL tool across patient populations versus a longer tool that may potentially measure subtle changes in HRQOL associated with a single disease or medical treatment. Several general and disease specific instruments have been developed and found to reliably measure HRQOL (Höfer, Lim, Guyatt, & Oldridge, 2004).

Among CAB patients, the most reliable and extensively validated generic instruments measuring HRQOL are the Medical Outcomes Study (MOS) Short Form 36-item Health Survey Standard Version (SF-36™) and revised versions SF-20™ and SF-12v2™ (Stewart & Ware, 1993; Scientific Advisory Committee of the Medical Outcomes Trust, 2002; Ware, 2008). The generic MOS instruments are constructed of items that measure the physical and mental health dimensions of HRQOL. Conceptually, the 2-factor construction of all SF questionnaires is based on five categories or indicators of physical and mental health measured by 8 domains of function. The indicators of physical and mental health: clinical status, physical function and well-being, mental functioning and well-being, social role functioning, and general health perception are measured by the domains: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH) (p. 14, Stewart & Ware, 1993). Results using MOS instruments are scored using the physical component (PCS) and mental component (MCS) subscales. Although versions of the MOS instruments vary in the number of items and approximate length of time required to complete each survey, psychometric properties are consistent. The subscales of the SF-12v2™ has been found to be internally consistent with reported Cronbach's alpha of .88 (PCS) and .89 (MCS) and weakly correlated with each other (*r* = .06) (Sansgiry, Chien, Jayawant & Raju, 2008).

In comparison, the 3-factor, cardiac disease or population specific, 27-item MacNew Heart Disease Health-related Quality of Life Questionnaire (MacNew) is conceptually constructed to measure the physical, social and emotional dimensions of HRQOL (Höfer, Lim, Guyatt, & Oldridge, 2004). Similar to the SF-12v2™, the 27 items of the MacNew demonstrates a reported internal consistency, or Cronbach's alpha, ranging from .93 to .95 (p < 0,001) (Höfer et al., 2005). In addition to the subscales, the MacNew was constructed to include a global score for HRQOL resulting from the averaging of all responses.

Both questionnaires are grounded in quality of life research and philosophically accept HRQOL as a distinct concept related to overall quality of life impacted by disease or medical treatments. In an effort to determine the accuracy of predicting HRQOL in cardiac patients, a comparison was made between SF-12v2™ and MacNew questionnaires among 111 cardiac patients (Sansgiry et al., 2008). Each patient acted as their own control and was provided both questionnaires. Strong correlations between instruments using Cronbach alpha demonstrate the reliability and validity of the 2-factor and 3-factor component scores. In comparing the SF-12v2™ and MacNew subscales, the

PCS scores were strongly correlated ($r = .74$; $p = .001$). The SF-12v2™ MCS of the SF-12v2™ and the emotional component scores of the MacNew were also strongly correlated ($r = 0.68$; $p = .001$). Consistent with previous studies, both questionnaires were found to be internally consistent and reliable measures of HRQOL among cardiac patients. However, the SF-12v2™ has the added advantage of shorter length of completion time and a high response rate. Limitations of the study included (1) providing only a single opportunity to complete the questionnaires did not allow for comparisons over time and (2) individual clinical risk factors information was not available for comparison purposes. Currently, few studies have been undertaken to describe the influence of time on changes in HRQOL for cardiac patients after CAB. The development of reliable measures promote this longitudinal exploration.

Risk Factors Influencing Health-related Quality of Life

Demographic characteristics.

Differences in HRQOL after CAB surgery have been inconsistently associated with the demographic characteristics of age and gender (Edwards et al., 2005; Rumsfeld et al., 1999). Regarding age, Jarvinen, Saarinen, Julkunen, Hutala, and Tarkka (2003) found patients less than 75 years of age at the time of surgery reported postoperative improvement in functional capacity and HRQOL. Höfer, et al. (2005) supported the age-related association, and suggested the decrease in HRQOL for adults > 75 years of age was mediated by higher surgical complication rates and resulting lower levels of physical function. Merkouris, et al. (2008) suggested that declining mental acuity and lack of social support contributed to age-related decreased in HRQOL. In contrast, Goyal, Idler, Krause and Contrada (2005) found no significant difference in surgical risk or improved HRQOL between 2 groups of adults: patients between the ages of 70 and 79 and patients 80 years of age and older.

The factors influencing gender differences in HRQOL following CAB are not clearly understood. Although men and women report improved HRQOL after CAB, women report, on average, poorer HRQOL before and after surgery (Lindquist et al., 2003). The individual characteristics associated with gender-related differences in postoperative HRQOL have not been established, however suggested causal relationships include (1) reduced sense of function (DiMattio & Tulman, 2003; Höfer et al., 2005); (2) an increased complication rate related to presurgical characteristics including anemia, hypothyroidism, and Diabetes Mellitus (Edwards et al., 2005); and (3) increased susceptibility to pain and sleep disturbances (Hunt, Hendrata, & Myles, 2000). Hogue, et al. (2008) supported the association between presurgical neurocognitive dysfunction and poorer post surgical HRQOL in postmenopausal women.

Clinical characteristics.

Selected clinical risk factors associated with the development of coronary artery disease and included in the mortality and morbidity risk assessment model have also been associated with changes in the physical function, mental function and general health perception domains of HRQOL.

After CAB, lower levels of physical function and poorer HRQOL have been reported by patients with severe comorbidities including Diabetes Mellitus (Dobre et al., 2006) and poor diabetic control (Deaton et al., 2006). Supporting the relationship between HRQOL and clinical variables, Martin, et al. (2008) prospectively studied changes in HRQOL in 836 adults following elective CAB. Perception of physical function improved but mental health function remained unchanged within the first postoperative year

The relationship between preoperative mental health function, neurocognitive dysfunction, depression, anxiety, and lower postoperative HRQOL is consistently reported (Hogue et al., 2008; Lindquist et al., 2003). The cumulative effect of preoperative neurocognitive dysfunction and risk of neurological injury during surgery may contribute to lower postoperative HRQOL (Puskas et al., 2004; Stygall et al., 2003).

General health perception or a combined effect of physical and mental health function is negatively impacted by the comorbidities of pulmonary disease or injury (Weissman, 2004), renal dysfunction (Cooper et al., 2006; Parikh et al., 2006), and neurocognitive function (Dobre et al., 2006). DiMattio and Tulman (2003) examined the functional capacity and general health perception of women before and after CAB at 2, 4 and 6 weeks after surgery. Although physical function improved, general health perception was unchanged. One possible explanation offered is that ongoing pain and sleep disturbances contribute to poorer general health perceptions after surgery.

Al-Ruzzeh, et al. (2005) examined the association between clinical characteristics and changes in both physical and mental components of HRQOL in 463 adults, one year after CAB. The study found that changes in the physical component scores of HRQOL were associated with gastrointestinal problems and cardiac-related physical disability. Significant difference in mental component scores were associated with primary subjects older than 70 years of age, previous primary pulmonary and neurological diagnoses, history of infection, smoking, anxiety and depression. HRQOL measures were not collected to establish baseline levels before surgery.

The conventional study of the association between clinical risk factors and changes in HRQOL has focused on individual characteristics. However, preliminary studies with oncology patients suggest symptom clusters may be more significant (Kim, McGuire, Tulman, & Barsevick, 2005). This association has been supported by the cluster analyses of elderly CAB patients preoperatively (Lindgren et al., 2008) and postoperatively (Fukuoka, Lindgren, Rankin, Cooper and Carroll, 2007). In both studies, the combination of continuing fatigue, shortness of breath, and sleep disturbances negatively influenced HRQOL.

Disease Burden and Changes in Health-related Quality of Life

The Wilson and Cleary model linking clinical variables with HRQOL has been extensively tested in cardiovascular patient populations and is raising questions about the causal relationships between the combined impact of biological and physiological clinical characteristics on patients' self-perception of physical and mental function (Ferrans et al., 2005; Höfer et al., 2006; Ulvik et al., 2008).

Höfer, et al. (2006) surveyed 432 patients with evidence of coronary artery disease before and 1 and 3 months after beginning treatment. The purpose of the study was to test the relationships among the variables of biological and physiological characteristics, symptoms, functional status, general health perception and overall quality of life proposed by the Wilson and Cleary model (1995). Biological and physiological characteristics included previously-identified coronary artery risk factors (Diabetes Mellitus, number of diseased vessels). Symptom status was measured using a classification for angina related disability. Physical function was measured with the SF-36™ physical function score. General health perception was measured by the SF-36 ™ general health perception question. Overall quality of life was conceptually viewed as a disease-specific HRQOL variable measured by the MacNew Heart Disease Quality of Life questionnaire. Findings suggested that the severity of illness or complication rates directly influence patient symptoms, which in turn directly influence physical function and HRQOL. Although the study did not explore longitudinal changes, the contribution of physical function (one month) and depression (three months) contributed to poorer HRQOL.

In contrast, using a cross-sectional design and convenience sample, Ulvik, et al. (2008) surveyed 753 cardiac patients to determine the influence of physical and mental function on HRQOL measured by the SF-36 TM. Results suggested that there is a direct relationship between the number of complications or severity of illness and reported symptoms and patient perception of symptoms that directly impact perceived physical function. However, patients with extensive, clinically-documented cardiovascular disease did not necessarily report poorer HRQOL.

Mortality and Morbidity Risk Assessment Models and HRQOL

Linking mortality risk assessment scores to changes in HRQOL is an innovation in outcomes research in which preliminary findings warrant further study. The Thoracic Surgeons (STS) Mortality Risk Assessment Score (Martin et al., 2008), Cardiac Care Network (CCN) of Canada (Fukuoka, Lindgren, Rankin, Cooper, & Carroll, 2007), and the European System of Cardiac-operative Risk Evaluation Score (EUROSCORE) (El Baz, Middel, Van Dijk, Wesselman, Boonstra, & Reijneveld, 2008) are examples of large standardized datasets in which (1) logistic regression models have been developed to identify the influence of patient demographics, clinical characteristics and surgical complications on mortality risk; and (2) rigorous data collection methods are consistent with recommended guideline for reporting quality outcomes (Krumholz et al., 2005). Mortality risk using the STS has been consistent with the EUROSCORES for CAB patients and used extensively throughout the cardiovascular surgical community (Ad et al., 2007).

Martin, et al. (2008) examined the impact of surgical complication on HRQOL at two time points, before surgery and at 1 year after cardiac surgery. HRQOL was measured using the SF-20 ™. Six hundred twenty out of a total of 836 participants had a CAB procedure and completed the HRQOL questionnaires. The STS score was the covariate in the analysis of the mean difference in all 6 domains of the SF-20 ™ (general health perception, mental health, bodily pain, physical function, role function, social function and overall HRQOL.) No significant difference in HRQOL was found between two subgroups of patients stratified by complications rates (0 / ≥1). The domains of general health perception, physical function and overall HRQOL significantly improved at both time points. There were no significant changes in the mental health domain. However, the results of the study were limited by a convenience sample that included only clinically-stable patients scheduled for elective surgery, excluding emergent or clinically-unstable patients that are at greater risk for complications and poor health outcomes. Furthermore, this and other studies have not established an optimal time point to identify and assess practical and significant changes in health status.

In contrast, El Baz, et al. (2008) (1) compared preoperative and six-month postoperative HRQOL in 181 consecutive CAB patients; and (2) tested whether a EUROSCORE predicts patients' HRQOL six months after surgery using the SF-36 ™. The study found that a higher EUROSCORE was associated with the poorer physical function component of HRQOL before and after surgery, hospital readmission rates within six weeks after surgery, increased surgical complications and length of hospitalization. No correlation was found between mortality risk and changes in the mental health domain of HRQOL. Clinical characteristics related to decreased HRQOL included the variables previous discussed.

