



4-2016

Is Preoperative Functional Status a Predictor of Postoperative Mortality, Morbidity and Quality of Life in Open Heart Patients?

A. Kate MacPhedran

Western Michigan University, adrlanekc13@aol.com

Follow this and additional works at: <https://scholarworks.wmich.edu/dissertations>



Part of the Cardiology Commons, and the Rehabilitation and Therapy Commons

Recommended Citation

MacPhedran, A. Kate, "Is Preoperative Functional Status a Predictor of Postoperative Mortality, Morbidity and Quality of Life in Open Heart Patients?" (2016). *Dissertations*. 1413.

<https://scholarworks.wmich.edu/dissertations/1413>

This Dissertation-Open Access is brought to you for free and open access by the Graduate College at ScholarWorks at WMU. It has been accepted for inclusion in Dissertations by an authorized administrator of ScholarWorks at WMU. For more information, please contact wmu-scholarworks@wmich.edu.



IS PREOPERATIVE FUNCTIONAL STATUS A PREDICTOR OF POSTOPERATIVE
MORTALITY, MORBIDITY AND QUALITY OF LIFE IN OPEN HEART
PATIENTS?

by

A. Kate MacPhedran

A dissertation submitted to the Graduate College
in partial fulfillment of the requirements
for the Degree of Doctor of Philosophy
Interdisciplinary Health Sciences
Western Michigan University
April 2016

Doctoral Committee:

Kieran Fogarty, Ph.D., Chair
David Barker, Ph.D.
Mark Marbey, M.D.
Eric Vangsnes, Ph.D.

IS PREOPERATIVE FUNCTIONAL STATUS A PREDICTOR OF POSTOPERATIVE MORTALITY, MORBIDITY AND QUALITY OF LIFE IN OPEN HEART PATIENTS?

A. Kate MacPhedran, Ph.D.

Western Michigan University, 2016

The very nature of mortality and morbidity surrounding cardiac surgery is complex with numerous risk factors involved and researchers have found functional status to be a stronger predictor of outcomes than the admitting diagnosis. Preoperative functional status, however, is not measured by any of the cardiac risk scores. Functional status can be objectively measured using validated outcome tools such as the *Late-Life Function and Disability Instrument* (LLFDI). In 3 studies, the impact and association of functional status changes over time was explored in patients who have undergone elective open heart surgery. Analyses in Study 1 demonstrated significantly improved functional status from preoperative to one year postoperative, both in performing routine tasks and in participating more frequently in social activities (components of LLFDI). With a strong influencing covariate, social support (or lack thereof), there appears to be a direct relationship between functional status and perceived quality of life (Study 2). Preoperative diminished functional status, as measured by the LLFDI, is associated with an increased risk of mortality and morbidity in patients undergoing elective cardiac surgery (Study 3). These findings suggest that careful consideration of all the risks and benefits of cardiac surgery should also include a patient's preoperative functional status,

especially in the case of an elective procedure. For patients, this may better assist them in what to expect for recovery so they can make a more informed decision.

ACKNOWLEDGMENTS

I would like to take the time to thank some wonderful people in my life, without whom, this proposal would never have come to fruition. Enduring the journey these past 5½ years would have been impossible had it not been for their assistance, encouragement, or continuous support. To my mama, Pauletta, there are not enough words to express how much I appreciate and love her. She truly has been my best teacher and given me a lifetime of advice, encouragement, support and love, so I dedicate this body of work as proof to the motto she instilled in my sister Sally and I that hard work pays off, but you have to do it yourself otherwise, “If I give you a fish, I feed you for a day, but if I teach you how to fish then I have fed you for a lifetime!” To my wonderful son, Alex, who’s always been the best part of my life, we are always there for each other despite the craziness of life, and I am so lucky, Bup, to have this great relationship with you. To my sweetheart, Wilbur, who supports my enthusiastic drive and work ethic, and reminds me that life’s too short to fret about the little stuff. Thank you for making me the happiest girl and asking me to spend the rest of our days together.

Special thanks also goes out to my committee members: Kieran, my advisor and chair, for always being there: weekly phone checks, advice, mentoring, grant writing assistance, power point scripts, just to mention a few things. I cannot thank you enough for all that you have done for me and how much I have grown in knowledge, but even more so in confidence, because of you. Thank you Marb, for discussing with me years

Acknowledgments—Continued

ago a subject we both were passionate about and a hope that eventually medical practice would change. David, I wish I had your 30 years expertise in statistics, but having you as part of my committee was the next best thing...what a life saver you were! Eric, I genuinely appreciated your perspective and advice throughout this process. Sincere thanks to the other core faculty members and staff of the Interdisciplinary Health Sciences Doctoral program, Ms. Kibler (all those last minute faxes...thank you!), Drs. Curtis, Nelson and Lagerwey (adjunct), I am proud and humbled to have learned from all of you. To my colleagues from Cohort 5, we really became comrades in this together, and to many more colleagues at Gannon University and Saint Vincent Hospital and to all my friends and extended family for all the uplifting support and words of encouragement. It really does take a village to complete a PhD! Thank you everyone.

A. Kate MacPhedran

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	ii
LIST OF TABLES	ix
LIST OF FIGURES	x
CHAPTER	
I. INTRODUCTION	1
Three-Paper Method	1
Background	2
Measurement for Functional Status: The Late-life Function and Disability Instrument.....	6
Significance of the Research.....	7
Methods.....	7
Paper One.....	7
Paper Two	10
Paper Three	14
Overall Research Questions	17
Summary	17
References	18
II. CHANGE IN FUNCTIONAL STATUS FROM PREOPERATIVE TO ONE YEAR POSTOPERAT IN PATIENTS WHO HAVE UNDERGONE ELECTIVE OPEN HEART SURGERY: A REPEATED-MEASURES STUDY	24

Table of Contents—Continued

CHAPTER

Abstract	24
Background	25
Significance.....	26
Methods.....	29
Study Design and Study Population	29
Procedures.....	30
Measures	30
Data Analysis	32
Results.....	32
Baseline Demographics and Distribution	32
Group Means.....	34
Repeated Measures ANOVA.....	34
Gender and Functional Status	36
Discussion	38
References.....	42
 III. A MIXED-METHODS APPROACH TO UNDERSTANDING THE ASSOCIATION BETWEEN CHANGES IN FUNCTIONAL STATUS AND QUALITY OF LIFE AFTER ELECTIVE OPEN HEART SURGERY	 49
Introduction.....	49
Methods.....	53
Study Population.....	53

Table of Contents—Continued

CHAPTER

Measurement: Late-Life Function and Disability Instrument (LLFDI)	54
Statistical Analysis (Qualitative Data).....	55
Qualitative Design	55
Study Population (Qualitative Design)	56
Measurement: Phone Interview	56
Statistical Analysis (Qualitative Design).....	57
Statistical Analysis (Mixed-methods).....	57
Results.....	58
Baseline Demographics and Distribution	58
Group Means.....	60
Repeated Measures ANOVA	61
Perceived Quality of Life...One Year Later	64
Axial Coding.....	66
Mixed Comparison Analysis.....	68
Discussion	69
References.....	73
IV. IS PREOPERATIVE FUNCTIONAL STATUS ASSOCIATED WITH POSTOPERATIVE MORTALITY AND MORBIDITY IN ELECTIVE OPEN HEART PATIENTS?	78
Introduction.....	78
Methods.....	82

Table of Contents—Continued

CHAPTER	
Study Design.....	82
Participants.....	83
Measures	83
STS Risk Calculator.....	84
Data Analysis	86
Results.....	87
Baseline Demographics and Variable Distribution.....	87
Regression Analysis.....	90
Discussion	92
References.....	94
V. CONCLUSION.....	100
Three-Paper Summary	100
Summary of Paper One and Recommendations for Clinical Practice	101
Summary of Paper Two and Recommendations for Clinical Practice	102
Summary of Paper Three and Recommendations for Clinical Practice	103
Study Limitations.....	104
Implications for Future Research.....	105
Clinical Relevance	106
References.....	107

Table of Contents—Continued

APPENDICES

A.	Late-Life Function and Disability Instrument—Function Component (p.1)	113
B.	Late-Life Function and Disability Instrument—Function Component (p.2)	115
C.	Late-Life Function and Disability Instrument—Function Component (p.3)	117
D.	Late-Life Function and Disability Instrument—Disability Component (p.1)	119
E.	Late-Life Function and Disability Instrument—Disability Component (p.2)	121
F.	Structured Phone Interview Questions.....	123
G.	Society of Thoracic Surgeons Risk Factors	125
H.	Informed Consent (Initial)	127
I.	Consent Letter (Follow-up Research One Year Later)	134
J.	Instructions to Participants.....	136
K.	Saint Vincent IRB Approval Letter	139
L.	Western Michigan University IRB Approval Letters	141

LIST OF TABLES

1.1.	Data Extracted from Subject's Medical Records.....	15
2.1.	Four Levels of Functional Limitation	31
2.2.	Study Demographics versus LLFDI Validation Demographic.....	33
2.3.	Functional Status (LLFDI)—Group Mean Changes over Time in Elective Cardiac Surgery Patients.....	35
2.4.	Main Effect of Time on Functional Status (LLFDI Components)	36
2.5.	LLFDI Total Function Component Scores by Age Groups Among those Undergoing Elective Cardiac Surgery (N=29)	37
3.1.	Study Demographics versus LLFDI Validation Demographics	59
3.2.	Four Levels of Functional Limitation	61
3.3.	Functional Status (LLFDI)—Group Mean Changes Over Time	62
3.4.	Main Effect of Time on Functional Status (each LLFDI Component).....	63
3.5.	Quality of Life - Open Coding Responses	65
4.1.	Data Abstracted for STS Risk Estimates and Actual Postoperative Events	86
4.2.	Patient Characteristics (based on n=43).....	89
4.3.	Bivariate Least Squares Regression Analysis: Mortality Risk (N=41).....	90
4.4.	Bivariate Least Squares Regression Analysis: Morbidity Risk (N = 42).....	91
4.5.	Negative Binomial Regression Analysis: Frequency of Complications (N=43)	91

LIST OF FIGURES

1.1.	Overview of study design	14
3.1.	Overview of study design	58
3.2.	Structured phone interview questions at one year postoperatively.....	63
4.1.	Late-Life Function and Disability Instrument (LLFDI) data flow diagram	88

CHAPTER I
INTRODUCTION
Three-Paper Method

This three-paper format dissertation aims to explore the impact of preoperative functional status on patients who have undergone *elective* open heart surgery, by observing (1) functional status changes over time as these patients recover, (2) the association between preoperative functional status and perceived quality of life one year post-surgery, and (3) whether functional status is associated with an increased risk of mortality or morbidity in this population. Chapter I provides background and significance on the general subject for the three papers. Chapters II-IV are three stand-alone yet related papers, each containing their own introduction, methods, results and discussion sections. Chapter V will integrate the key findings from all three papers in order to derive clinical implications, discuss the overall study limitations, and provide recommendations for future research in this field. The three-paper method benefits the dissertation by containing three stand-alone articles ready to submit for publication. There is some unavoidable redundancy when read cover to cover, due to the overlapping content and repetition of the same sections in each paper.

Background

Over 16.3 million Americans suffer from coronary heart disease (CHD), which results in roughly 500,000 coronary artery bypass graft (CABG) surgeries annually.¹ In 2010, the mean age for patients who underwent recommended CABG surgery was sixty-five and it is not uncommon for surgical patients to be well into their eighties.² With greater than 60 percent of the adult cardiac surgery patients being part of the geriatric population (at least 65 years of age),^{2,3} patients and surgeons have to weigh the benefits and risks more carefully to make an informed decision, especially when elective surgery is proposed. Furthermore, with patients having numerous comorbidities and often complex cardiac surgery, an accurate assessment of patients' preoperative functional status is important given that surgery is often performed to improve function and quality of life.⁴ *Functional status*, for this study, is an individual's ability to do activities within his/her regular environment, an ability that may be limited by physical disabilities due to cardiac disease or perception of symptoms, or extend to a variety of environmental, social and psychological factors.⁵

Determining the efficacy of cardiac surgery which includes coronary artery bypass grafting (CABG) and/or valve repair/replacement surgery is complex, and involves taking several risk factors into consideration and measuring numerous patient outcomes.⁶⁻¹¹ Mortality and morbidity risk with surgery are measures cardiac surgeons universally calculate¹²⁻¹³ using a risk score model such as EuroSCORE or Society of Thoracic Surgeons (STS) risk score. These risk score models have only moderate predictive power for 30-day mortality¹²⁻¹³ and morbidity¹³ and none of them capture the influence of functional status on surgical risk or patient recovery. Researchers have

found functional status level prior to admission to be a strong prognostic predictor of outcomes such as 90-day¹⁴ and 6-month mortality¹⁵ with the hospitalized elderly population and more predictive than their principal admitting diagnosis.^{14,15} It is important to gather objective functional status measures both preoperatively and postoperatively, in order to accurately determine the functional status changes that occur and their effect on patient recovery. From a clinical perspective, STS made a recommendation in 2011, to begin collecting preoperative functional measures such as gait speed^{2,3} on adult cardiac surgery patients, but such data has yet to be gathered for any standardized comparison.

Only a few studies to date have explored preoperative functional status as a possible predictor of postoperative cardiac surgery mortality and morbidity.¹⁶⁻¹⁸ Mayer & Morin¹⁶ retrospectively concluded that geriatric CABG surgery patients' preoperative functional status predicted their two-year postoperative functional status with a positive angina (chest pain) correlation using Seymour and Pringle's Level of Activity questionnaire. Mayer continued her research but switched to using the Short Form-36 (SF-36) instrument, and with Ergina, Morin, & Gold¹⁷ retrospectively followed elderly patients up to 18 months status-post CABG to determine that preoperative functional status (based on physical and general health component scores) was predictive of postoperative complications and mortality. Rumsfeld et al¹⁸ assessed preoperative CABG surgery patients using the SF-36 instrument and concluded that the physical component of the SF-36 was an independent risk factor for 6 month-mortality following CABG surgery. While these findings may indicate changes regarding physical activity and general health, the SF-36 is considered a health-related quality of life instrument and has

not been validated to measure functional status. Therefore, it remains unknown if functional status is a predictor of mortality and morbidity in the cardiac surgery population.

With the cardiac population in general, functional status has primarily been measured as an outcome rather than a predictor, using self-reported “general health” questionnaires to calculate postoperative changes following cardiac surgery.¹⁹⁻²² There is no consensus, however, on the outcome measure to use, ranging from Medical Outcomes Study SF-36^{19,20,22} or SF-12²¹ (MOS SF-36 or MOS SF-12), RAND 36-Item Health Survey (RAND 36-IHS),²¹ Modified 7-Day Activity tool,²⁰ New York Heart Association (NYHA) classifications,²² Duke Activity Status Index (DASI),²¹ 6-Minute Walk Test (6MWT),²¹ and Functional Status Index (FSI).²³ Many of these self-reported questionnaires such as the SF-36, often used to measure “functional status” in longitudinal studies,^{17,19,20,22} lack specificity²⁰ and as such, the same tool has been used in different studies to measure quality of life,^{18,24} depression,¹⁹ postoperative pain,^{17,24} as well as functional status.^{20,22} There is no standardized tool, as yet, for prediction of outcome that includes a measure of functional status, with respect to research on the cardiac surgery population.

There is also no consensus in the literature as to postoperative functional status recovery in patients post-open heart surgery, both in terms of how soon before improvement is detected as well as how long until full recovery is restored. LaPier and Howell²¹ studied cardiac patients within three months post-surgery and used the Duke Activity Status Index and RAND 36 Item Health Survey to discover improvements in functional status as early as 2 months following CABG surgery, but did not capture

preoperative or early (first 6 weeks postoperative) data to determine if improvement occurred sooner. Ballan et al²⁵ recommended exploring the early postoperative period, citing that there was a gap in prospective research from a preoperative period to the early stage of six weeks postoperative in CABG surgery. Artinian et al,²⁶ one of the only studies to examine function and age, as well as differences in recovery the first 6 weeks after CABG, noted functional gains across all age groups. However, there was no baseline (preoperative) data for comparison, and Sickness Impact Profile and Symptom Inventory tools were used rather than tools validated to measure functional status. In terms of reaching full recovery, Barnason et al²⁰ found that postoperative functional status responses (using MOS SF-36) in patients post-CABG, surpassed those of their baseline readings six to twelve months postoperatively. LaPier²³ used several different assessment tools to measure functional status and found patients continued to report moderate deficits in performing daily activities and in function three and a half to six months post-CABG. Hunt, Hendrata, & Myles,²⁴ found mixed results with the MOS SF-36 and a combined quality of life questionnaire. Patients, despite significantly improved physical function 12 months after CABG, did not perceive an improvement in their general health, which was significant. Douki et al²² conducted a study using the MOS SF-36 questionnaire on cardiac patients and concluded that functional status was significantly improved 18 months after CABG surgery as compared to their preoperative data, but did not obtain any measure to track progress in between. Though these studies may shed some light on patient recovery symptoms over time, the tools used were not validated to measure functional status, but rather health-related quality of life. Without a validated tool designed to measure function, it remains unclear if significant functional

gains occur in that preoperative to early postoperative (~ 6 weeks) phase or are back to baseline by 12 months postoperative.

Measurement for Functional Status: The Late-Life Function and Disability Instrument

The *Late-Life Function and Disability Instrument* (LLFDI) is a self-reported questionnaire with established valid and reliable function and disability components,²⁷⁻³⁰ that when combined, yield outcome measures for functional status.³⁰ LLFDI was specifically developed for community-dwelling and ambulating adults over the age of 60 and tested on 60 to 90 year olds.^{27,31,32} LLFDI has been established as an appropriate outcome measure for patients with cardiovascular disease,^{29,33} which makes it an appropriate tool to use on the cardiac surgery population.³⁰ The LLFDI has been used to assess single time measurements on patients with cardiovascular disease,^{30,33} but to date, has not been used in a longitudinal study with open heart surgery patients. Additionally, research has yet to be conducted using the LLFDI to assess functional status as a predictor of cardiac surgery mortality and morbidity.

The LLFDI has established concurrent validity with moderate to high correlation with the SF-36. The SF-36 is a well-established health-related quality of life questionnaire often used in research to calculate the relative burden of disease or health benefits produced by a health care intervention.³⁴ The LLFDI questionnaire assesses physical activities (function component), as well as personal and social life participation frequency and extent of limitation (disability component.) Any of these components may be hindered by physical, emotional or psychological factors in the recovery process

which influence a patient's quality of life. Furthermore, the LLFDI measures aspects of socialization, interpersonal and community interaction, which significantly impact one's life satisfaction. In totality, all of these aspects of the LLFDI measurement seem to encompass, but as yet, have not been validated as a tool to measure quality of life.

Significance of the Research

This study has the potential to contribute to the general knowledge in the field of cardiovascular disease. Heart disease is frequently a quiet disease which gradually progresses over time. Often it is not until changes are seen in one's endurance, physical mobility, and/or socialization, one's quality of life, that the impact of the disease becomes evident. This study may shed light on patients' perception of open heart surgery recovery and its effects on patients' function and disability. Using a standardized functional tool such as LLFDI to measure functional status may help refine a more comprehensive cardiac surgery risk model. Such a tool may also help identify high risk surgical patients, thus permitting surgeons and patients to ultimately make a more informed decision regarding heart surgery.

Methods

Paper One

Research Questions

Is there a change in functional status, preoperatively to one year postoperatively, as measured by the LLFDI, in patients who undergo elective open heart surgery? What specific aspect(s) of patients' functional status change, if any, preoperatively to

postoperatively, as measured by Function Total, Disability Frequency, and Disability Limitation components of the LLFDI?