Fukuoka, et al. (2007) interviewed 206 patients, 65 years of age or older, one year after CAB or an acute myocardial infarction, and found significant differences in HRQOL among three subgroups of patients based on individual characteristics and ongoing symptoms. Patients with a history of hypertension, Diabetes Mellitus, sleep disturbances, and shortness of breath reported significantly poorer HRQOL than adults with ongoing pain. Cluster analysis by symptoms and previously collected individual patient characteristics (CNN) provided insight into HRQOL among subgroups of patients. However, single observations at 12 months did not suggest potential longitudinal changes or support previous studies in which pain is associated with lower HRQOL (Le Grande et al., 2006; Ware, 2008).

Summary

Determining appropriate therapeutic interventions for patients with CAD has evolved from the goal of preventing death to improving quality of life. As a result, frequently reported measures of treatment effectiveness are mortality and morbidity rates and HRQOL. The combined influence of clinical risk factors (disease burden) on patients' risk of mortality and morbidity is well established.

Patients with greater disease burden have higher mortality rates and experience more complications, longer recovery periods and higher hospital readmission rates after discharge. The value of risk adjusted models to systematically estimate the impact of clinical risk factors on surgical outcomes has promoted changes in clinical practice that have effectively improved survival rates.

Among CAB patients, there is also growing theoretical and empirical evidence establishing a relationship between clinical risk factors and HRQOL outcomes. These findings support the hypothesized relationship between clinical variables and HRQOL proposed by Wilson and Cleary (1995), and suggest that CAB patients with greater disease burden have an increased risk of poorer HRQOL, and experience higher readmission rates and shorter life expectancies after surgery. These findings were reported after HRQOL measures were obtained retrospectively at one point during the postoperative period. However, while current research supports the connection between clinical factors and post-operative changes in HRQOL, there remains a lack of consensus regarding (1) the relative contribution of individual clinical risk factors to predicting HRQOL after CAB; or (2) the postoperative time at which clinically significant changes in HRQOL are most likely to occur.

This study will test whether the Society of Thoracic Surgeons (STS) mortality and morbidity risk assessment score will predict changes in patients' HRQOL after surgery and which risk factors have the greatest influence on HRQOL. The proposed study will contribute to an understanding of the phenomena of HRQOL after CAB and offer patients the opportunity to make an informed decision based on predicted quality of life after surgery and physicians the confidence to discuss surgical outcomes other than mortality and morbidity rates.

Chapter 3

Methodology

Design

The overall goal of this descriptive, retrospective, longitudinal study was to explore the influence of preoperative HRQOL (baseline) and clinical risk factors on postoperative HRQOL at 6 and 12 months after (CAB) using a secondary data set. The analysis of previously collected data provided the opportunity to study the variables of interest for a large sample of patients at three points in time. The primary data were collected and reviewed for accuracy using national guidelines. The richness of the data set and theoretical and empirical support for secondary analysis outweighed the disadvantages associated with using previously collected data. Several clinical studies have established the reliability of secondary data analysis of patient reported, HRQOL outcomes (Al-Ruzzeh, et al., 2005; Cooper et al., 2006; El Baz et al., 2008; Ferrans et al., 2005; Sousa & Kwok, 2006). For the purpose of this analysis, 2 previously collected primary data sets were merged at the individual level of observation. The consolidated data from the Adult Cardiac Surgical Database and Cardiac Surgical Health-related Quality of Life datasets were de-identified for the current study.

Dataset 1: Adult Cardiac Surgical Database

The original purpose of the locally-administered Adult Cardiac Surgical Database is to provide a consistent method of collecting patient information on variables associated with mortality and morbidity after CAB. Data collected provides the opportunity to analyze outcomes of care, controlled for illness severity, and facilitate early interventions to minimize surgical complications. Standardized data collection forms are used by all members of the cardiac team. Institutional review for primary data collection was obtained based on compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and permission to collect data has been included in the standard of care during the surgical consenting process. All adults consenting to cardiac surgery at the local participating hospital are included in the data collection process. Conceptual and operational definitions of the variables included in the STS risk assessment are provided (Appendix B).

Data collected locally is merged quarterly with the Society of Thoracic Surgeons (STS) National Registry and ensures the operation and management of the local database complies with strict STS national guidelines for data collection, data entry and quality assurance review processes. Database managers are formally trained and participate in inter-rater reliability exercises. Once locally-collected data is submitted to the National registry, audits are conducted to ensure consistency with previous submissions and national findings (Ferguson, et al, 2000).

The calibration and testing of the STS risk assessment model has been conducted on 3 previous versions and compared to version 2.61, used in the current study. The variables included in the prediction model were selected by an expert panel comprised of cardiac surgeons, health researchers and biostatisticians. Operational definitions of the selected variables were consistent with national standards, and correlation coefficients confirmed both convergent and discriminant construct validity (Shahian, et al, 2009). The risk assessment model, graphically represented by a receiver operating characteristic (ROC) curve, is a robust predictor of mortality for patients undergoing CAB, discriminating between patients who survive surgery and patients who die within 30 days of surgery (C-index, 0.82). A calibration sample confirmed the proportion of expected to observed deaths was < 1.5% (Shahian, 2009).

Dataset 2: Health-related Quality of Life Database

Patients consenting to surgery complete a Health Survey Standard Version SF-12v2™ questionnaire before surgery and 6 and 12 months after surgery. The return of the completed questionnaires was accepted as a continuing "willingness to participate." Returned data was entered into a locally-administered database and reviewed for data accuracy monthly.

Research Questions

The previously described, de-identified data was used to answer the following research questions.

For coronary artery bypass patients (CAB):

Research Question 1: Is there a significant difference in HRQOL at three points in time: before surgery and at 6 and 12 months after surgery?

Research Question 2: Do the preoperative variables - Society of Thoracic Surgeons (STS) Risk Assessment score and HRQOL (physical and mental components) predict HRQOL at 6 and 12 months after surgery?

Research Question 3: Do age and ejection fraction predict HRQOL at 6 and 12 months after surgery?

Sample

Between October 3, 2005 and August 22, 2008, preoperative data was collected on a total of 770 adults prior to coronary artery bypass surgery (CAB). Of the 770 records, 330 records met the inclusion criteria, and were included in the current study. Data collected included the study population's demographic characteristics and risk factors included in the STS Mortality and Morbidity risk assessment model. Among the respondents, the frequencies and percentages of factors included in the STS mortality and morbidity risk model are presented in table format (Appendix C). Included in clinical risk factors are selected demographics, preoperative characteristics, chronic health history, cardiac history and preoperative cardiac status.

The sample of 330 subjects consisted of 282 males (85.5%) and 48 females (14.5 %). Subjects' age ranged from 39 to 90 years, with a mean of 65.15. Subjects' were predominately male, and had a low STS risk profile (Mean = .09; SD = .01). Females had a higher risk profile than men (Mean= .14; SD =

.01). Subjects included in the study were 87.0% (n= 287) Caucasian, 5.80% (n= 19) Asian, 3.0% (n= 10) African American, 1.2% (n= 4) Hispanic, .03% (n = 1) Native American and 2.70% (n= 9) other. On average, subjects fell within the “over-weight” category based on Body Mass Index (BMI) with males (BMI = 28.8) slighter higher than females (BMI = 28.6). Males on average were taller and heavier than females and demonstrated higher serum creatinine levels and ejection fractions. The average creatinine levels for males and females were well within the expected range of 0.8 to 1.4 mg/dL. The average ejection fraction, based on body surface area, for males (Mean = 55.45; SD = 10.13) and females (Mean = 54.7; SD = 9.98) fell within the normal range of 50% to 65%. A large proportion of the subjects had a history of chronic illnesses including frequency of diabetes (27.3%) and hypertension (76.4%). Prior to the current CAB, 84.90% of the respondents included in the sample had undergone other cardiac procedures (14.7%) and had a previously diagnosed myocardial infarction (27.7%). At the time of surgery, a total of 19 subjects (6.4%) were determined to have heart failure with moderate (n= 7, 2.1%) or severe (n= 14, 4.27%) symptoms.

Prior to surgery, 277 subjects (83.2%) required postive or negative inotropic medications, 3 subjects (0.09%) required intra-aortic balloon pumping, and 2 subjects (.06%) were considered in cardiogenic shock.

At the time of surgery, a large proportion of the study population was diagnosed with triple coronary artery disease (n= 276, 82.9%), had previous cardiac interventions (n = 49, 14.7%), and urgently underwent CAB to prevent cardiac complications and or death (n=170, 52.0%).

Setting

Participants were admitted to a 156 bed, comprehensive cardiovascular care center located on the campus of an 833 bed, regional medical center in the northeastern United States. Approximately 1500 cardiac surgical procedures are performed annually, in which 600 procedures are isolated CAB.

Measurement

Health-related quality of life.

The outcome variable, HRQOL at 6 and 12 months after surgery, was measured using the self-administered SF-12v2™ questionnaire (Appendix D). Used extensively in social and psychological research, the SF-12 v2™ consists of 12-items with 3 or 5 choice, Likert-like responses that measure eight domains of function (Appendix E). Each domain measured by a corresponding scale included physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), mental health (MH). Each domain scale contributes, to a varying degree, to the measure of overall physical and mental health function. Aggregated standardized domain scores produce physical (PCS) and mental (MCS) component summary scores. The PCS is an overall measure of physical health and a reflection of an individual's satisfaction with their perceived level of physical function, mobility and role limitations due to health. The MCS is an overall measure of mental health impacted by depression, sense of well-being, and the ability to participate in social activities. Supported by previous studies, the domains of PF, RP, BP, and GH are strongly correlated with overall physical health (PCS) and domains VT, SF, RE and MH are strongly correlated with overall mental health (MCS). Measures of HRQOL are reported as PCS and MCS.

Scoring of the SF-12v2™ followed the guidelines recommended by the author and established by several validation studies (Ware, Kosinski, Turner-Bowker, & Gandek, 2002). Following data screening of response frequencies for answers outside the expected range, scale scores were computed by (1) recalibrating and reverse coding of raw scores for scale GH from 1-5 to 5.0 -1.0; (2) reverse coding of scales BP, VT, and MH from 1-5 to 5-1; (3) computing scores for scales with multiple items (PF, RP, RE, and MH) by subtracting the lowest possible raw scale score from the sum of the raw item scores and dividing by the possible raw score range; and (4) transforming raw scale scores to 0-100, with higher scores corresponding to better health. Final scale scores for 10 respondents were calibrated by hand and compared to computer-generated scores to ensure accuracy. All item-scale correlations were positive, and ranged from .56 to 1.0. Applying factor coefficients calculated from the general U.S. population in 1990, standardized scale scores were aggregated to calculate the

PCS and MCS. Based on the general population of the United States (1998), PCS and MCS were standardized to have a mean = 50 and SD = 10. The previously described measurement model is illustrated in Figure 3.