Design

This study is a prospective, non-experimental, longitudinal design which measures subjects' functional status within one week preoperatively, six weeks postoperatively and one year postoperatively using the self-reported LLFDI (see Appendix A). Subjects are mailed the questionnaires within one week of each measured time period and asked to self-complete and mail them back.

Subjects

From a local tertiary care hospital, a sample of convenience will be recruited from subjects who have been informed by a cardiac surgeon that non-emergency cardiac surgery is recommended. To be included in the study, subjects must: 1) be at least 18 years old, 2) be able to communicate fluently in English, and 3) undergo non-emergency initial or redo open heart surgery which requires sternotomy and involves either coronary artery bypass grafting (CABG), valve repair or replacement, or a CABG/valve combination procedure. Subjects are excluded if non-emergency cardiac surgery becomes emergency surgery or a subject fails to submit or sufficiently complete their preoperative LLFDI. The study has been approved by the human subjects review committees at Western Michigan University and Saint Vincent Health Center.

Measurements

Late-Life Function and Disability Instrument. The LLFDI is a self-reported questionnaire with established valid and reliable function and disability components,²⁷⁻³⁰ that combined, yield outcome measures for functional status.³⁰ The LLFDI is made up of two components, function and disability, which can be stand-alone instruments.^{27,31-32} The Function component is made up of (32) questions that start with asking, “How much difficulty do you have?” (Function) on routine physical actions and activities such as unscrewing a jar lid or running a ½ mile.^{27,32} The higher the Function score, the more functionally able/active one is. The Disability component is made up of (16) questions that start with asking two parts: How often do you participate? (Frequency) and “To what extent do you feel limited?” (Limitation) on social life tasks such as taking part in recreational activities.^{27,31} The higher the Disability scores, the less disabled one is, both in frequency and limitation.^{27,31} This tool has standardized instructions for subjects to answer all 48 questions using a 0 to 5 Likert scale. Each question carries a different weight,^{27,31,32} therefore, raw scores must be transformed to 0-100 scaled scores using the LLFDI computer program. The preoperative LLFDI measurement will serve as the baseline and be compared to repeated LLFDI measurements at 6 weeks and one year postoperative.

Prospective chart reviews will be conducted preoperatively at time of informed consent to obtain data on age, gender, and specific cardiac surgical procedure, and data will be compiled in an Excel spreadsheet.

Statistical Analysis

Descriptive and inferential statistics will be conducted and all data will be analyzed using the statistical package SPSS 18.0.0 (SPSS Inc., Chicago, IL). Descriptive statistics will be conducted on each LLFDI variable at each time period to examine assumptions of normality. Non-parametric tests will be run in addition to parametric if non-normality is identified. If results are similar, parametric test results will be used. Repeated measures analyses (repeated measures ANOVA or Friedman's ANOVA) will be conducted to determine functional status changes from preoperative to 6 weeks postoperative to one year postoperative, as based on LLFDI (Disability Limitation, Disability Frequency, and Function Total) scores. Any significant main effects found in mean LLFDI changes will be further analyzed for specific interactions using post-hoc tests with Bonferroni adjustment. Mixed-design analyses will also be conducted to examine the influence of age and gender on functional status changes over time, as measured by the LLFDI. Data will be considered significant at $p < 0.05$.

Paper Two

Research Question

Are changes in functional status, as measured by the LLFDI, associated with changes in subjects' perceived quality of life?

What is the relationship between functional status and quality of life?

Design

Mixed-methods study comparing changes in functional status, as measured by the LLFDI, at preoperative, and six weeks and one year postoperative, to qualitative data obtained from a phone interview on these same subjects' perception of their functional status progress and quality of life at one year postoperative.

The research design for the qualitative component of the mixed-methods will be based on a psychological phenomenology approach. Subjects will be contacted by phone approximately one year after their open heart surgery to participate in a one-time phone interview to answer structured, open-ended questions (see Appendix B).

Subjects

The subjects in this study are the same ones appearing in paper #1, recruited from a sample of convenience. Subjects included in this study must: 1) return their completed preoperative LLFDIs, and 2) undergo non-emergency initial or redo open heart surgery with sternotomy that involves either coronary artery bypass grafting (CABG), valve repair or replacement, or a CABG/valve combination procedure. Subjects are excluded/eliminated from the study if: 1) non-emergency cardiac surgery becomes emergency surgery, 2) subjects fail to submit or sufficiently complete their preoperative LLFDI, or 3) subjects expire prior to their one year postoperative anniversary. The study has been approved by the human subjects review committees at Western Michigan University and Saint Vincent Health Center.

Measurements

Late-Life Function and Disability Instrument (LLFDI). The LLFDI is a self-reported questionnaire made up of a 32-question Function component and two-part Disability component with 16 questions each on frequency and limitation.^{27,31,32} The higher the Function score, the more functionally able/active one is in performing routine physical activities. The higher the Disability scores, the less disabled one is in social life tasks. This tool has standardized instructions for subjects to answer all 48 questions using a 0 to 5 Likert scale. Each question carries a different weight,^{27,31,32} therefore, raw scores must be transformed to 0-100 scaled scores using the LLFDI computer program. The preoperative LLFDI measurement will serve as the baseline and be compared to repeated LLFDI measurements at 6 weeks and one year postoperatively.

Phone Interview. The phone interview consists of 11 structured, yet open-ended questions (Appendix B) about subjects' perceived postoperative recovery, present functional status, and changes in quality of life as a direct result of the cardiac surgery. The researcher will ask every subject the same questions, in the exact same order. The researcher will use a hands-free headset to communicate with the subject while recording all answers on an Excel spreadsheet. Questions will be pre-typed in columns in Excel and the researcher will verbally restate what is recorded as the subject's response after each question is answered. Corrections will be retyped immediately. The estimated total time for each interview to be conducted is 15-25 minutes per subject.

Statistical Analysis

All quantitative data will be analyzed using the statistical package SPSS 18.0.0 (SPSS Inc., Chicago, IL). Repeated measures analyses (repeated measures ANOVA or Friedman's ANOVA) will be conducted to determine functional status changes from preoperative to 6 weeks postoperative to one year postoperative, as based on LLFDI (Disability Limitation, Disability Frequency, and Function Total) scores. Any significant main effects found in mean LLFDI changes will be further analyzed for specific interactions using post-hoc tests with Bonferroni adjustment. Data will be considered significant at $p < 0.05$.

Qualitative data will be analyzed using a constant comparative analysis method to identify patterns and themes through a process of coding data.³⁵ Data on subjects' incidents will be compared and similar ones will be grouped into categories (open coding). Strategies will then be used to make connections between categories (axial coding). Finally, the core category (central phenomenon) will be selected and used to relate to all the other categories (selective coding).³⁶

Additionally, the relationship between LLFDI and quality of life may be assessed by conducting logistic regression, with LLFDI as the independent (continuous) variable and quality of life responses as the dependent (categorical) variable, pending the diversity of quality of life responses needed to be able to dichotomize categories into high/increased versus low/decreased quality of life. If diversity of quality of life data is not sufficient to dichotomize into categories, quantitative data (LLFDI) and qualitative data (quality of life) from Excel files will be analyzed for overarching themes using Dedoose, a mixed-methods software.³⁷

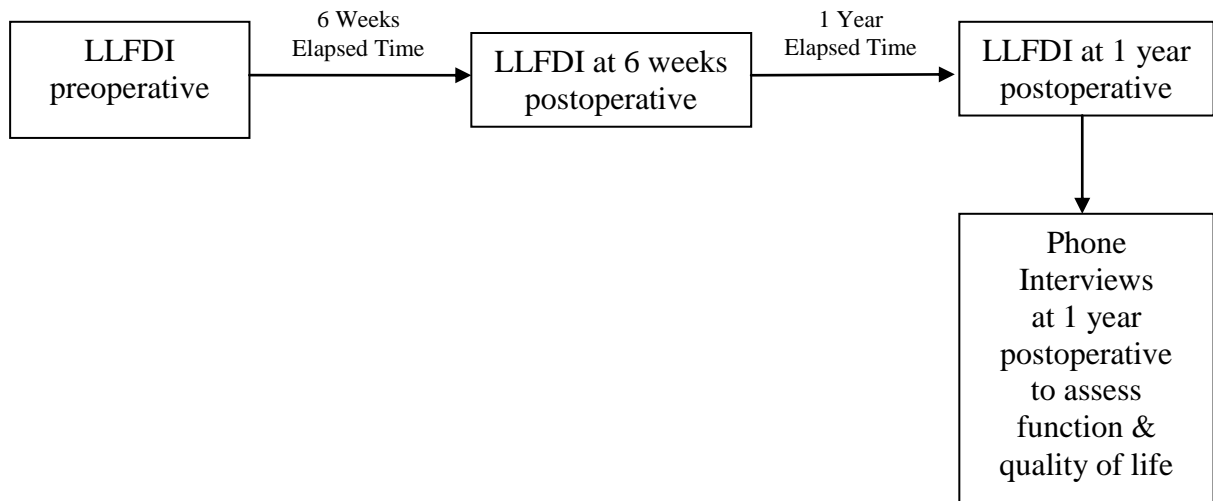


Figure 1.1. Overview of study design.

Paper Three

Research Questions

Does functional status, as measured by the LLFDI, significantly influence the predictive mortality and morbidity risk to change the actual mortality and morbidity?

Does preoperative functional status, as measured by the LLFDI, significantly enhance the cardiac risk score to better predict mortality and morbidity in open heart surgery?

Design

Non-experimental study conducting prospective chart abstraction of preoperative and postoperative clinical data will be obtained one year postoperatively to calculate mortality and morbidity risk. Regression analysis will be conducted to assess the relationship between the LLFDI preoperative score (independent/predictor variable) and the STS mortality and morbidity risk scores (dependent/outcome variables).

Subjects

Subjects will be included if they underwent open heart surgery and completed their preoperative LLFDI questionnaire. Access to subjects' medical/health records for chart abstraction will be obtained when they sign their informed consents. The study has been approved by the human subjects review committees at Saint Vincent Health Center and Western Michigan University.

Measurements

Clinical Data Abstraction. The following data will be extracted from the subject's medical records (McKesson Electronic Medical Record, MIS medical record) and stored on an Excel spreadsheet (see Table 1.1):

Table 1.1

Data Extracted from Subject's Medical Records

Preoperative	Postoperative
Age	Specific cardiac surgical procedure
Gender	Hospital length of stay
Ethnicity	Postoperative bleeding (return to O.R.)
Ejection fraction % (EF)	Sternal infection
NYHA	Intubation > 24 hours (and re-intubation)
Creatinine	Neurologic event
Body Mass Index (BMI)	Adverse arrhythmia (pacemaker or defibrillator required)
Number of vessel disease	Creatinine within 72 hours
Myocardial Infarct history	Co-morbidities (progressed/new diagnoses)
Prior neurologic event	Mortality (all-cause, at 30-days & 1-year)
Co-morbidities	Total cross-clamp time
Valve disease/insufficiency	

Specific preoperative and postoperative information selected to be retrieved has been identified by STS as demographic information, risk factors, or significant predictors of mortality and morbidity in cardiac surgery.^{2,6-11} Because mortality and morbidity data is often extended beyond the patients' hospitalization, including data at 30, 60, or 90 days postoperatively, and as far out as one year postoperatively,^{2,8,9} retrospective data abstraction will be most appropriate to capture this trend.

Society of Thoracic Surgeons (STS) Risk Calculator. The STS cardiac risk score calculator (version 2.81) allows health care workers and researchers free access to the calculator in the capacity of entering all data points and receiving the predicted mortality and morbidity risk scores.² However, individual weights for specific variables and mathematical formulas for deriving at the end calculations are proprietary information of STS,²

Late-Life Function and Disability Instrument (LLFDI). The LLFDI tool has standardized instructions for subjects to answer all 48 questions using a 0 to 5 likert scale. Since each question carries a different weight,^{27,31,32} the raw scores will be converted to 0-100 scaled scores using the accompanying LLFDI computer program. The LLFDI will be conducted for a single preoperative measurement.

Statistical Analysis

Bivariate least squares regression will explore the relationship between preoperative LLFDI and STS mortality risk, as well as preoperative LLFDI and STS morbidity risk score. By adding the LLFDI preoperative scores to the STS mortality and morbidity risk scores, ordinary least square regression will be conducted to determine

how much variance in the new scores is accounted for by the LLFDI, and ultimately, if preoperative LLFDI predicts mortality and morbidity risk.

Overall Research Questions

Paper one will utilize repeated methods analyses to explore changes in functional status over time in patients who have undergone elective open heart surgery. Paper two will take those findings and compare them in a mixed-methods approach using phone interview responses to determine if the LLFDI tool depicts changes in patients' perceived quality of life at one year post-surgery. Paper three will also utilize patients' preoperative LLFDI Function Total scores from paper one and compare them to their calculated STS mortality and morbidity risk scores (obtained from conducting extensive chart reviews) to determine if preoperative functional status is a predictor of postoperative mortality and morbidity in open heart patients.

Summary

This study hopes to provide more insight to the role preoperative functional status plays postoperatively in recovery for open heart surgery patients. This study may help surgeons, future patients, and their loved ones, when making informed decisions about recommending or undergoing elective open heart surgery. Preoperative functional status may potentially be indicated as a cardiac risk factor among the other known influencing risks, and if so, may warrant refining current risk stratification score models.

References

1. American Heart Association. (2011). Heart disease and stroke statistics 2011 update: A report. from the American Heart Association. *Circulation*, 123, e18-e209.
2. Society of Thoracic Surgeons National Database (2010).
3. Afilalo J, Eisenberg MJ, Morin JF, et al. Gait speed as an incremental predictor of mortality and major morbidity in elderly patients undergoing cardiac surgery J Am Coll Cardiol 2010;56:1668-1676.
4. Daley J, Henderson WG, Khuri SF. Risk-adjusted surgical outcomes. *Annu Rev Med.* 2001;52:275-287.
5. Bennett JA, Riegel B, Bittner V, Nichols J. Validity and reliability of the NYHA classes for measuring research outcomes in patients with cardiac disease. *Heart Lung.* 2002;31:262-270.
6. Charlson M, Krieger KH, Peterson JC, Hayes J, Isom OW. Predictors and outcomes of cardiac complications following elective coronary bypass grafting. *Proc. Assoc. Am. Physicians.* 1999;111(6):622-632.
7. Alexander KP, Anstrom KJ, Muhlbaier LH, et al. Outcomes of cardiac surgery in patients age ≥ 80 years: Results from the National Cardiovascular Network. J Am Coll Cardiol. 2000;35:731-738.

8. Akins CW, Miller C, Turina MI, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. *Ann Thorac Surg.* 2008;85:1490-1495.
9. Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity of The American Association for Thoracic Surgery and The Society of Thoracic Surgeons. *Ann Thorac Surg.* 1996;62:932-935.
10. Ferguson TB, Hammill BG, Peterson ED, DeLong ER, Grover FL. A decade of change-risk profiles and outcomes for isolated coronary bypass grafting procedures, 1990-1999: A report from the STS National Database Committee and the Duke Clinical Research Institute. *Ann Thorac Surg.* 2002;73:480-490.
11. Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. *Circulation.* 1989;79(6)Supplement I:3-12.
12. Granton J, Cheng D. Risk stratification models for cardiac surgery. *Semin. Cardiothorac. Vasc. Anesth.* 2008;12:167-174.
13. Geissler HJ, Hölzl P, Marohl S, Kuhn-Régner F, Mehlhorn U, Südkamp M, de Vivie ER. Risk stratification in heart surgery: comparison of six score systems. *Eur J Cardiothorac Surg.* 2000;17:400-406.

14. Inouye SK, Peduzzi PN, Robison JT, Hughes JS, Horwitz RI, Concato J. Importance of functional measures in predicting mortality among older hospitalized patients. *JAMA*. 1998;279:1187-1193.
15. Narain P, Rubenstein LZ, Wieland GD, Rosbrook B, Strome LS, Pietruszka F, Morley JE. Predictors of immediate and 6-month outcomes in hospitalized elderly patients. The importance of functional status. *J Am Geriatr Soc*. 1988;36:775-783.
16. Mayer C, Morin JF. Functional status may serve as a predictor of CABG outcome in the elderly patient. *McGill Journal of Medicine*. 1996; 2(2):78-83.
17. Mayer C, Ergina P, Morin JF, Gold S. Self-reported functional status as a predictor of coronary artery bypass graft surgery outcome in elderly patients. *Can J Cardiol*. 2003;19:140-144.
18. Rumsfeld JS, MaWhinney S, McCarthy Jr M, et al. Health-related quality of life as a predictor of mortality following coronary artery bypass graft surgery. *JAMA*. 1999;281:1298-1303.
19. Sorensen EA, Wang F. Social support, depression, functional status and gender differences in older adults undergoing first-time coronary artery bypass graft surgery. *Heart Lung*. 2009;38:306-317.
20. Barnason S, Zimmerman L, Anderson A, Mohr-Burt S, Nieveen J. Functional status outcomes of patients with a coronary artery bypass graft over time. *Heart Lung*. 2000;29:33-46.

21. LaPier TK, Howell D. Functional status deficits in patients recovering from coronary artery bypass: An application of evidence-based practice. *Cardiopulm Phys Ther J*. 2002;13:12-19.
22. Douki ZE, Vaezzadeh N, Zakizad M, Shahmohammadi S, Sadeghi R, Mohammadpour RA. Changes in functional status and functional capacity following coronary artery bypass surgery. *Pakistan J Biol Sci*. 2010;13:330-334.
23. LaPier TK. Functional status of patients during subacute recovery from coronary artery bypass surgery. *Heart Lung*. 2007;36:114-24.
24. Hunt JO, Hendrata MV, Myles PS. Quality of life 12 months after coronary artery bypass graft surgery. *Heart Lung*. 2000;269:401-411.
25. Ballan A, Lee G. A comparative study of patient perceived quality of life pre and post coronary artery bypass graft surgery. *Aust J Adv Nurs*. 2007; 24: 24-28.
26. Artinian NT, Duggan C, Miller P. Age differences in patient recovery patterns following coronary artery bypass surgery. *Am J Crit Care*. 1993;2(6):453-61.
27. Jette AM, Haley SM, Kooyoomjian JT. *Late Life Function and Disability Instrument*. Boston, MA: Trustees of Boston University; 2002.
28. Sayers SP, Jette AM, Haley SM, Heeren TC, Guralnik JM, Fielding RA. Validation of the Late-Life Function and Disability Instrument. *J Am Geriatr Soc*. 2004;52: 1554-1559.

29. Dubuc N, Haley SM, Ni P, Kooyoomjian JT, Jette AM. Function and disability in late life: Comparison of the Late-Life Function and Disability Instrument to the Short-Form-36 and the London Handicap Scale. *Disabil Rehabil.* 2004;26:362-370.
30. LaPier TK, Mizner R. Outcome measures in cardiopulmonary physical therapy: Focus on the Late-Life Function and Disability Instrument (LLFDI). *Cardiopulm Phys Ther J.* 2009;20:32-35.
31. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. Development and evaluation of the disability component. *J Gerontol.* 2002;57A:M209-M216.
32. Haley SM, Jette AM, Coster WJ, et al. Late Life Function and Disability Instrument: II. Development and evaluation of the function component. *J Gerontol.* 2002;57A:M209–M216.
33. Kinney LaPier TL, Waitt M. Using the Late Life Function and Disability Instrument as a self-report outcome measure in patients with cardiovascular disease. *J Cardiopulm Rehabil Prevent.* 2007;27(5):331.
34. Ware Jr. JE, Kosinski M, Bjorner JB, Turner-Bowker DM, Gandek B, Maruish ME. (2007) User's Manual for the SF-36v2™ Health Survey. 2nd Ed. 2007. Lincoln: RI; Quality Metric Incorporated.
35. Fram SM. The constant comparative analysis method outside of grounded theory. *Qual Rep.* 2013;18(1):1-25.