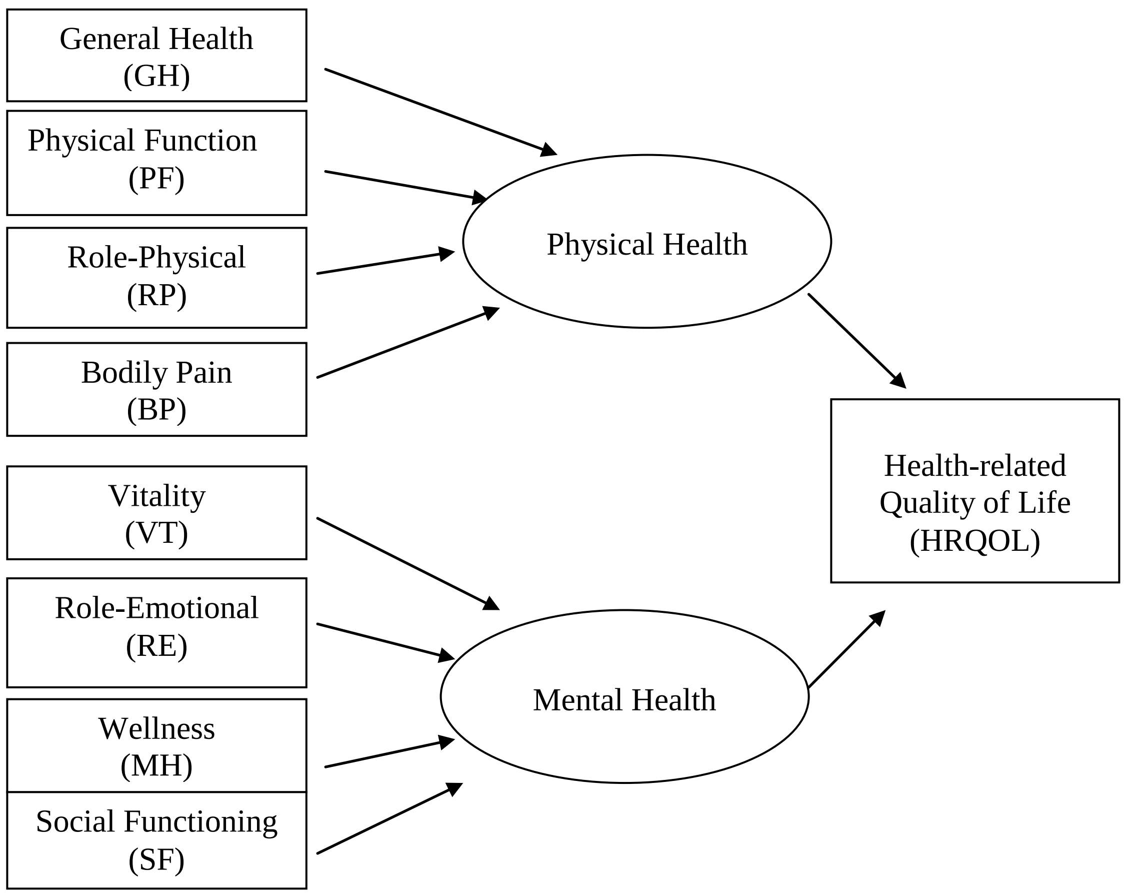

Figure 3: Measurement Model of the SF-12 v2™ (Ware, Kosinski , & Keller, 1996).

Physical component scores (PCS) and mental component scores (MCS) have been independently validated and found to consistently measure changes in the physical and mental dimensions of HRQOL. The PCS and MCS scores have been normalized for subgroups of respondents by age (18-44; 45-64; 65-74;75+), gender (female; male) and chronic disease states (Stewart & Ware, 1993). The reliability estimates, or Cronbach's Alpha, reported for cardiovascular patients range from .88 (PCS) and .89 (MCS) (Resnick & Parker, 2001; Sansgiry et al., 2008; Ware et al., 1996). Previous studies have reported patients' general health perception based on a single item (GH) in the SF-12v2™. The question: "In general, would you say your health is," provides a reliable measure, over time, of perceived general health not related to a specific disease or medical intervention (Lane, Langman, Lip , & Nouwen, 2009) Using the SF-36v2™, the earlier version of the SF-12v2™, Höfer, et al. (2005) found that 31% ($p = .05$) of the variability in GH was explained by the PCS using the single global general health question. Each of the 12 items included in the SF-12v2™ and their associated definitions and domains are provided to clarify the measurement model (Appendix D).

Preoperative clinical risk factors.

The burden of preoperative clinical risk factors was measured by the STS mortality and morbidity risk assessment score (STS). Individual clinical risk factors, for each CAB patient, are entered into a computerized logistic regression model. When data entry is completed for each person, a probability of mortality and morbidity is calculated by the standardized program based on the regression coefficients established by model testing and validation procedures (Shahian, et al., 2009). As each factor is added, a regression is performed resulting in a risk score. The risk score is a predicted probability of the patient dying or being disabled within 30 days after surgery. For example, a STS risk of 20% represents a ratio between actual and predicted outcomes. Applied to a sample of 100 patients with similar clinical risk factors, 20 out of 100 patients have a high probability of dying or being disabled within 30 days after surgery. The STS score has been extensively tested and found to reliably discriminate between patients with and without a high probability of death and chronic health problems after surgery (Ad et al., 2007).

Procedure

Approval from both the institutional and university Protection of Human Research Subjects Review Boards was obtained before de-identified data from the Adult Cardiac Surgery and HRQOL databases was merged, using a statistical analysis software (SAS) format. All cases meeting the inclusion criteria were selected. In determining a desired sample size of 338, considerations included: cases to independent variables ratio, desired alpha and power levels, and effect size. Green's (1991) guideline (50 cases + 8 (N) where N is the number of variables of interest) was used to determine adequate sample size for the study based on the chosen parameters of an alpha = .05, power = .80, medium size relationship (effect size= .40) and critical table value= 14.35 (Cohen, 1988). Prior to the current analysis, data was reviewed for quality and accuracy based on the guidelines of the National STS Cardiac Surgery Registry. Statistical analysis was conducted using the Statistical Package for the Social Sciences, Version 15 (SPSS, 2006).

Statistical Analysis Plan

The following is a summary of the statistical plan guided by the research questions (Table 1). For coronary artery bypass patients (CAB):

Table 1
Statistical Analysis Plan

Research Question	Variable		Measurement		Statistics
	IV	DV	IV	DV	
RQ 1: Is there a significant difference between HRQOL at three points in time: before surgery and 6 and 12 months after surgery?	Time in reference to surgery	HRQOL (PCS) and (MCS)	SF-12v2™ Health Survey Standard Version	SF-12v2™ Health Survey Standard Version (PCS and MCS scores)	Repeated Measures Analysis of Variance

Research Question	Variable		Measurement		Statistics
	IV	DV	IV	DV	
RQ 2: Do the preoperative variables of HRQOL and the Society of Thoracic Surgeons (STS) Risk Assessment score predict HRQOL at 6 and 12 months after surgery?	Health-related quality of life ($HRQOL_{pre}$) STS Risk Assessment	HRQOL at 6 and 12 months after surgery	(STS) Risk Score SF-12v2™ Health Survey Standard Version) (PCS and MCS scores	SF-12v2™ Health Survey Standard Version) (PCS and MCS scores	Multiple Regression with 2 predictor variables and 1 dependent variable at 2 points in time
RQ 3: Do age and ejection fraction predict HRQOL at 6 and 12 months after surgery?	Age and Ejection Fraction (EF)	HRQOL at 6 and 12 months after surgery	(STS) Mortality and Morbidity Risk Assessment	SF-12v2™ Health Survey Standard (PCS and MCS scores)	Multiple Regression with 2 predictors and 2 dependent variables at 2 points in time.

Research Question 1: For isolated coronary artery bypass (CAB) patients: “Is there a significant difference between health-related quality of life (HRQOL) at three points in time: before surgery and 6 and 12 months after surgery” was answered using repeated measures analysis of variance. It is hypothesized that (1) CAB will have a positive influence on HRQOL at 6 and 12 months with the greatest improvement at 6 months.

Research Question 2: For isolated coronary artery bypass (CAB) patients: "Do the preoperative variables HRQOL and STS clinical risk assessment score predict HRQOL at 6 and 12 months after surgery" was answered using multiple regression with 2 predictor variables and 2 dependent variables. It is hypothesized that (1) HRQOL and STS risk assessment will predict HRQOL at 6 months and 12 months after surgery.

Research Question 3: "Do age and ejection fraction predict HRQOL at 6 and 12 months after surgery" was answered using simultaneous regression with 2 age and ejection fraction (EF) as predictor and PCS and MCS of HRQOL as outcome variables at each time point. It was hypothesized that age and ejection fraction - variables included in the STS risk model - will predict poorer HRQOL 6 months after surgery.

Ethical Considerations

Integrating data on individuals from different sources was accomplished using a unique case number. Individual patient data in the local Adult Cardiac Dataset was matched to patients' responses from the completed SF-12 using the case number only. In compliance with the Health Insurance Portability and Accountability Act (1996) and Privacy Rule (2003), records were not accessed until agency and university approval is obtained.

Summary

Advancing knowledge about factors or processes that effect health care outcomes has gained support as health care systems, health care providers and third party payers seek to deliver appropriate, cost effective care. HRQOL is one recognized outcome of care which provides, from the patient perspective, a measure of the effect of chronic illness or medical treatment on day to day life. To that end, this study utilized previously collected data to explore the influence of clinical risk factors on HRQOL after CAB. The purpose of the statistical plan was to examine selected preoperative clinical risk factors' influence on HRQOL after CAB; and identify subgroups of patients at risk for poorer HRQOL outcomes. Findings will support the evaluations of therapeutic decisions in light of the impact of CAB on HRQOL. Health care providers, cognizant of clinical factors that negatively influence HRQOL, will have the opportunity to intervene before declining HRQOL is irreversible.

Chapter 4

Findings

Pre-analysis Data Screening

The purpose of this study is to explore the influence of preoperative HRQOL (baseline) and clinical risk factors on postoperative HRQOL at 6 and 12 months after coronary artery bypass (CAB). The data from this exploratory study is presented in two sections. The sections include (1) preliminary analysis of demographics and preoperative risk factors; (2) psychometric properties of the SF-12v2™; and (3) hypothesis testing.

Prior to conducting the analysis, the data file was examined to ensure accuracy, identify missing data and outliers and decrease the likelihood of drawing incorrect conclusions. Using SPSS Version 15.0, frequency distributions, histograms, and descriptive statistics for quantitative variables STS risk score, PCS, and MCS were examined. Values were found to correspond to the expected ranges for mean, standard deviation (SD), standard error of the mean (SEM), minimum and maximum values. Frequencies and percentage distributions for nominal level data was examined and found to correspond to coded values for categories. Boxplots and stem & leaf graphs were examined for quantitative variables to determine extreme cases for variables STS risk score, PCS and MCS at Baseline, 6 and 12 Months. Eighteen cases (5%) of STS risk scores > .22 were found to be higher than expected. Lower than expected STS risk scores were not found during the analysis. Outliers with PCS < 13 (1%) at baseline, < 22 (3%) at 6 months, and < 26 (6%) at 12 months were found to be lower than expected and accounted for < 6% of the total number of scores measured at each time point. Outliers with MCS < 31 or > 66 (baseline), <30 or > 61 (6 months), and <30 or > 60 (12 months) accounted for < 5% of the MCS at each time point. As a result, transformation of the distributions was not undertaken because of the small proportion of extreme cases for each variable.

Preliminary Analyse

Postoperative PCS improved at all time points, with the greatest improvement between baseline (Mean = 47.87; SD =10.94) and 12 months (Mean = 51.47; SD = 10.46). Preoperative MCS were higher (Mean = 48.75; SD = 6.78) than postoperative scores at 6 months (Mean = 47.86, SD = (6.02), and 12 months (Mean = 47.83; SD = 6.33) (Table 2).

Table 2

Mean Scores for SF-12v2™ Subscales Physical Function (PCS) and Mental Function (MCS) At Baseline, 6 and 12 months after CAB (N = 330)

	PCS:		MCS:	
	M(SD)	95% CI	M(SD)	95% CI
Baseline	47.87 (10.94)	[46.66 ,49.08]	48.75 (6.78)	[48.00, 49.50]
6 Months	51.06 (10.22)	[49.93,52.19]	47.86 (6.02)	[47.19, 48.52]
12 Months	51.47 (10.46)	[50.32, 52.63]	47.83 (6.33)	[47.13, 48.53]

The bivariate correlations between component summary scores ranged from .42 to .69 (PCS) and .33 to .47 (MCS). With an alpha level of .01, the correlations between PCS baseline and 6 months (.42) and 12 months (.43) were significant, with the strongest correlation between 6 and 12 months (.69). Correlations between MCS baseline and 6 months (.33) and 12 months (.32) were significant with the strongest correlation in MCS between 6 and 12 months (.47). No significant correlations were found between PCS and MCS at any time point (Table 3).