36. Strauss AL, Corbin J. Basics of qualitative research: Grounded Theory procedures and techniques. 1990. Thousand Oaks, CA: Sage.
37. Qualitative research data analysis software. www.dedoose.com.

CHAPTER II

CHANGE IN FUNCTIONAL STATUS FROM PREOPERATIVE TO ONE YEAR POSTOPERATIVE IN PATIENTS WHO HAVE UNDERGONE ELECTIVE OPEN HEART SURGERY: A REPEATED-MEASURES STUDY

Abstract

Although patient-related factors affect surgical outcomes, preoperative functional status is not measured by any cardiac risk score, even though functional status can be objectively measured using validated outcome tools such as the *Late-Life Function and Disability Instrument* (LLFDI). The purpose of this study was to determine 1) if there was a change over time in functional status, as measured by the LLFDI, in patients who underwent elective cardiac surgery, and if so, 2) what specific aspect(s) of LLFDI functional status changed.

Methods: A prospective longitudinal study of one year was conducted on elective cardiac surgery patients (n=43) using the self-reported LLFDI. Three components of LLFDI (Function Total, Disability Frequency and Disability Limitation) were compared at three times (preoperative, six weeks postoperative and one year postoperative) using repeated measures ANOVA. Post hoc pairwise comparison was conducted for specific interactions.

Results: Both Function Total (ability to perform routine activities) and Disability Frequency (participation frequency in social tasks) significantly increased over time ($p=.047$ and $p=.013$, respectively). Specifically, Function Total was significantly higher

from preoperative to one year postoperative (M difference =+3.48, SE=1.48, p= .026). Likewise, Disability Frequency significantly increased from preoperative to one year postoperative (M difference= +5.98, SE=2.19, p=.033), with increased participation frequency indicating decreased disability. Disability Limitation scores were not significantly different between any time points ($p > .05$).

Conclusion: According to LLFDI scores, patients who underwent elective cardiac surgery demonstrated significant improvement from preoperative to one year postoperative, both in performance of routine activities (Function Total) and in increased participation in social life tasks (Disability Frequency). These findings may assist cardiac patients in what to expect for recovery.

Background

Determining the efficacy of cardiac surgery, which includes coronary artery bypass grafting (CABG) and/or valve repair/replacement surgery, is complex and involves taking into consideration several risk factors and measuring numerous patient outcomes.¹⁻⁶ Mortality and morbidity risk after surgery are measures cardiac surgeons universally calculate^{7,8} to estimate patient outcomes. However, these scores do not capture the influence of functional status on patient recovery. Functional status is defined as an individual's ability to do activities within his/her regular environment, an ability that may be limited by physical disabilities due to cardiac disease, perception of symptoms, or extend to a variety of environmental, social and psychological factors.⁹ Researchers have found functional status to be a strong prognostic predictor^{10,11} of outcomes such as 90-day¹¹ and 6-month mortality¹⁰ with the hospitalized elderly

population. It has also been found to be more predictive than a patient's principal admitting diagnosis.^{10,11} Greater than 60 percent of the adult cardiac surgery population is older than 65.^{12,13} Gathering objective functional status measures, both preoperatively and postoperatively, is an important tool in exploring the functional status changes that occur during patient recovery.

With the cardiac population in general, functional status has primarily been measured as an outcome using self-reported "general health" questionnaires to calculate postoperative changes following cardiac surgery.²⁵⁻²⁸ Ballan and Lee¹⁷ supported the use of questionnaires as a possible tool for determining patients' quality of life and well-being, especially pre- and post-CABG surgery. There is no consensus, however, on the outcome measure to use, ranging from Medical Outcomes Study Short Form 36^{25,26,28} or Short Form 12,²⁷ RAND 36-Item Health Survey,²⁷ Modified 7-Day Activity tool,²⁶ New York Heart Association classes,²⁸ Duke Activity Status Index,²⁷ 6-Minute Walk Test,²⁷ to Functional Status Index.²⁹ Furthermore, many of the self-reported questionnaires such as the Short Form 36 (MOS SF-36), often used in functional status longitudinal studies,^{25,26,28,30} lack specificity²⁶ as seen by their use in measuring quality of life,^{32,33} depression,²⁵ post-operative pain,^{30,33} as well as functional status.^{26,28}

Significance

There is currently no standardized tool used for outcome prediction, which includes a measure of functional status, with respect to research on the cardiac surgery population. Also, there is no consensus in the literature concerning postoperative functional status recovery in patients post-open heart surgery, both in terms of how soon

before improvement is detected as well as how long until full recovery is restored.

LaPier and Howell²⁷ studied cardiac patients within three months post-surgery and used the Duke Activity Status Index and RAND 36 Item Health Survey to measure improvements in functional status as early as 2 months following CABG surgery, but did not capture preoperative or early (first 6 weeks) postoperative data to determine if improvement occurred sooner. Ballan et al¹⁷ recommended exploring the early postoperative period, citing that there was a gap in prospective research from a preoperative period to the early stage of six weeks postoperative in CABG surgery. Artinian et al³¹ was one of the only studies to examine function and age differences on recovery the first 6 weeks after CABG. This study noted functional gains across all age groups, however, there was no baseline (preoperative) data for comparison, and function was based on symptoms rather than tools validated to measure functional status.

In terms of reaching full recovery, Barnason et al²⁶ found that postoperative functional status responses (using MOS SF-36) in patients post-CABG, surpassed those of their baseline readings six to twelve months postoperatively. LaPier,²³ however, used several different assessment tools to measure functional status, and found patients continued to report moderate deficits with performing daily activities and function three and a half to six months post-CABG. Hunt, Hendrata, & Myles,³³ found mixed results with the MOS SF-36 and a combined quality of life questionnaire; despite significantly improved physical function 12 months after CABG, patients did not perceive an improvement in their general health which was significant. Douki et al²⁸ conducted a study using the MOS SF-36 questionnaire on cardiac patients and concluded that functional status was significantly improved 18 months after CABG surgery as compared

to their preoperative data, but did not obtain any measure in between to track progress. Though these studies may shed some light on patient recovery symptoms over time, the tools used were not validated to measure functional status, but rather health-related quality of life. Without using a validated tool designed to measure function, it remains unclear if significant functional gains occur in that preoperative to early postoperative (~6 weeks) phase and whether function is back to baseline by 12 months postoperative.

One validated functional status tool is the *Late-Life Function and Disability Instrument* (LLFDI). It is a self-reported questionnaire which specifically targets a wide variety of physical activities and social life tasks, which defines one's functional status. The LLFDI has established valid and reliable function and disability components that, when combined, yield outcome measures for functional status.¹⁸⁻²³ The LLFDI has been used on patients with cardiovascular disease^{23,24} to assess a single time measurement, but to date, has not been used to track cardiac surgery patients' functional status in a longitudinal study.

Given the prevalence that mortality and morbidity in cardiac surgeries differ by gender, the association between gender and functional status changes over time was examined in this study. With previous studies' limitations, particularly related to functional status definitions and non-specific tools used, the aim of this study was to determine: 1) if there was a change in functional status from preoperative, to six weeks postoperative, to one year postoperative, as measured by the LLFDI, in patients who underwent elective cardiac surgery and 2) what specific aspect(s), if any, of LLFDI functional status changed?

Methods

Study Design and Study Population

This was a prospective, non-experimental, longitudinal design using a sample of convenience. Subjects ($n=43$) were recruited from Saint Vincent Health Center from June to December, 2010, after a cardiac surgeon informed them non-emergency cardiac surgery was recommended. Inclusion criteria were subjects at least 18 years old, able to communicate fluently in English, and undergoing elective cardiac surgery which was one of the following: coronary artery bypass graft (CABG) as an initial or redo procedure, valve repair/replacement, or any CABG/valve combination procedure. If elective cardiac surgery became emergency surgery or a subject failed to submit or sufficiently complete their preoperative LLFDI, then they were excluded/ terminated from the study. This study was a collaborative venture between Saint Vincent Health Center and Gannon University Doctor of Physical Therapy Program. Human subject approval was obtained from the institutional review boards of each participating institution in this study. Seventy-seven individuals met eligibility criteria and were invited to participate. The purpose and procedure of the study were explained and informed consents were obtained in person by the primary investigator. All 77 subjects consented, however, of the subjects that returned their preoperative LLFDI's ($n=55$), 12 of them were excluded from the study due to insufficiently completed preoperative LLFDI's. The total number of subjects in this study was therefore, $n=43$. From the subjects with completed preoperative LLFDIs ($n=43$), the total LLFDIs returned/complete at six weeks postoperative were $n=34$ (6 returns incomplete). At one year postoperative, total LLFDIs returned/complete were $n=38$ (1 return incomplete). Incomplete LLFDIs were resolved

with phone calls made by the primary investigator to the subjects with missing question(s) read aloud, responses recorded and read back for verification. There were 29 complete LLFDI responses at all three time points.

Procedures

Preoperative LLFDIs were mailed to subjects' residences approximately one week prior to surgery with instructions to return completed form by mail. Fifty-three percent of the 77 subjects remained as inpatients until cardiac surgery and their completed preoperative LLFDIs were collected by the primary investigator in-person in sealed provided envelopes. All returned LLFDIs were mailed directly to the research assistants to maintain a single-blind study. LLFDIs were again mailed to subjects' residences approximately one week prior to their six week and one year postoperative surgery dates with instructions to return completed form by mail. Within one week of mailing LLFDIs, contact by phone was used to obtain clarification on any incomplete LLFDI received or as a means to retain subjects.

Measures

Late-Life Function and Disability Instrument

In this study, functional status was measured using the LLFDI. There are two components to the LLFDI: The Function component is made up of (32) questions that start with "How much difficulty do you have?" (Function) regarding routine physical actions and activities such as unscrewing a jar lid or running a ½ mile.^{19,20} The higher the Function score, the more functionally able/active one is. The Disability component is

made up of (16) two part questions that start with: “How often do you participate?” (Frequency) and “To what extent do you feel limited?” (Limitation) on social life tasks such as taking part in recreational activities.^{18,20} The higher the Disability scores, the less disabled one is, both in frequency and limitation.^{18,20} Each question carries a different weight and raw scores must be transformed to have a consistent 0-100 range.^{18-21, 23,24} The authors of the LLFDI also classified the scaled scores into four statistically different subgroups based on limitation (Table 2.1) for easier clinical interpretation.^{18,19} For this study, functional status was measured using LLFDIs Function Total, Disability Frequency and Disability Limitation scores.

Table 2.1

Four Levels of Functional Limitation
(Based on converted mean LLFDI scaled 0-100 scores)^{18,19}

Classification	Total Function	Disability Frequency	Disability Limitation
Severe Limitation	41.7	44.3	55.4
Moderate Limitation	53.2	49.5	63.5
Slight Limitation	65.6	53.6	73.8
No Limitation	75.6	58.1	82.5

LLFDI = Late Life Function and Disability Instrument

In addition to calculating the LLFDI, data on gender, race/ethnicity, and age information was collected. For this study, age groups were defined as <60 years, 60-69 years, and ≥70 years. Race/ethnicity was defined as Caucasian, African American, Hispanic or “other.” Age and gender were controlled to assess functional status change over time.

Data Analysis

All data were analyzed using the statistical package SPSS 18.0.0 (SPSS Inc., Chicago, IL). Study demographics were collected on gender, age, and race/ethnicity and compared with those of the original LLFDI sample used to validate the instrument (Table 2.2). Descriptive statistics were conducted to examine sample demographics and frequency distribution (Table 2.2). Repeated measures analyses were conducted to determine functional status changes from preoperative to 6 weeks postoperative to one year postoperative, as based on LLFDI (Disability Limitation, Disability Frequency, and Function Total) scores. Any significant main effects found in mean LLFDI changes were further analyzed for specific interactions using post-hoc tests with Bonferroni adjustment. Mixed-design analyses were also conducted to examine the association between age and gender on functional status changes over all three time measures with the three LLFDI components. Data were considered significant at $p < 0.05$. Descriptive statistics were conducted on each LLFDI variable at each time period to examine assumptions of normality. Non-parametric tests were conducted in addition to parametric, if non-normality was identified. If results were similar, parametric test results were used.

Results

Baseline Demographics and Distribution

The study data were very similar to the data originally used to validate the LLFDI tool, which was specifically developed for community-dwelling adults over 60 (Table 2.2).^{24,25} Both samples, as seen in Table 2.2, were similar in gender make-up (28% female/ 72% male in preoperative phase of study; 23% female/ 77% male in LLFDI validation sample) and in distribution of subjects in their 60s and 70s (65% in the

preoperative study; 68% in LLFDI validation.) The mean age in the study was 66.3 ± 9.74 and in patients undergoing coronary bypass in 2010 was 64.9. Eighty-one percent of the subjects (n=35) underwent an elective CABG procedure, 5 of which were performed off pump. A total of 8 subjects (19%) underwent elective valve repair or replacement surgery, including 3 subjects (7%) who underwent a combination valve/CABG procedure. All of the subjects in the study received physical therapy postoperatively as inpatients and were recommended for cardiac rehabilitation upon discharge.

Table 2.2

Study Demographics versus LLFDI Validation Demographic

Study Demographics			LLFDI Demographics		
Preoperative	N	% of Total	L LFDI Development	N	% of Total
Gender			Gender		
Female	12	28%	Female	34	23%
Male	31	72%	Male	116	77%
Race/ Ethnicity			Race/ Ethnicity		
Caucasian	41	95%	Caucasian	126	84%
Hispanic	1	2%	Hispanic	8	5%
African Amer.	1	2%	African Amer.	11	7%
Age			Age		
40-49	1	2.3%	40-49	X	0%
50-59	9	20.9%	50-59	X	0%
60-69	17	39.5%	60-69	41	27.3%
70-79	11	25.6%	70-79	61	40.7%
80-89	5	11.7%	80-89	40	26.7%
Median	66		90+	8	5.3%
SD	9.739		Mean age for CABG (STS, 2010)	64.9	
Mean	66.35		LLFDI = Late Life Function and Disability Instrument		
Mode	54, 61, 62, 66				

Group Means

Preoperative group means for the three LLFDI components of functional status were: $M=62.34$ ($SD= 8.90$) for Function Total, $M=51.80$ ($SD=6.20$) for Disability Frequency, and $M=75.65$ ($SD= 14.93$) for Disability Limitation, which is consistent with the “moderate to slight limitation” classification^{18,19} (Table 2.1). Mean difference was not significant for any of the LLFDI components, either preoperative to six weeks postoperative or six weeks to one year postoperative. Group means at one year postoperative (based on significant mean difference preoperative to one year postoperative) were: $M=65.82$ ($SD=10.99$) for Function Total and $M=57.79$ ($SD=12.48$) for Disability Frequency, which is consistent with the “slight limitation” classification^{18,19} (Table 2.3).

Repeated Measures ANOVA

Repeated measures ANOVA was conducted on the three time measures and each of the three LLFDI components for functional status ($n=29$). Repeated measures ANOVA sphericity assumption was met and Function Total was significantly affected by time, $F(2, 56) = 3.232$, $p=.047$, meaning the patients’ ability to perform routine activities significantly changed over time (Table 2.4). Preoperative Total Function scores ($M=62.34$, $SD= 8.90$) were not significantly different from 6 week postoperative scores ($M=62.97$, $SD=8.70$) but were significantly different from one year postoperative scores ($M=65.82$, $SD=10.99$), as revealed by post hoc tests using Bonferroni adjustment (M difference $=+3.48$, $SE=1.48$, $p= .026$).

Table 2.3

Functional Status (LLFDI)—Group Mean Changes over Time in Elective Cardiac Surgery Patients

Variable	Time	Mean	Std. Deviation	LLFDI Limitation Classification ^{18,19}	Sig.
Function total	Preoperative	62.3424	8.90171	Moderate to Slight	
N=29	6 Weeks Postoperative	62.9655	8.70044	Moderate to Slight	
	1 Year Postoperative	65.8210	10.98957	Slight	
(PreOp to 1 Year PostOp)	M Difference	+ 3.4786	1.48 (SE)		.026*
Disability Frequency	Preoperative	51.8141	6.20402	Moderate to Slight	
N=29	6 Weeks Postoperative	52.9041	8.17441	Moderate to Slight	
	1 Year Postoperative	57.7921	12.48259	Slight	
(PreOp to 1 Year PostOp)	M Difference	+ 5.978	2.19 (SE)		.033*
Disability Limitation	Preoperative	75.6497	14.93365	Slight	
N=29	6 Weeks Postoperative	75.6317	15.57000	Slight	
	1 Year Postoperative	81.6524	15.44953	Slight	
(PreOp to 1 Year PostOp)	M Difference	+ 6.0207	2.55 (SE)		.075

* p < .05 denotes statistical significance

The higher the mean score = the more functional, less disabled the individual

LLFDI = Late Life Function and Disability Instrument

The sphericity assumption was violated for Disability Frequency, but using Greenhouse-Geisser correction, repeated measures ANOVA revealed significant differences over time for Disability Frequency, $F(1.53, 42.70) = 5.49$, $p = .013$, $\epsilon = .763$, which indicated subject participation in social life tasks significantly changed over time (Table 2.4). Specifically, preoperative Disability Frequency scores ($M=51.80$, $SD=6.20$) were significantly lower than one year postoperative scores ($M=57.79$, $SD=12.48$), which

indicated that social task participation significantly increased from preoperative to one year postoperative (M difference= +5.98, SE=2.19, p=.033 (Table 2.3) as revealed by post hoc pairwise comparison tests using Bonferroni adjustment.

Table 2.4

Main Effect of Time on Functional Status (LLFDI Components)

Variable	Sphericity Test	Df	F	Sig
Functional total	Sphericity Assumed	(2 56)	3.232	.047*
Disability Frequency	Greenhouse Geisser	(1.53, 42.70)	5.494	.013*
Disability Limitation	Sphericity Assumed	(2.56)	2.423	.098

* p < .05 denotes statistical significance

LLFDI = Late Life Function and Disability Instrument

Disability Limitation was not significantly associated with time (p=.098), which meant that capabilities in performing social life tasks did not significantly change preoperatively to postoperatively (Table 2.4).

Gender and Functional Status

With n=29, for the 3 time periods, there was no significant main effect for gender, regardless of Function Total (p= .097), Disability Frequency (p=.816), or Disability Limitation (p=.473). Furthermore, gender did not significantly interact with Function Total (p=.825), with Disability Frequency (p=.257), or with Disability Limitation (p=.315), indicating results did not differ by gender.

Age and Functional Status

Overall, there was minimal difference among the three age groups (n=7 for <60 years, n= 13 for 60-69 years, and n= 9 for ≥ 70 years) on LLFDI functional status over time. There was no significant main effect of age group, indicating that all 3 age groups responded, in general, the same, regardless of Disability Frequency ($p = .738$) or Disability Limitation ($p = .364$), although there was a main effect of age group when age group was examined with Total Function, $F(2, 26) = 4.683$, $p = .018$. Upon further analysis, there was not a significant interaction effect between age group and Total Function ($p = .795$), however, the ≥ 70 year age group ($M = 57.78$, $SE = 2.51$) mean responses on Function Total were significantly lower than the 60-69 year age group ($M = 67.91$, $SE = 2.17$) with a mean difference = ± 10.13 , $SE = 3.31$, $p = .015$ (Table 2.5).