Table 3

Product Moment Correlation Coefficient Between PCS and MCS at Baseline, 6 and 12 Months After CAB (N = 330).

	PCS Baseline	PCS 6 Months	PCS 12 Months	MCS Baseline	MCS 6 Months	MCS 12 Months
PCS Baseline	1.00	.42**	.43**	-.04	.05	.03
PCS 6 Months	.42**	1.00	.69**	.05	.01	.13
PCS 12 Months	.43**	.69**	1.00	-.01	.07	.00
MCS Baseline	-.04	.05	-.01	1.00	.33**	.32**
MCS 6 Months	.05	.01	.07	.33**	1.00	.47**
MCS 12 Months	.03	.13	.00	.32**	.47**	1.00

** Correlation is significant at the 0.01 level (2-tailed)

Prior to surgery, PCS was lowest among the youngest (44.43) and oldest (46.86) respondents . PCS improved at 6 and 12 months for all respondents.(Table 4).

Table 4

Mean Scores for SF-12v2™ Subscale Physical Function (PCS) For Age Groups At Baseline, 6 and 12 months after CAB (N = 330)

	M (SD)	95% CI
Ages 35-44		
Baseline	44.43 (13.09)	[30.69, 58.17]
6 Months	51.24 (8.69)	[42.12, 60.37]
12 Months	50.59 (8.75)	[41.39, 59.78]
N - 6		

Table Continues

	M (SD)	95% CI
Ages 45-54		
Baseline	49.34 (9.38)	[46.21, 52.47]
6 Months	52.18 (9.49)	[49.01, 55.34]
12 Months	52.75 (10.89)	[49.12, 56.38]
N = 45		
Ages 55-64		
Baseline	48.32 (11.44)	[45.94, 50.65]
6 Months	52.49 (10.56)	[50.29, 54.64]
12 Months	53.19 (10.19)	[51.09, 55.29]
N = 95		
Ages 65-74		
Baseline	47.73 (10.77)	[45.83, 49.63]
6 Months	50.62 (9.71)	[48.91, 52.33]
12 Months	51.15 (10.25)	[49.34, 52.95]
N = 135		
Ages 75 & Over		
Baseline	46.86 (11.40)	[43.77, 49.94]
6 Months	48.90 (11.26)	[45.85, 51.95]
12 Months	48.53 (10.88)	[45.59,51.47]
N = 49		

In contrast, preoperative baseline MCS were highest among younger respondents and lowest among oldest respondents. In comparison, postoperative MCS remained lower than baseline scores for all age groups except the ages 75 and older (Table 5).

Table 5

Mean Scores for SF-12v2™ Subscale Mental Function (MCS) For Age Groups At Baseline, 6 and 12 months after CAB (N = 330)

	M (SD)	95% CI
Ages 35-44		
Baseline	50.36 (4.15)	[4656, 54.72]
6 Months	44.17 (10.34)	[33.31, 55.02]
12 Months	48.62 (3.88)	[44.54, 52.70]
N = 6		
Ages 45-54		
Baseline	49.78 (5.14)	[48.07, 51.50]
6 Months	45.97 (6.98)	[43.64, 48.30]
12 Months	46.60 (6.70)	[44.36, 48.83]
N = 45		
Ages 55-64		
Baseline	48.37 (6.96)	[46.93, 49.80]
6 Months	48.42 (5.12)	[47.36, 49.47]
12 Months	47.82 (6.19)	[46.55, 49.10]
N = 95		
Ages 65-74		
Baseline	49.34 (6.05)	[48.27, 50.41]
6 Months	48.42 (5.54)	[47.44, 49.39]
12 Months	48.41 (5.56)	[47.43, 49.39]
N = 135		
Ages 75 & Over		
Baseline	47.16 (8.82)	[44.77, 49.54]
6 Months	45.41 (6.94)	[49.16, 47.63]
12 Months	47.22 (7.97)	[45.06, 49.38]
N = 49		

PCS and MCS were examined for females and males. Female PCS are presented in Table 6. Females reported improved PCS for all age groups except the 45 to 54 year olds. The lowest PCS were found among the oldest cohort.

Table 6

Mean Scores for SF-12v2™ Subscale Physical Function (PCS) For Females By Age Groups At Baseline, 6 and 12 months after CAB (N= 48)

	M (SD)	95% CI
Ages 45-54		
Baseline	49.15 (8.95)	[34.91, 63.40]
6 Months	42.24 (15.54)	[17.50, 66.98]
12 Months	46.01 (16.86)	[19.17, 72.85]
N = 12		
	M (SD)	95% CI
Ages 55-64		
Baseline	42.32 (9.86)	[36.05, 48.59]
6 Months	44.77 (8.42)	[39.42, 50.13]
12 Months	46.17 (13.95)	[37.32, 55.04]
N = 13		
Ages 65-74		
Baseline	44.65 (10.86)	[38.21, 51.11}
6 Months	52.32 (9.47)	[46.60, 58.04]
12 Months	52.79 (6.75)	[48.71, 56.86]
N = 17		
Ages 75 & Over		
Baseline	41.08 (13.80)	[13.89, 42.26]
6 Months	42.25 (12.52)	[35.32. 49.19]
12 Months	44.07 (12.57)	[37.11, 51.04]
N = 6		

The lowest mean MCS were found among the youngest and oldest females. Postoperative scores remained lower than preoperative scores for females in all age groups. The study population did not include younger female subjects, ages 39-45. MCS mean scores by age group is presented in Table 7.

Table 7

Mean Scores For SF-12v2™ Subscale Mental Function (MCS) For Females By Age Groups At Baseline, 6 And 12 Months After CAB (N = 48)

	M (SD)	95% CI
Ages 45-54		
Baseline	47.40 (8.85)	[33.30, 61.49]
6 Months	40.96 (3.75)	[34.98. 46.94]
12 Months	43.38 (7.05)	[32.15, 54.60]
N = 12		
Ages 55-64		
Baseline	48.22 (8.62)	[42.75, 53.70]
6 Months	47.28 (6.20)	[43.34, 51.23]
12 Months	47.87 (6.23)	[43.91, 51.83]
N = 13		
Ages 65-74		
Baseline	50.86 (2.74)	[49.20, 52.52]
6 Months	49.47 (4.43)	[46.79, 52.15]
12 Months	49.14 (4.23)	[46.59, 51.70]
N = 17		
Ages 75 & Over		
Baseline	44.57 (6.52)	[40.97, 48.18]
6 Months	46.18 (7.57)	[41.99, 50.38]
12 Months	46.62 (9.38)	[41.43, 51.82]
N = 6		

Among male respondents, baseline PCS were lowest among the youngest males and scores improved between baseline and 6 months. Scores between 6 and 12 months were relatively unchanged (Table 8).

Table 8

Mean Scores For SF-12v2™ Subscale Physical Function (PCS) For Males By Age Groups At Baseline, 6 And 12 Months After CAB (N = 282)

	M (SD)	95% CI
Ages 35-44		
Baseline	44.43 (13.09)	[30.69, 58.17]
6 Months	51.24 (8.69)	[42.12, 60.37]
12 Months	50.59 (8.75)	[41.39, 59.78]
N= 6		
Ages 45-54		
Baseline	49.36 (9.57)	[45.98, 52.76]
6 Months	53.38 (8.05)	[50.53, 56.24]
12 Months	53.57 (10.02)	[50,02, 57.13]
N = 33		
Ages 55-64		
Baseline	49.18 (11.45)	[46.65, 51.72]
6 Months	53.60 (10.42)	[51.30, 55.91]
12 Months	54.23 (9.19)	[52.21, 56.27]
N = 82		
Ages 65-74		
Baseline	48.08 (10.77)	[46.08, 50,09]
6 Months	50.43 (9.76)	[48.61, 52.25]
12 Months	50.96 (10.59)	48.99, 52.94]
N = 118		

Table Continues

	M (SD)	95% CI
Ages 75 & Over		
Baseline	49.02 (9.65)	[45.94, 52.12]
6 Months	51.39 (9.81)	[48.26, 54.43]
12 Months	50.20 (9.84)	[47.06, 53.35]
N = 43		

In comparison to baseline, postoperative mean MCS at 6 months after CAB declined for all male respondents except for males 55 to 64 years of age. Postoperative MCS at 12 months remained lower than preoperative baseline scores. Mean MCS for males are presented in Table 9.

Table 9

Mean Scores For SF-12v2™ Subscale Mental Function (MCS) For Males By Age Groups At Baseline, 6 And 12 Months After CAB (N = 282)

	M (SD)	95% CI
Ages 35-44		
Baseline	50.36 (4.15)	[4656, 54.72]
6 Months	44.17 (10.34)	[33.31, 55.02]
12 Months	48.62 (3.88)	[44.54, 52.70]
N= 6		
Ages 45-54		
Baseline	50.07 (4.66)	[48.43, 51.73]
6 Months	46.57 (7.08)	[44.07, 49.09]
12 Months	46.99 (6.67)	[44.63, 49.36]
N = 33		
Ages 55-64		
Baseline	48.39 (6.75)	[46.90, 49.89]
6 Months	48.59 (4.96)	[47.50, 49.69]
12 Months	47.82 (6.23)	[46.44, 49.20]
N = 82		

Table Continues

	M (SD)	95% CI
Ages 65-74		
Baseline	49.17 (6.31)	[47.99, 50.35]
6 Months	48.29 (5.66)	[47.24, 49.35]
12 Months	48.32 (5.71)	[47.27, 49.39]
N = 118		
Ages 75 & Over		
Baseline	48.13 (9.44)	[45.11, 51.15]
6 Months	47.70 (6.74)	[45.55, 49.86]
12 Months	47.44 (7.50)	[45.05, 49.85]
N = 43		

In addition to the physical and mental health summary component scores, mean domain scores of the SF-12v2™, were examined for the entire sample, and presented in Table 10. Preoperative scores physical function (PF), physical role (RP), bodily pain (BP), and general health (GH), vitality (VT), and mental health (MH) were < 50th percentile when compared to the general population of the United States (1998), were domain and component scores were standardized to have a mean = 50 and SD = 10. Only domains social function (SF) and emotional role (RE) had a mean average > 50.00.

Table 10

SF-12v2™ Baseline Domain Scores (N= 330)

Baseline	PF	RP	BP	GH	VT	SF	RE	MH
M	46.38	45.19	49.54	48.52	45.65	50.94	50.10	43.73
SD	11.78	11.17	11.09	11.53	11.88	10.07	10.21	5.79
Minimum	22.11	20.32	16.68	18.87	27.62	16.18	11.35	21.87
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	64.54

Domain scores at 6 months after surgery are presented in Table 11. Domain average scores for physical function (PF), physical role (RP), bodily pain (BP), general health (GH), and social function (SF) improved while domain scores for emotional role (RE) and mental health (MH) declined at 6 months after surgery.

Table 11

SF-12v2™ Domain Scores 6 Months After CAB (N= 330)

6 Months	PF	RP	BP	GH	VT	SF	RE	MH
Mean	48.47	47.70	51.17	51.27	42.58	51.64	49.89	42.40
SD	10.13	10.11	9.13	8.81	9.56	8.45	8.73	4.86
Minimum	22.11	20.32	16.68	18.87	27.62	16.18	11.35	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	64.54

In comparison to mean domain scores at 6 months, a small decline in general health (GH) was reported at 12 months after surgery. Postoperative domain scores at 12 months are presented in Table 12.

Table 12

SF-12v2™ Domain Scores 12 Months After CAB (N= 330)

12 Months	PF	RP	BP	GH	VT	SF	RE	MH
M	48.50	48.62	51.21	50.96	42.57	51.56	49.65	42.56
SD	10.44	9.55	9.24	9.52	9.62	8.68	9.48	5.11
Minimum	22.11	20.32	16.68	18.87	27.62	16.18	11.35	15.77
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	64.54

Mean scores for the eight domains of the SF-12v^2 were examined for females and males in age groups: 39-45, 46-54, 55-64, 65-74 and 75 years and older, at baseline, 6 and 12 months. Baseline domain scores presented in Table 13 (females) and Table 14 (males) indicate the domain scores associated with physical health (PF, RP, BP) declined with age for females and males. Domains associated with mental health (MH, RE) were lower for females than males at each time point. Domains associated with perception of health (GH), vitality (VT) and social function (SF) were consistently lower for females and older adult males.