Table 2.5

LLFDI Total Function Component Scores by Age Groups Among those Undergoing Elective Cardiac Surgery (N=29)

Independent Variable	Outcome Variable	Mean	Std. Error	95% CI	
				Lower Bound	Upper Bound
≥ 70 years (n= 9)	Function Total				
	Preoperative	57.099	2.813	51.318	62.880
	6 Weeks Post-Op	56.884	2.552	51.638	62.131
	1 Year Post-Op	59.356	3.399	52.368	66.343
60-69 years (n= 13)	Function Total				
	Preoperative	65.248	2.436	60.241	70.254
	6 Weeks Post-Op	67.641	2.210	63.098	72.184
	1 Year Post-Op	70.827	2.944	64.775	76.878
< 60 years (n = 7)	Function Total				
	Preoperative	63.884	2.983	57.752	70.016
	6 Weeks Post-Op	62.794	2.707	57.229	68.358
	1 Year Post-Op	65.586	3.606	58.175	72.998
LLFDI = Late Life Function and Disability Instrument					

Discussion

Recovery from cardiac surgery appears to be a lengthy process reflected in this study's findings that participation in social life tasks (Disability Frequency) and routine physical activities (Function Total) significantly improved from preoperative to one year postoperative, but not from preoperative to 6 weeks postoperative. These findings are consistent with prior longitudinal studies that explored functional status changes after CABG surgery,^{29,31} but adds information regarding change from the preoperative period. Cardiac surgery is a major operation, typically including sternal precautions for 6 weeks, helping to explain why patients did not report significant improvement six weeks after surgery.

Based on the results of the LLFDI measurements, subjects overall did not surpass their baseline (preoperative) functional status levels until one year postoperatively. This finding was relatively consistent with some of the other research which indicated functional recovery by 12 months post-cardiac surgery.^{26,33} This study, however, added to the body of knowledge by using a validated tool (LLFDI)²¹ specifically designed to measure function and disability over time.

The results revealed that subjects' limitation in social life tasks (Disability Limitation) did not prove to be significant at any of the time periods and was not associated with gender or age. In interpreting these findings, it is important to note that LaPier and Mizner²³ published a study which calculated the LLFDI minimally detectable change (MDC) for the Disability Limitation component as being 16.7, which was impacted by large standard deviations in the measure. This is in high contrast to the 7.8 minimally detectable change for the Disability Frequency component and 4.3 for the

Function Total component (95% confidence interval).²³ Given the wide variance in response noted for Disability Limitation, the change needed to exceed level of measurement error in order to detect meaningful change in Disability Limitation was not likely to be reached with this sample size. Unlike the frequency to which one participates in personal and social life tasks (Disability Frequency), Disability Limitation refers to one's capability in participating. Since people participate in activities with great variance in capability, a wide range of scores around the means is not unexpected. However, this may have reduced the power and inflated the risk of a type II error.

In this study, gender did not have a significant relationship with functional status, and results over time did not differ by gender. These results are contrary to several studies which found women had poorer functional status compared to men, both preoperatively and postoperatively.^{25,26,28,33} The relatively small sample used in this study may not have been representative of the population. In Sorensen & Wang's study,²⁵ females were significantly older and rated significantly higher on their depression scores than their male counterparts, adding weight to the view that recovery is often multifactorial and perhaps additional variables need to be explored in future studies with a larger sample size.

Overall, age did not have a significant association with functional status over time in this study. The one exception to these findings was the ≥ 70 year age group, whose mean response on Function Total was significantly lower than the 60-69 year olds. A lower score in function indicates more difficulty with routine physical actions and daily living tasks. This finding is consistent with Artinian et al's findings on age differences 6 weeks postoperative after CABG.³¹ Knowledge that routine physical tasks (Function

Total) continued to be more difficult for older (70's versus 60 year old) individuals at one year post-surgery, may be key information that aids in the decision-making for older patients (>70) when cardiac surgery is recommended but elective.

In terms of clinical relevance and research to date in this field, this study was one of the first to explore changes in functional status from preoperative to as early as 6 weeks postoperatively (often not captured in studies), and as far out as one year postoperative using an outcome tool specifically designed to measure functional status and one that has been tested on patients with cardiovascular disease.^{18-20,23,24} The self-reported LLFDI is a simple, straight-forward questionnaire, which participants can complete in roughly 10 minutes^{20,21} without needing administration by a clinician,^{20,23,24} adding to its overall feasibility.

This study had limitations with attrition rate from consent to preoperative LLFDIs of 29% (n=22). One explanation may have been that subjects were met briefly, typically after just receiving news of needing cardiac surgery, without much time to process all of the information. Unfortunately, there is a small window of time (roughly two hours) to approach these potential subjects in person after their consults and tests have been completed and before they are discharged home. This issue could potentially be improved in future studies by conducting a follow-up call 1-2 days later.

Another limitation with this study was incomplete/unusable preoperative LLFDIs which accounted for 16% (n=12). In an attempt to create a single-blind study, all preoperative LLFDIs were mailed directly to the primary investigator's assistants (four graduate students) rather than to the primary investigator (first author). Preoperative LLFDIs were not opened and examined promptly enough, prior to the subject's surgery,

to allow follow-up correction of missing responses. Once subjects underwent surgery, the influence of surgery itself had the potential to taint subjects' preoperative perception, and we felt it would be inaccurate to go back retrospectively to obtain data. This design weakness was rectified with follow-up phone calls made for both postoperative LLFDIs to subjects who returned incomplete LLFDIs. Postoperative response rates for this study were well above the 61% average response rate for physician questionnaires, which according to Cummings et al,³⁶ have remained rather constant for the past twenty years. In a study by Kinney LaPier and Waite,²⁴ self-reported LLFDI scores correlated strongly to those obtained during interviews, which provided confidence that both methods used to obtain subjects' preoperative LLFDI scores provided valid results.

The relatively small sample impacted the statistical power of the study, and possibly explains the inability to reach any of the standardized minimally detectable change (MDC) levels, according to a validation study by LaPier and Mizner²³ for the LLFDI tool, despite reaching statistical significance on Disability Frequency and Function Total with the data. A larger sample in the future would help detect if clinically relevant effects occurred, help reduce type II error, and strengthen the overall power of this study. The demographics of the subjects from the LaPier and Mizner validation study, however, were quite dissimilar to this study, both in race/ethnicity make-up and cardiac procedures. Furthermore, the overall n from the LaPier and Mizner²³ study was only 29, which calls into question the statistical power from that study and the ability to extrapolate those findings to reach any standardized validation of MDC levels to this study.

Conducting this study at a single site with a sample of convenience (i.e., elective, primarily on-pump cases) without a control group certainly challenges the ability to generalize findings to this population. Closer examination of the data revealed that all but six of the participating subjects underwent CABG surgery (n=37) and only one of the six valve procedures was a combination valve/CABG surgery; therefore, the sub-groups were too small to do any comparative studies. This research did not take into account other factors that also may have influenced postoperative functional status such as whether or not subjects participated in cardiac rehabilitation. Ghashghaei et al³⁷ concluded that two months of cardiac rehabilitation following CABG significantly improved functional capacity. Barnason et al²⁶ did not find participation in cardiac rehabilitation to be a significant influence on postoperative functional status and subjects were followed for one year, however, both comparative groups had extremely large standard deviations around the means so interpretation of the latter results should be taken with caution. For our study, every subject was recommended for phase II cardiac rehab upon discharge as part of the doctors' orders, but actual tracking of participation was not the primary purpose of our study. Ultimately, cardiac rehab participation should be treated as a covariant in future studies, due to its potential to influence results.

References

1. Charlson M, Krieger KH, Peterson JC, Hayes J, Isom OW. Predictors and outcomes of cardiac complications following elective coronary bypass grafting. *Proc. Assoc. Am. Physicians.* 1999;*III*(6):622-632.

2. Alexander KP, Anstrom KJ, Muhlbaier LH, et al. Outcomes of cardiac surgery in patients age ≥ 80 years: Results from the National Cardiovascular Network. *J Am Coll Cardiol.* 2000;35:731-738.

3. Akins CW, Miller C, Turina MI, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. *Ann Thorac Surg.* 2008;85:1490-1495.

4. Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity of The American Association for Thoracic Surgery and The Society of Thoracic Surgeons. *Ann Thorac Surg.* 1996;62:932-935.

5. Ferguson TB, Hammill BG, Peterson ED, DeLong ER, Grover FL. A decade of change-risk profiles and outcomes for isolated coronary bypass grafting procedures, 1990-1999: A report from the STS National Database Committee and the Duke Clinical Research Institute. *Ann Thorac Surg.* 2002;73:480-490.

6. Daley J, Henderson WG, Khuri SF. Risk-adjusted surgical outcomes. *Annu Rev Med.* 2001;52:275-287.

7. Granton J, Cheng D. Risk stratification models for cardiac surgery. *Semin. Cardiothorac. Vasc. Anesth.* 2008;12:167-174.

8. Geissler HJ, Hölzl P, Marohl S, Kuhn-Régnier F, Mehlhorn U, Südkamp M, de Vivie ER. Risk stratification in heart surgery: comparison of six score systems. *Eur J Cardiothorac Surg*. 2000;17:400-406.
9. Bennett JA, Riegel B, Bittner V, Nichols J. Validity and reliability of the NYHA classes for measuring research outcomes in patients with cardiac disease. *Heart Lung*. 2002;31:262-270.
10. Narain P, Rubenstein LZ, Wieland GD, Rosbrook B, Strome LS, Pietruszka F, Morley JE. Predictors of immediate and 6-month outcomes in hospitalized elderly patients. The importance of functional status. *J Am Geriatr Soc*. 1988;36:775-783.
11. Inouye SK, Peduzzi PN, Robison JT, Hughes JS, Horwitz RI, Concato J. Importance of functional measures in predicting mortality among older hospitalized patients. *JAMA*. 1998;279:1187-1193.
12. Afilalo J, Eisenberg MJ, Morin JF, et al. Gait speed as an incremental predictor of mortality and major morbidity in elderly patients undergoing cardiac surgery *J Am Coll Cardiol* 2010;56:1668-1676.
13. Society of Thoracic Surgeons National Database (2010).
14. Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. *Circulation*. 1989;79(6)Supplement I:3-12.