Table 13

Mean Scores For SF-12v2™ Domains At Baseline For Females By Age Group (N = 48)

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 45-54								
M	49.59	47.04	47.25	49.05	41.71	48.49	49.37	45.03
SD	11.20	10.50	10.19	5.90	11.47	13.17	15.00	2.73
Minimum	23.01	22.32	27.92	19.23	35.08	36.37	21.58	38.21
Maximum	55.45	53.98	57.44	49.33	65.05	56.57	56.08	46.25
N = 12								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 55-64								
M	41.93	38.04	46.47	36.12	47.75	49.58	43.50	46.72
SD	12.34	12.31	13.46	15.70	10.06	12.63	12.42	5.82
Minimum	22.11	20.32	16.68	18.87	27.62	16.18	22.53	40.16
Maximum	56.47	57.18	57.44	55.52	67.88	56.57	56.08	58.45
N = 13								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 65-74								
M	43.25	44.77	48.82	45.90	45.43	50.35	53.07	43.91
SD	10.29	9.29	10.89	12.86	8.37	8.78	4.34	3.96
Minimum	30.70	29.54	26.87	18.87	27.62	36.37	44.90	40.16
Maximum	56.47	57.18	57.44	61.99	57.81	56.57	56.08	52.35
N = 17								

Table Continues

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 75 & Over								
M	40.80	39.56	43.66	49.31	51.89	41.72	44.90	42.67
SD	12.97	11.88	13.45	12.89	11.28	14.77	11.01	6.84
Minimum	22.11	20.32	16.68	18.87	27.62	16.18	22.53	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	52.35
N = 6								

Table 14

Mean Scores For SF-12v2™ Domains At Baseline For Males By Age Group (N = 282)

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 35-44								
M	43.58	44.12	48.95	44.74	44.40	48.15	52.35	44.22
SD	13.03	10.27	11.91	0.00	10.39	11.80	9.13	9.18
Minimum	22.11	29.54	26.87	44.74	27.62	26.27	33.71	27.97
Maximum	56.47	57.18	57.44	44.74	57.81	56.57	56.08	52.35
N = 6								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 45-54								
M	48.14	47.96	48.49	51.99	44.09	52.90	51.84	44.59
SD	11.05	10.11	12.68	7.71	10.62	6.59	8.39	6.33
Minimum	22.11	29.54	16.68	29.65	27.62	36.37	16.94	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	58.45
N = 33								

Table Continues

N = 82	PF	RP	BP	GH	VT	SF	RE	MH
Ages 55-64								
M	47.27	47.10	50.21	49.38	46.35	51.64	50.82	43.35
SD	11.76	10.81	9.62	11.71	11.77	9.00	9.10	5.27
Minimum	22.11	20.32	26.87	18.87	27.62	16.18	16.94	21.87
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	58.45

N = 118	PF	RP	BP	GH	VT	SF	RE	MH
Ages 65-74								
M	47.14	44.98	50.15	47.47	45.49	52.48	50.44	43.78
SD	11.47	11.06	11.23	12.14	12.80	8.10	10.77	6.01
Minimum	22.11	20.32	16.68	18.87	27.62	16.18	11.35	21.87
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	64.54

N = 43	PF	RP	BP	GH	VT	SF	RE	MH
Ages 75 & Over								
M	45.78	44.25	51.23	51.79	43.33	48.69	49.12	42.90
SD	12.71	12.11	10.41	7.50	12.13	13.83	11.17	5.51
Minimum	22.11	20.32	16.68	29.65	27.62	16.18	11.35	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	52.35

Domain scores at 6 months after CAB are presented in Table 15 (females) and Table 16 (males). In comparison to males by age groups, females report lower physical and mental health function across all domains of the SF-12v2™, except vitality (VT) among females 55 to 64 years of age.

Table 15

Mean Scores For SF-12v2™ Domains 6 Months After CAB for Females By Age Group (N = 48)

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 45-54								
Mean	42.72	43.36	45.21	40.97	51.77	48.49	40.42	42.60
SD	13.03	15.28	11.16	15.58	15.26	8.45	12.75	3.34
Minimum	22.11	20.32	26.87	18.87	37.69	36.37	22.53	40.16
Maximum	56.47	57.18	57.44	55.52	67.88	56.57	56.08	46.25
N = 12								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 55-64								
Mean	42.59	41.94	47.25	46.56	48.52	49.58	45.76	43.91
SD	10.83	8.06	8.32	9.10	9.60	8.63	8.80	3.96
Minimum	22.11	29.54	26.87	29.65	37.69	36.37	33.71	40.16
Maximum	56.47	52.57	57.44	55.52	67.88	56.57	56.08	52.35
N = 13								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 65-74								
Mean	48.54	48.67	54.31	52.87	40.01	52.68	53.50	41.56
SD	8.91	7.94	7.65	8.63	8.37	8.78	4.90	3.65
Minimum	30.70	34.14	37.06	29.65	27.62	26.27	39.30	34.06
Maximum	56.47	57.18	57.44	61.99	57.81	56.57	56.08	46.25
N = 17								

Table Continues

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 75 & Over								
Mean	40.30	40.65	43.66	47.78	46.49	46.47	43.15	43.59
SD	10.47	11.64	15.26	8.99	9.63	14.28	11.32	6.28
Minimum	22.11	20.32	16.68	29.65	37.69	16.18	22.53	34.06
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	58.45
N = 6								

Table 16

Mean Scores For SF-12v2™ Domains 6 Months After CAB For Males By Age Group (N = 282)

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 35-44								
Mean	49.31	44.89	48.95	51.21	42.72	49.84	43.03	41.17
SD	10.04	11.89	7.67	7.47	5.51	8.24	17.92	4.59
Minimum	30.70	24.93	37.06	44.74	37.69	36.37	11.35	34.06
Maximum	56.47	57.18	57.44	61.99	47.75	56.57	56.08	46.25
N = 6								
Ages 45-54								
	PF	RP	BP	GH	VT	SF	RE	MH
Mean	52.04	49.78	50.65	52.58	42.87	50.75	49.81	42.56
SD	6.49	8.06	8.70	6.42	9.11	8.76	7.88	5.04
Minimum	39.29	29.54	16.68	44.74	27.62	26.27	33.71	34.06
Maximum	56.47	57.18	57.44	61.99	57.81	56.57	56.08	58.45
N = 33								

Table Continues

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 55-64								
Mean	50.97	50.64	52.59	53.26	41.78	53.05	52.18	42.78
SD	9.76	10.00	8.67	8.86	9.93	6.53	7.48	4.13
Minimum	22.11	20.32	16.68	29.65	27.62	36.37	22.53	34.06
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	52.35
N = 82								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 65-74								
Mean	47.73	46.89	51.38	50.32	42.28	52.39	49.76	42.15
SD	10.13	9.99	8.71	8.96	9.51	7.54	8.36	5.56
Minimum	22.11	20.32	26.87	18.87	27.62	16.18	22.53	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	64.54
N = 118								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 75 & Over								
Mean	48.30	47.51	52.47	52.21	41.12	50.41	50.49	41.64
SD	10.51	9.82	7.25	8.03	8.30	10.32	7.91	4.26
Minimum	22.11	20.32	26.87	29.65	27.62	16.18	22.53	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	52.35
N = 43								

The SF-12v2™ postoperative mean domains at 12 Months are presented in Table 17 (females) and Table 18 (males). Males consistently report higher domain scores than females, 1 year after surgery. However, females 55 to 64 years of age report better mental health (MH) when compared to males of the same age.

Table 17

Mean Scores For SF-12v2™ Domains 12 Months After CAB For Females By Age Group (N= 48)

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 45-54								
Mean	49.59	47.96	47.25	43.02	43.72	48.49	46.01	41.38
SD	15.37	15.96	12.48	15.43	15.26	8.45	13.92	5.10
Minimum	22.11	20.32	26.87	18.87	27.62	36.37	22.53	34.06
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	46.25
N = 12								
	PF	RP	BP	GH	VT	SF	RE	MH
Ages 55-64								
Mean	42.59	44.77	47.25	47.56	46.98	47.25	48.34	45.32
SD	13.82	11.95	11.01	10.39	11.95	9.63	9.56	6.51
Minimum	22.11	29.54	26.87	29.65	37.69	36.37	28.12	40.16
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	64.54
N = 13								

Table Continues

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 65-74								
Mean	51.84	48.67	51.96	51.87	40.78	55.01	51.35	42.97
SD	6.67	7.49	6.73	6.12	7.56	3.79	7.52	4.73
Minimum	39.29	38.75	37.06	44.74	27.62	46.47	33.71	34.06
Maximum	56.47	57.18	57.44	61.99	57.81	56.57	56.08	46.25
N = 17								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 75 & Over								
Mean	38.78	42.81	49.65	47.66	45.97	48.25	45.22	39.80
SD	11.15	11.73	12.23	10.89	9.57	13.47	13.90	8.20
Minimum	22.11	20.32	26.87	29.65	27.62	16.18	11.35	15.77
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	46.25
N = 6								

Table 18

Mean Scores For SF-12v2™ Domains 12 Months After CAB For Males By Age Group (N = 282)

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 35-44								
Mean	47.88	48.73	50.65	51.21	42.72	51.52	49.56	44.22
SD	9.41	6.12	8.32	7.47	5.51	8.45	5.50	3.15
Minimum	30.70	38.75	37.06	44.74	37.69	36.37	44.90	40.16
Maximum	56.47	57.18	57.44	61.99	47.75	56.57	56.08	46.25
N = 6								

Table Continues

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 45-54								
Mean	50.74	51.73	50.65	53.04	42.57	51.37	48.45	44.04
SD	10.22	8.02	9.76	8.37	9.45	6.74	9.96	5.01
Minimum	22.11	29.54	16.68	29.65	27.62	36.37	28.12	34.06
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	58.45
N = 33								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 55-64								
Mean	51.47	51.18	52.11	52.58	41.78	51.82	49.97	43.21
SD	8.98	8.42	8.08	9.68	10.51	8.89	9.84	5.10
Minimum	22.11	20.32	26.87	29.65	27.62	16.18	22.53	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	58.45

N = 82	PF	RP	BP	GH	VT	SF	RE	MH
Ages 65-74								
Mean	48.02	48.00	51.21	50.33	42.63	52.22	50.54	42.47
SD	9.81	10.04	9.67	9.46	9.15	8.45	8.43	4.15
Minimum	22.11	20.32	16.68	18.87	27.62	26.27	22.53	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	52.35
N = 118								

	PF	RP	BP	GH	VT	SF	RE	MH
Ages 75 & Over								
Mean	46.62	46.16	51.98	50.79	41.61	51.40	49.67	40.31
SD	11.29	8.04	8.56	9.23	8.68	8.49	9.49	5.01
Minimum	22.11	29.54	26.87	29.65	27.62	26.27	22.53	27.97
Maximum	56.47	57.18	57.44	61.99	67.88	56.57	56.08	52.35
N = 43								

Principal Component Analysis of the SF-12v^2

A principal component analysis after varimax rotation was conducted to validate the 2-factor structure of the SF-12v^2. Using criteria, scree plots and eigenvalue, a comparison of the solutions for the 12-item SF-12v^2 at baseline, 6 and 12 months found the variability in HRQOL explained by the 2-factor solution was 54.91% (baseline), 65.83 (6 months), and 68.67% (12 months).(Table 19).

Table 19

Rotated Component Matrix For The SF 12v2 At 12 Months After CAB

	Component	
	1 (Physical)	2 (Mental)
Role Physical (RP)	.89	.12
Physical Functioning (PF)	.86	-.01
Vitality (VT)	-.80	.02
General Health (GH)	.78	.01
Bodily Pain (BP)	.75	.09
Social Functioning (SF)	.69	.35
Role Emotional (RE)	.62	.52
Mental Health (MH)	-.07	.93

Hypothesis Testing

***Research question 1*.**

A one-way repeated measures ANOVA was conducted to answer Research Question 1, “Is there a significant difference between HRQOL at three points in time: before surgery at baseline, and 6 and 12 months after surgery?” For the analysis, PCS and MCS of HRQOL were analyzed and results reported separately.

Applying a Greenhouse-Geisser correction for heterogeneity of covariance not assumed, the mean self-reported PCS were significantly different for subjects at 3 time points, $F (2, 632) = 22.61$, $p < .01$. Estimates of effect size, however, indicated a weak association between time points, $\eta^2_p = .06$. Bonferroni’s adjusted post hoc pairwise comparisons were examined to determine at which time point the PCS were significantly different. Three paired samples t-tests were used to make post hoc comparisons. A significant difference was found between the mean PCS at baseline, 47.87 (10.94) and 6 months, 51.06 (10.22), in reference to time ($t (321) = 5.26$, $p <.01$). A second paired samples t-test indicated that there was a significant difference in the mean PCS at baseline, 47.87 (10.60) and 12 months, 51.47(10.46) in reference to time ($t (319) = 5.65$, $p < .01$). A third paired samples t-test indicated that there was no significant difference in the mean PCS at 6 months, 51.06 (10.22) and 12 months, 51.47 (10.46) in reference to time ($t (321) = .67$, $p = .503$).

Applying a Greenhouse-Geisser correction for heterogeneity of covariance not assumed, the mean self-reported MCS were significantly different for subjects at 3 time points, $F(2, 632) = 3.384$, $p < .05$. Estimates of effect size indicated a weak association between time points, $\eta^2_p = .01$. Bonferroni's adjusted post hoc pairwise comparisons were examined and three paired samples t-tests used to make post hoc comparisons in reference to time. A significant difference was found between the mean MCS at baseline (Mean = 48.75, SD= 6.78) and 6 months (Mean = 47.85, SD= 6.02) ($t(321) = -2.132$, $p < .01$). A second paired samples t-test indicated that there was a significant difference in the MCS at baseline (Mean 48.75, SD= 6.02) and 12 months (M= 47.83, SD= 6.33) ($t(319) = -2.21$, $p = .02$). A third paired samples t-test indicated that there was no significant difference in the MCS at 6 months (Mean = 47.86, SD= 6.781) and 12 months (Mean = 47.83, SD= 6.33) ($t(321) = -.263$, $p = .866$).

***Research question 2*.**

Simultaneous regressions were conducted to answer Research Question 2, "Do the preoperative variables HRQOL and the Society of Thoracic Surgeons STS Mortality and Morbidity risk assessment score predict HRQOL at 6 and 12 months after surgery?" For the purposes of the analysis, the physical and mental health components of the outcome variable, HRQOL, were measured by PCS and MCS at 6 and 12 months. Prior to the analysis, scatter plots of standardized residuals against standardized predicted scores were examined and found to contain points adjacent to the diagonal confirming that the assumptions of linearity and homogeneity of variance have been met.

Regression results are presented for the predictors, STS risk score, PCS and MCS and outcome variables PCS and MCS at 6 months. (Table 17) Results indicate the overall model of 2 predictors, STS risk score and PCS predict PCS ($R^2 = .25$, $R^2_{adj} = .24$, $F(3, 321) = 35.64$, $p < .001$) and MCS ($R^2 = .11$, $R^2_{adj} = .10$, $F(3, 321) = 13.88$, $p < .001$) 6 months after CAB.

Table 20

Summary of Simultaneous Regression for Variables Predicting PCS and MCS At 6 Months After Coronary Artery Bypass. (N = 330)

	PCS			MCS		
Variable	B	SE B	β	B	SE B	β
STS Score	-40.44	7.38	-.27***	-6.42	4.76	-.07
PCS Baseline	.34	.04	.37***	.02	.03	.05
MCS Baseline	.06	.07	.008	.28	.04	.32***

* p < .05 *** p < .001

Simultaneous regression with the same predictors was performed for outcome variables, PCS and MCS at 12 months. (Table 18). Results indicate the model predicts PCS ($R^2 = .24$, $R^2_{adj} = .23$, $F(3, 319) = 33.83$, $p < .001$) and

MCS (R^2 = .11, R^2_{adj} = .10, F (3, 319) = 13.11, p < .001) at 12 months after surgery.

Table 21

Summary of Simultaneous Regression for Variables Predicting PCS and MCS At 12 Months After Coronary Artery Bypass. (n = 330)

	12 Months					
		PCS			MCS	
Variable	B	SE B	β	B	SE B	β
STS Score	-36.99	7.63	-.24***	-5.38	5.01	-.05
PCS Baseline	.37	.04	.38***	.23	.03	.03
MCS Baseline	-.02	.07	-.01	.30	.05	.32***

* p < .05 *** p < .001

Research question 3.

Supported by previous analyses, a forward regression was conducted to answer Research Question 3, “Do age and ejection fraction predict HRQOL at 6 and 12 months after surgery?” Based on previous results, predictor variables, age and ejection (EF) were screened and found to meet the assumptions of linearity and homogeneity of variance.

Regression results indicate EF predict PCS at 6 months ($R^2 = .19$, $R^2_{adj} = .03$, F (3, 326) = 6.33, p < .01) and 12 months ($R^2 = .02$, $R^2_{adj} = .02$, F (3, 326) = 4.19, p = .01) after CAB. The model does not predict MCS at 6 months ($R^2 = .02$, $R^2_{adj} = .01$, F (3, 323) = 1.74, p = .17) or 12 months, $R^2 = .275$, $R^2_{adj} = -.005$, F (3, 294) = .24, p = .78. The variable "age" was not a significant predictor of PCS or MCS at 6 (Table 19) or 12 months after CAB (Table 20).

Table 22

Summary of Simultaneous Regression for Selected Clinical Variables Predicting Physical (PCS) and Mental Health (MCS) At 6 Months After CAB (N = 330)

	PCS			MCS		
Variable	B	SE B	β	B	SE B	β
Age	-.11	.06	-.10	.06	.03	.09
Ejection Fraction (EF)	.15**	.56	.15	.02	.03	.04

* p < .05 ** p < .01 *** p < .001

Table 23

Summary of Simultaneous Regression for Selected Clinical Variables Predicting Physical (PCS) and Mental Health (MCS) At 12Months After CAB (N = 330)

	PCS			MCS		
Variable	B	SE B	β	B	SE B	β
Age	-.11	.06	-.10	.02	.03	.03
Ejection Fraction (EF)	.11	.05	.11	-.002	.03	.00

* $p < .05$ ** $p < .01$ *** $p < .001$

Summary

Using repeated measures ANOVA, a statistically significant difference was found between subjects' physical and mental component summary scores for HRQOL at 3 time points: before surgery and 6 and 12 months after surgery. The greatest difference in scores was between baseline and 12 months for both PCS and MCS with the greatest difference in PCS. Applying a simultaneous multiple regression design, the predictors preoperative HRQOL and the STS Risk Score accounted for the variability in HRQOL at 6 (21%) and 12 months (27%) after CAB. The clinical variable EF, included in the STS model, predicted PCS at 6 and 12 months.

Chapter 5

Discussion

Health-related Quality of Life After Coronary Artery Bypass

In comparison to preoperative baseline, the greatest improvement in HRQOL was seen in improved physical function (PCS). A modest change in physical function between 6 and 12 months did not support further postoperative measures beyond 6 months.

In contrast to improved physical function, mental function declined after surgery with postoperative scores never returning to baseline. Negative changes in mental health function suggest the importance of accurate and objective measurements of baseline mental health function before postoperative changes in mental function are attributed to the impact of surgery or inform treatment decisions.

In comparison to the general population stratified by age and severity of illness, both physical (PCS) and mental component scores (MCS) were lower than expected (Ware, et al, 2002). This result was unpredicted considering the low surgical risk profiles at the time of surgery (Ware, 1996). Among the general population, similar PCS have been associated with the chronically ill, and diagnoses of hypertension, myocardial infarction, congestive heart failure, and insulin dependent diabetes. The small proportion of respondents with these comorbidities prevents explanation. In reference to mental health and well-being, the MCS were similar to scores reported for patients with a diagnosis of depressive symptoms and major depression. Previous studies support the association between mental health disorders and depression and poorer quality of life outcomes after CAB (Goyal, Idler, Krause, & Contrada, 2005).

In addition to changes in the physical and mental component scores of HRQOL, the single item of the SF-12v2™ measuring the domain general health (GH) was found to have a high positive correlation with physical function and a high negative correlation with mental function. This finding suggests a single question may accurately capture information about subjects' perception of the impact of surgery on their overall HRQOL and warrant further study. The contrast between patients' perception of health and health care providers clinical assessments of disease burden remains a challenge across patient populations.

Although a statistically significant difference was found in subjects' physical and mental health components of HRQOL at baseline and 6 months after CAB, practical significance was low. The small observed difference in PCS and MCS suggest further studies are necessary to validate the magnitude of change between preoperative and postoperative HRQOL outcomes before changes in HRQOL inform treatment decisions.

Clinical Risk Assessment and Health-Related Quality of Life

STS risk score and physical function (PCS) at baseline are predictors of physical function (PCS) at 6 and 12 months after surgery. A moderate effect size was calculated at both time points, with PCS the strongest contributor to the prediction model. This result is consistent with a previous study in which the EUROSCORE, a similar assessment of disease burden, was found to predict 11% of the variance in PCS at 6 months after CAB (EL Baz, et al, 2008). As predicted, the STS risk score and PCS did not correlate with mental function (MCS) at any time point. With a moderate effect size, preoperative mental health function (MCS) is the strongest predictor of postoperative mental health function at both postoperative time points. In considering this finding, physical and mental health components of HRQOL provide valuable information about the impact of surgery on patients' overall HRQOL.

Selected Clinical Risk Factors and Health-Related Quality of Life

Ejection fraction (EF), a clinical risk factor included in the STS risk model, was found - with a small effect size - to predict physical function at 6 months after surgery. No association between baseline EF and PCS at 12 months was found. Although statistical significance was not found, observed differences in mean PCS and MCS were found in reference to age. Consistent with Lindquist's (2003) observations, men and women report improved physical function after CAB, with women reporting, on average, poorer PCS and MCS than men. Jarvinen, et al, (2003) reported similar findings for subjects less than 75 years of age at the time of surgery. In comparing surgical outcomes among subjects grouped by age, mean differences in PCS and MCS at baseline and 6 months after surgery, were found between the oldest and youngest subjects. Younger adults (< 44) with lower STS risk scores reported less improvement in physical function and mental well-being after surgery then older adults (> 65) with higher risk profiles. This finding is consistent with previous studies suggesting that additional variables not captured by the STS risk model impact individual assessment of physical and mental function during the postoperative period.

Theoretical Implications

The most significant predictor of HRQOL after CAB is the patient's preoperative perception of physical and mental health function. As such, the characteristics of the individual moderate the impact of clinical variables on general health perception. Findings support the Wilson and Cleary (1995) comprehensive conceptual framework, which proposes (1) a direct relationship between patients' perception of functional status and general health; and (2) an indirect relationship between biological and physiological characteristics and general health perception. The discrepancy between lower baseline PCS and MCS reported by patients with lower preoperative risk profiles is unclear and supports further model modification to capture the nature of the relationship between personal characteristics and overall quality of life. The moderating effect of individual characteristics on functional status and HRQOL warrants further conceptual and methodological study.

Literature

In comparison to similar analyses of the clinical records of cardiovascular surgical patients using the National STS (Shroyer, 2003; Ad, Barnett, & Speir, 2007), and the Department of Veterans Affairs (Grover, et al, 2001) databases, the baseline clinical characteristics of the respondents were similar for age and a chronic disease history of hypertension and lung disease.

In contrast to national averages, a larger proportion of respondents had lower STS risk scores or risk profiles at the time of surgery, yet surgery was deemed urgent. In comparison, a greater number of patients with higher risk profiles were electively scheduled for surgery based on the STS and Department of Veterans Affairs reporting systems. A larger proportion of the study population required triple vessel procedure (83.50%) in comparison to the STS (63%) and VA (70%) populations. The proportion of the study population categorized as "urgent" and in need of immediate surgery (51.60%), but found to have lower risk profiles based on STS risk scores, was an unanticipated finding. However, immediate surgical intervention for subjects with lower risk profiles is associated with lower complication rates.

Measurement Methodology and Instruments

The SF-12v2™ questionnaire is an extensively-tested, generic HRQOL tool, found to be less sensitive to measuring physical function and mental well-being before surgery. Higher factor-item correlations at 6 and 12 months after CAB suggest the SF-12v2™ is less sensitive to changes in HRQOL among disease-specific patient populations during the acute phase of treatment. Higher

PCS and MCS factor-item correlations at 6 and 12 months after surgery suggest that the SF-12v2™ is more appropriate for monitoring HRQOL trends in populations with chronic versus acute illness. As anticipated, this finding is consistent with the purpose of the SF-12v2™ as a useful and straightforward measure of physical function and general health among the chronically ill and a valuable tool for monitoring HRQOL trends in populations with chronic versus acute illness (Stewart & Ware, 1992). During the study, there was a noteworthy, 100% completion rate of the SF-12v2™.

Limitations

Interpretation of the findings was limited by sample size and characteristics, instrumentation, and methodology. The study population was predominately male, 45 to 65 years of age, healthy, and had a low STS mortality and morbidity risk score at the time of surgery. Difference in outcomes with respect to gender could only be described by measures of central tendency and dispersion. Similar limitations were found in reference to age, with unequal groups threatening to violate assumptions underlying the statistical tests. Comparisons between age groups were therefore not statistically possible. The frequency of variables associated with chronic health problems and poorer quality of life were not sufficiently present in the study population to provide additional correlations between preoperative clinical characteristics and surgical outcomes. Consequently, the study population's range of STS risk scores was small and fell into the low risk category.

Methodologically, primary analysis of pre-collected data did not allow for follow-up interviews or measurement of additional variables. Overall, bias was introduced by selecting a homogeneous sample of CAB patients, which historically are the healthiest subgroup of surgical patients and unlikely to demonstrate significant differences in treatment outcomes.

Recommendations

Prior to surgery, health care providers should consider STS risk scores, comprehensive mental health assessment, and patients' perception of baseline function when discussing surgical outcomes. In some cases, the modest improvement in physical function and negative change in mental function and sense of well-being may encourage patients to select less invasive treatment options. Effectively incorporating quality of life outcomes for patients will require curriculum changes to prepare health care providers for monitoring patients' indicators of declining quality of life. Recognizing patients at risk for poorer health outcomes provides administrative support for extending postoperative care for subgroups of surgical patients at risk for poorer surgical outcomes.

Future research in HRQOL outcomes for cardiovascular patients would benefit from the use of a disease-specific tool, sensitive to subtle changes in physical, psychological, and social functioning. The 27-item MacNew Heart Disease Health-related Quality of Life Questionnaire (MacNew**)** is longer than the SF-12v2™, but has shown to be a reliable measure of the impact of treatment on patients with cardiovascular disease (Höfer, Lim, Guyatt, & Oldridge, 2004).

Conclusions

In summary, the statistical findings support the following conclusions: (1) the preoperative STS risk score and PCS of HRQOL (baseline) predict postoperative PCS 6 and 12 months after CAB; (2) PCS (baseline) is the strongest predictor of postoperative physical function at 6 and 12 months; (3) MCS (baseline) is the strongest predictor of postoperative MCS at 6 and 12 months after surgery; and (4) there is no association between either the baseline STS risk score or PCS and postoperative mental function. The results of this exploratory study support further testing of the STS risk score to predict the influence of surgery on postoperative physical function for cardiovascular patients with higher risk scores.

Although the study will contribute to understanding the relationship between preoperative variables and HRQOL after CAB, limitations are acknowledged. The use of previously-collected information from a local disease-specific register (original purpose, selected variables, methodology) restricts research questions. The locally-collected dataset does conform to national registry standards, requiring data cases to be based on individuals with a common diagnosis and information to be updated systematically. However, single-site collection methods and convenience sampling limit generalizations about the population from which the sample is drawn (Donaldson, 1992).

Appendix A

Conceptual and Operational Definitions

Variable	Conceptual Definition	Operational Definition	Measurement Tool
Health-related Quality of Life (HRQOL)	Personal perception of the effects of a medical condition or treatment on functioning and well-being.	Self-reported ability to meet day to day responsibilities defined by family and social roles.	SF-12v2™ Health Survey Standard Version 12-items; 2 scales (physical and mental components) Range 0 to 100 points. Normalized to a mean= 50; standard deviation= 10.
Physical function. Individual perception of a physical condition effecting activities of daily living.	Perceived inability to meet required activities of daily living.	Physical Health Scores (PCS)	SF-12v2™ Health Survey Standard Version Range 0 to 50.

Variable	Conceptual Definition	Operational Definition	Measurement Tool
Mental health status. Individual perception of emotions effecting activities of daily living.	Perceived inability to meet required activities of daily living.	Mental Health Scores (MCS).	SF-12v2™ Health Survey Standard Version Range 0 to 50.
General health perception. Individual perception of physical or emotional conditions affecting a sense of wellbeing.	Perception of adequate social support in the presence of sadness, decreased energy level or discontentment with life.	Question 1: “ In general, would you say your health is”	SF-12v2™ Health Survey Standard Version Item 1: 5 point likert scale. Range from excellent to poor.

Appendix B

Society of Thoracic Surgeons Mortality and Morbidity Risk Factors

Variable	Conceptual Definition	Operational Definition	Measurement
Selected Demographic			
Age	Current age.	Number of years since birth.	Age in years.
Society of Thoracic Surgeons Mortality and Morbidity Risk Assessment	Disease burden calculated by the weighted contribution of preoperative clinical risk factors.	Risk of mortality or morbidity within 30 days of surgery.	STS Risk Score
Gender	Category assigned by reproductive role.	Assignment at birth.	Male; Female
Race/ Ethnicity	Category based on physical characteristics or a common origin or sense of belonging.	Reported by the patient or significant other. The indicator “black”, for example, includes African American, Haitian, or Negro. (www.whitehouse.gov/	Caucasian; Black; Hispanic; Asian; Native American; Other

Variable	Conceptual Definition	Operational Definition	Measurement
		omb/fedreg/1997standards.html)	
Preoperative Characteristics			
Height	Length from floor to top of head.	Vertical distance measured with a rod or ruler.	Height in centimeters
Weight	Body weight before surgery.	Weight in kilograms closest to day of surgery.	Weight in kilograms
Last Preoperative Creatinine Level	Renal complications: evidence of altered renal control of metabolic balance.	Most recent serum creatinine level. Normal range: .8 to 1.2 mg/dl	Documented value in mg/dl.
Ejection Fraction	Efficiency with which the left ventricle of the heart pumps blood into the arterial circulation.	Percentage of blood ejected from the left ventricle of the heart. Normal range: 55% to 70%.	Normal = 60% Good function = 50% Mildly reduced = 45% Fair function = 40% Moderately reduced = 30% Poor function = 25% Severely reduced = 20%

Variable	Conceptual Definition	Operational Definition	Measurement
Chronic Health History			
Diabetes	History of altered glucose metabolism	Previously diagnosed with elevated serum glucose levels.	Yes; No
Diabetes Control	Documented control of glucose metabolism confirmed by laboratory analysis.	Hemoglobin A1C within normal range of 4.0 - 8.0 mg/dl.	None; Diet; Oral Medications; Insulin; Other
Hypertension	Elevated systolic or diastolic pressures.	Prior documentation of : systolic pressure >140 mmHg diastolic pressure > 90 mmHg	Yes; No
Chronic Lung Disease	Inability of the pulmonary system to maintain normal expiratory volumes or arterial oxygen levels.	Mild: 60% to 75% of normal functional expiratory volumes. Moderate: 50% to 59% of normal functional expiratory volumes. Severe: < 50% of normal functional	No; Mild; Moderate; Severe

Variable	Conceptual Definition	Operational Definition	Measurement
Chronic Health History			
Immunosuppressive Treatment	Medications known to decrease individuals' ability to fight infection.	Evidence of steroid or chemotherapy within 30 days of surgery.	Yes; No
Peripheral Arterial Disease	Diseases of arteries and veins that reduce oxygenation to tissue.	Evidence of a history of altered peripheral circulation or claudication, amputation, or peripheral vascular surgery.	Yes; No
Cerebrovascular Disease	Diseases of the arteries or veins of the cerebral circulation resulting in altered cerebral function.	History of cerebrovascular disease.	Yes; No
Cerebrovascular Accident	Permanently altered cerebral function due to altered oxygenation of tissue.	Presence of a new neurological deficit within 2 weeks of surgery.	< 2 weeks; > 2 weeks

Variable	Conceptual Definition	Operational Definition	Measurement
	Previous surgeries of the heart, arteries, or veins.	Previous coronary artery or vascular surgery indicated by lineal order.	First; Second; Third; Fourth
Cardiac History			
Heart Failure	Inability of the heart to meet the oxygenation requirements of the body.	At least 1 of the following present within 2 weeks of CABG; (1) nocturnal dyspnea, (2) dyspnea on exertion, (3) pulmonary congestion on chest X-ray, (4) pedal edema, (5) dyspnea, after diuretics, and (6) pulmonary edema	Present; Absent
Cardiac Valve Procedure	Surgical or non-surgical interventions of the coronary valves.	Previous interventions performed on the tricuspid, pulmonic, mitral, and aortic valves.	Yes; No
Percutaneous Coronary Intervention (PCI)	Non-surgical opening of an occluded coronary artery.	Time interval between PCI and CAB.	<6 hours; < 24 hours; , 21 or > 21 days

Variable	Conceptual Definition	Operational Definition	Measurement
Preoperative Cardiac Status			
Inotropes	Drugs that mimic the adrenergic responses of the sympathetic nervous systems	Documented treatment with alpha or beta stimulators including dopamine and epinephrine.	Yes; No
Cardiogenic Shock	Failure of the heart to maintain normal circulation or oxygenated blood to tissues.	Systolic blood pressure of 80 mm/Hg or less for 30 minutes or more.	Yes; No
Resuscitation	Artificial cardiac and pulmonary support to maintain circulation.	Cardiopulmonary support within 1 hour of surgery.	Yes; No
I Intra-aortic Balloon Pump Timing	Time pump was inserted.	Time period during hospitalization pump was inserted.	Preoperatively; Intraoperatively; Postoperatively

Variable	Conceptual Definition	Operational Definition	Measurement
Atrial Arrhythmias	Abnormal rate or rhythm of the heart.	Abnormal rate or rhythm of the heart resistant to medication.	Yes; No
Preoperative Cardiac Status			
Number of diseased vessels	Number of native coronary vessels with significant narrowing.	Number of major coronary arteries from the right, left, and circumflex systems with > 50% narrowing.	None; One; Two; Three
Left Main Coronary Disease	Narrowing of the artery providing oxygen to the lateral and anterolateral wall of the left ventricle.	Stenosis of the left main coronary artery is > 50%.	Yes; No
Aortic Valve Stenosis Mitral Valve Insufficiency	Narrowing of the valve between the left ventricle and the aorta.	Decreased blood volume is ejected from the left ventricle through the aortic valve into the systemic circulation.	Yes; No; NA

Variable	Conceptual Definition	Operational Definition	Measurement
Preoperative Cardiac Status			
	Any previous surgery on the valve between the left atrium and left ventricle of the heart.	History of surgery to correct and incompetent valve which causes abnormal blood flow from the left atrium to the left ventricle.	No surgery; Replacement; Reconstruction
Tricuspid Valve Insufficiency	Any previous surgery on the valve between the right atrium and right ventricle of the heart.		No surgery; Annuloplasty; Annuloplasty with Replacement; Annuloplasty with Reconstruction;
Preoperative Indication and Number of Cardiac Surgeries			
Incidence	Lineal number of procedures during this hospitalization.	Previous surgeries indicate greater probability of mortality and morbidity.	First; Second; Third
Status	Clinical status prior to surgery.	Delay in surgery would result in increased risk of death.	Elective; Emergent; Urgent; Emergent Salvage

Variable	Conceptual Definition	Operational Definition	Measurement
Angina	Cardiac pain resulting from decreased oxygenation of the myocardium.	Subjective complaints of pain.	No symptoms; Stable; Unstable; EKG changes

Appendix C

Distribution of Study Populations' Variables Included in the STS Mortality and Morbidity Risk Model.

	N	M (SD)	Minimum	Maximum
Age [a]	330	65.15 (9.37)	39	90
Male	282	64.77 (9.28)	39	90
Female	48	67.40 (9.64)	45	87
Height [b]				
Male	282	177.06 (7.40)	154.4	197.84
Female	48	160.47 (6.28)	149.7	174.87
Weight [c]				
Male	330	90.87 (18.80)	39.90	180.5
Female	48	73.73 (19.59)	38.1	114

(a) Years (b) Centimeters (c) Kilograms
(d) Society of Thoracic Surgeons Mortality and Morbidity Risk Score (%)
(e) Ejection Fraction (%) (f) Serum Level (mg/dl)
(g) Percutaneous Coronary Interventions
(h) Intra-aortic Balloon Pump

	N	M (SD)	Minimum	Maximum
STS [d]	330	0.10 (0.06)	0.03	0.56
Male	282	0.09 (0.01)	0.03	0.56
Female	48	0.14 (0.01)	0.05	0.45
Creatinine [e]				
Male	330	1.15 (0.49)	0.6	6.9
Female	48	1.13 (1.20)	0.5	8.8
	n	M (SD)	Minimum	Maximum
EF[f]				
Male	330	55.26 (10.08)	20	84
Female	48	55.13 (9.76)	35	70

	f	%
Race/Ethnicity		
Asian	19	5.8
Black	10	3
Caucasian	287	87
Hispanic	4	1.2%
Native American	1	0.3%
Other	9	2.7%
Diabetes	91	27.3%
Diabetes Treatment	91	27.3%
Diet	12	3.7%
Insulin	24	5.7%
None	8	2.7%

	f	%
Oral Medication	47	13.4%
Hypertension	252	76.4%
Chronic Lung Disease	32	19.40%
Mild	26	7.9%
Moderate	5	1.5%
Severe	1	0.3%
Chronic Lung Disease	32	19.4%
Mild	26	7.9%
Moderate	5	1.5%
Severe	1	0.3%
Immunosuppressives	7	2.1%
Peripheral Arterial Disease	35	10.6%
Cerebrovascular Disease	32	9.7%
Cerebrovascular Accident	13	3.9%
Cardiac History		
CAB	8	2.7%
Valve Surgery	1	0.3%
Other Procedures/PCI[g]	49	14.7%
Myocardial Infarction	13	27.7%
Heart Failure	14	4.7%

	19	6.4%
NYHA Classification		
Class I	2	0.7%
Class II	6	2%
Class III	8	2.7%
Class IV	3	1%
Preoperative Cardiac Status		
Inotropes	277	83.90%
Cardiogenic Shock	2	0.66%
Resuscitation	1	0.30%
IABP [a]	3	0.09%
Atrial Arrhythmias	22	6.6%
Number Diseased Vessels		
None	1	0.3%
One	8	2.4%
Two	45	13.5%
Three	276	82.9%
Left Main Coronary Disease	108	32.4%
Aortic Valve Stenosis	1	0.3%
Mitral Valve Insufficiency	21	7.1%
Tricuspid Valve Insufficiency	13	4.3%

	19	6.4%
Incidence		
First cardiac surgery	156	47.28%
Other cardiac surgeries	174	52.72%
Timing		
Elective	160	48%
Urgent	170	52%

	f	%
Angina		
No symptoms	9	2.7%
Stable	30	9%
Unstable	2	0.6%
EKG changes	5	1.5%

Appendix D

(SF12v2 Standard, US Version 2.0)

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐1	☐2	☐3	☐4	☐5

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
	▼	▼	▼
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3

b Climbing several flights of stars .... ☐1 .... ☐2......... ☐3

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
b Were limited in the kind of work or other activities	☐1	☐2	☐3	☐4	☐5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
b Did work or other activities less carefully than usual	☐1	☐2	☐3	☐4	☐5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
b Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
c Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities

8. (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐1	☐2	☐3	☐4	☐5

Thank you for completing these questions!

Appendix E

SF-12v2™: Item, Response Scale and Associated Domain

Item	Item Description (Domain)	Item and Response Scale
1.	General Health (GH)	In general, would you say your health is: 1 Poor · 2 Fair · 3 Good · 4 Very Good · 5 Excellent
2A.	Moderate Activities (PF)	How much does your health now limit you in 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
2B.	Strenuous Activities (PF)	During a typical day, how much does your health now limit you in climbing several flights of stairs? 1 Yes, limited a lot · 2 Yes, limited a little · 3 No, not limited at all

Item	Item Description (Domain)	Item and Response Scale				
3A.	Activity Limitations (RP)	How much of the time has your physical health prevented you from accomplished less than you would like?				
		1 All of the time	2 Most of the time	3 Some of the time	4 A little of the time	5 None of the time
3B.	Work Limitations (RP)	How much of the time has your physical health limited your work or activities?				
		1 All of the time	2 Most of the time	3 Some of the time	4 A little of the time	5 None of the time
4A.	Accomplish Less (RE)	How much of the time has your emotional health (such as feeling depressed or anxious) prevented you from accomplishing less than you want?				
		1 All of the time	2 Most of the time	3 Some of the time	4 A little of the time	5 None of the time

Item	Item Description (Domain)	Item and Response Scale				
4B.	Carefulness (RE)	How much of the time has your emotional health (such as feeling depressed or anxious) prevented you from being careful?				
		1	2	3	4	5
		All of the time	Most of the time	Some of the time	A little of the time	None of the time
5.	Bodily Pain (BP)	During the past 4 weeks, how much did pain interfere with your normal work?				
		1	2	3	4	5
		Extremely	Quite a bit	Moderately	A little bit	Not at all
6A.	Well-being (MH)	How much of the time during the past 4 weeks have you felt calm and peaceful?				
		1	2	3	4	5
		None of the time	A little of the time	Some of the time	Most of the time	All of the time
6B.	Vitality (VT)	How much of the time during the past 4 weeks have you had a lot of energy?				
		1	2	3	4	5
		None of the time	A little of the time	Some of the time	Most of the time	All of the time

Item	Item Description (Domain)	Item and Response Scale				
6 C.	Depressed (MH)	How much of the time during the past 4 weeks have you felt downhearted and depressed?				
		1	2	3	4	5
		All of the time	Most of the time	Some of the time	A little of the time	None of the time
7.	Social Activities (SF)	How much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?				
		1	2	3	4	5
		All of the time	Most of the time	Some of the time	A little of the time	None of the time

Appendix F

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AMA AMERICAN MEDICAL ASSOCIATION

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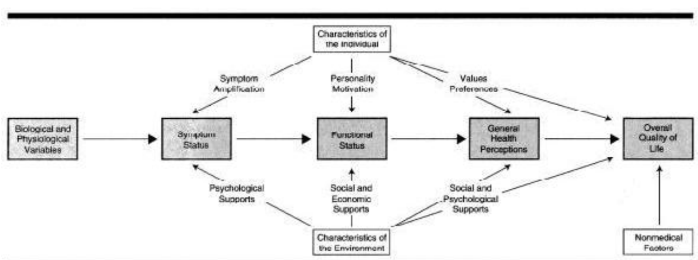

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Appendix G

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Quality Metric Permission to Use Copyrighted Material

AMENDMENT TO LICENSE AGREEMENT (OGSR)

Effective Date: November 18, 2009

Licensee Name: George Mason University

License: CT118867 / OP002734

Approved Purpose: "descriptive, longitudinal study"

This Amendment to License Agreement (OGSR) (the "Amendment") is entered into as of the Effective Date, by and between QualityMetric Incorporated ("QM") and Licensee.

Amended Terms of License

The following term(s) of the License are modified as indicated below.

Change: Licensee Name: From George Mason University to **Janet Boyd**

Except as expressly modified by this Amendment, all terms and conditions of the License shall continue in full force and effect without change.

EXECUTED, as of the Effective Date, by the duly authorized representatives as set forth below.

Janet Boyd
[Licensee]

Signature: ______________________________

Name: ______________________________

Title: ______________________________

Date: ______________________________

Appendix H

Institutional Review Board Certificate of Exemption

INOVA HEALTH SYSTEM

Inova Health System Institutional Review Board
Inova Fairfax Hospital
3300 Gallows Road,
Falls Church, Virginia 22042-3300

Tel 703-776-3167
Fax 703-776-6678

Certificate of Exemption

The following was reviewed and has been found to meet the requirements under 45-CFR-46 as being exempt from the requirement of IRB review

Date:	October 16, 2009
Investigator:	Linda Henry, RN, PhD and Janet Boyd, RN, PhD
Study Name:	Factors Influencing Health-Related Quality of Life Following Coronary Artery Bypass
IRB Number:	09.135
Study Site(s):	Inova Fairfax Hospital
Exemption Category:	45-CFR-46 101 (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, that are publicly available or collected anonymously. ("Anonymous" means the HIPAA definition of de-identified data. "Existing" means that all the data, documents, records, or specimens are in existence prior to IRB evaluation, therefore specimens obtained prospectively from future discarded clinical samples do not qualify as exempt).
Exemption is granted subject to:	1. Deidentified and unlinked dataset from previously collected data in existing database 2. At no time will the George Mason researcher be provided with personal health information linked to the individual.

If you have questions, please contact the Inova IRB at 703-776-3167 or 703-776 -3370

This is to certify that the information contained herein is true and correct as reflected in the records of the Inova Institutional Review Board. I certify that the Inova IRB is in full compliance with all conditions pursuant to the Inova Federal Wide Assurance (FWA)

Laura Miller, MSHA, Inova IRB Manager

10/16/09
Date

Appendix I

Approval to Conduct Research by the University Human Subject Review Board

From	"hsrb@gmu.edu" <hsrb@gmu.edu>
Sent	Tuesday, November 17, 2009 11:53 am
To	Janet E Boyd <jboyd1@gmu.edu>
Cc	Jean B Moore <jmoore@gmu.edu>
Bcc	
Subject	GMU HSRB Approval Notification Protocol #6622

Dear Janet,
The HSRB has approved your protocol #6622 entitled “Factors influencing health-related quality of life following coronary artery bypass”. The approval letter is being sent to you and to Dr. Moore today. You should not begin your data collection before receiving this document.
Please contact me if you have any questions.
Thank you,
Karen
Office of Research Subject Protections

--
Karen Motsinger
Office of Research Subject Protections
Research 1, Room 142
MS 4C6
Fairfax, VA 22030
703-993-4208
703-993-9590 (fax)

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Curriculum Vitae

Janet S. Boyd was born January 4, 1953, in Chicago, Illinois. She received a Bachelor of Science degree in nursing from Marquette University, Milwaukee, Wisconsin, in 1975. Janet has been employed in nursing education, clinical practice, and federal health care policy development. She is a Clinical Specialist in Critical Care and retired United States Navy Nurse Corps Officer.