15. Severo M, Gaio R, Lourenço P, Alvelos M, Bettencourt P, Azevedo A. Indirect calibration between clinical observers -application to the New York Heart Association functional classification system. *BMC Research Notes*. 2011;4(276):1-9.
16. Raphael C, Briscoe C, Davies J. Limitations of the New York Heart Association functional classification system and self-reported walking distances in chronic heart failure. *Heart*. 2007;93:476–482.
17. Ballan A, Lee G. A comparative study of patient perceived quality of life pre and post coronary artery bypass graft surgery. *Aust J Adv Nurs*. 2007; 24: 24-28.
18. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I development and evaluation of the disability component. *J Gerontol*. 2002;57A: M209–M216.
19. Haley SM, Jette AM, Coster WJ, et al. Late Life Function and Disability Instrument: II. development and evaluation of the function component. *J Gerontol*. 2002;57A:M209–M216.
20. Jette AM, Haley SM, Kooyoomjian JT. *Late Life Function and Disability Instrument*. Boston, MA: Trustees of Boston University; 2002.
21. Sayers SP, Jette AM, Haley SM, Heeren TC, Guralnik JM, Fielding RA. Validation of the Late-Life Function and Disability Instrument. *J Am Geriatr Soc*. 2004;52: 1554-1559.
22. Dubuc N, Haley SM, Ni P, Kooyoomjian JT, Jette AM. Function and disability in late life: Comparison of the Late-Life Function and Disability Instrument to the Short-Form-36 and the London Handicap Scale. *Disabil Rehabil*. 2004;26:362-370.

23. LaPier TK, Mizner R. Outcome measures in cardiopulmonary physical therapy: Focus on the Late-Life Function and Disability Instrument (LLFDI). *Cardiopulm Phys Ther J*. 2009;20:32-35.
24. LaPier TK, Waitt M. Using the Late Life Function and Disability Instrument as a self- report outcome measure in patients with cardiovascular disease. *J Cardiopulm Rehabil Prevent*. 2007;27(5):331.
25. Sorensen EA, Wang F. Social support, depression, functional status and gender differences in older adults undergoing first-time coronary artery bypass graft surgery. *Heart Lung*. 2009;38:306-317.
26. Barnason S, Zimmerman L, Anderson A, Mohr-Burt S, Nieveen J. Functional status outcomes of patients with a coronary artery bypass graft over time. *Heart Lung*. 2000;29:33-46.
27. LaPier TK, Howell D. Functional status deficits in patients recovering from coronary artery bypass: An application of evidence-based practice. *Cardiopulm Phys Ther J*. 2002;13:12-19.
28. Douki ZE, Vaezzadeh N, Zakizad M, Shahmohammadi S, Sadeghi R, Mohammadpour RA. Changes in functional status and functional capacity following coronary artery bypass surgery. *Pakistan J Biol Sci*. 2010;13:330-334.
29. LaPier TK. Functional status of patients during subacute recovery from coronary artery bypass surgery. *Heart Lung*. 2007;36:114-24.

30. Mayer C, Ergina P, Morin JF, Gold S. Self-reported functional status as a predictor of coronary artery bypass graft surgery outcome in elderly patients. *Can J Cardiol.* 2003;19:140-144.
31. Artinian NT, Duggan C, Miller P. Age differences in patient recovery patterns following coronary artery bypass surgery. *Am J Crit Care.* 1993;2(6):453-61.
32. Rumsfeld JS, MaWhinney S, McCarthy Jr M, et al. Health-related quality of life as a predictor of mortality following coronary artery bypass graft surgery. *JAMA.* 1999;281:1298-1303.
33. Hunt JO, Hendrata MV, Myles PS. Quality of life 12 months after coronary artery bypass graft surgery. *Heart Lung.* 2000;269:401-411.
34. American Thoracic Society Statement: Guidelines for the 6 minute Walk Test. *Am J Respir Crit Care Med.* 2002;166:111-117.
35. Dubuc N, Haley SM, Ni P, Kooyoomjian JT, Jette AM. Function and disability in late life: comparison of the Late-Life Function and Disability Instrument to the Short Form-36 and the London Handicap Scale. *Disability Rehabil.* 2004;26(6):362-370.
36. Cummings SM, Savitz LA, Konrad TR. Reported response rates to mailed physician questionnaires. *Health Serv Res.* 2001;35(6):1347-1355.

37. Ghashghaei FE, Sadeghi M, Marandi SM, Ghashghaei SE. Exercise-based cardiac rehabilitation improves hemodynamic responses after coronary artery bypass graft surgery. *ARYA Atherosclerosis J.* 2012;7:151-156.

CHAPTER III.

A MIXED-METHODS APPROACH TO UNDERSTANDING THE ASSOCIATION BETWEEN CHANGES IN FUNCTIONAL STATUS AND QUALITY OF LIFE AFTER ELECTIVE OPEN HEART SURGERY

Introduction

Mortality and morbidity risk after surgery are measures cardiac surgeons universally calculate^{1,2} to estimate patient outcomes, however, these scores do not capture the influence of functional status on patient recovery. Functional status is an individual's ability to do activities within his/her regular environment, an ability that may be limited by physical disabilities due to cardiac disease or perception of symptoms, and may extend to a variety of environmental, social and psychological factors.³ With the cardiac population in general, functional status has primarily been measured as an outcome using self-reported "general health" questionnaires to calculate postoperative changes following cardiac surgery.⁴⁻⁷ Ballan & Lee (2007) supported the use of questionnaires as a possible tool for determining patients' quality of life and well-being, especially pre- and post-CABG surgery.⁸ There is no consensus, however, on the outcome measure to use, ranging from Medical Outcomes Study Short Form 36^{4,5,7} or Short Form 12,⁶ RAND 36-Item Health Survey,⁶ Modified 7-Day Activity tool,⁵ New York Heart Association classifications,⁷ Duke Activity Status Index,⁶ 6-Minute Walk Test,⁶ and Functional Status Index.⁹ Furthermore, many of the self-reported questionnaires such as the Medical Outcomes Study SF-36 (MOS SF-36), often used in functional status longitudinal

studies,^{4,5,7,10} lack specificity,⁵ meaning the very same tool has been used to measure quality of life,^{11,12} depression,⁴ postoperative pain,^{10,12} as well as functional status.^{5,7} Thus, there is no standardized outcome tool used to specifically measure functional status with respect to research on the cardiac surgery population.

The Late-Life Function and Disability Instrument (LLFDI) is a self-reported questionnaire which specifically targets a wide variety of physical activities and social life tasks, defining one's functional status. The LLFDI has established valid and reliable function and disability components that, when combined, yield outcome measures for functional status.¹³⁻¹⁸ Concurrent validity of the LLFDI has been supported by the SF-36, frequently used to measure quality of life in persons with cardiovascular disease,¹⁸⁻²⁰ and like the SF-36, the LLFDI examines aspects of socialization and interpersonal relationships within one's own physical environment, which are essential quality of life components. It is unclear, however, if the LLFDI, which measures functional status, accurately measures quality of life as well. To date, the LLFDI has assessed patients with cardiovascular disease^{18,19} in a single time measurement, but has not tracked open heart surgery patients' functional status in a longitudinal study.

Taking a departure from a strictly quantitative approach, the lived experiences of those who had undergone open heart surgery was explored using a psychological phenomenological approach developed by Amedeo Giorgi. Specifically, we wanted to ascertain how individuals who had undergone heart surgery recovered and perceived functional status and quality of life, and how they possibly changed as they recovered. Giorgi (2009) stated that, whether using a questionnaire [like the LLFDI] or interviewing subjects directly, "data acquired through self-report methods are always subject to

memory decay, alterations or participant response errors;” however the interview is not meant or intended for participants to recall every minute or obscure detail.²¹ More importantly, interviews from a phenomenological perspective are attempts to convey as fully as possible, “what it was like” for them to go through that experience. There is something to be said for the memories kept and why “those” particular ones were chosen, and through the phenomenological process, one may retrieve important meanings from those experiences.²²

Another area of literature where there has been limited research conducted and there also lacks consensus on the findings, is in functional status recovery timeframe in patients post-open heart surgery. LaPier & Howell (2002)⁶ studied cardiac patients within three months post-surgery and used the Duke Activity Status Index and RAND 36 Item Health Survey to discover improvements in functional status as early as 2 months following CABG surgery, but did not capture preoperative or early (first 6 weeks postoperative) data to determine if improvement occurred sooner. Ballan & Lee (2007)⁸ recommended exploring the early postoperative period, citing that there was a gap in prospective research from a preoperative period to the early stage of six weeks postoperative in CABG surgery. The study by Artinian, Duggan & Miller (1993),²³ one of few to examine function and age differences on recovery the first 6 weeks after CABG, noted functional gains across all age groups, although there was no baseline (preoperative) data for comparison and function was based on symptoms rather than use of tools validated to measure functional status. In terms of reaching full recovery, Barnason, Zimmerman, Anderson, Mohr-Burt, & Nieveen (2000)⁵ found that postoperative functional status responses (using MOS SF-36) in patients post-CABG,

surpassed those of their baseline readings six to twelve months postoperatively. LaPier (2002)¹⁸ used several different assessment tools to measure functional status and instead found patients continued to report moderate deficits with performance of daily activities and function three and a half to six months post-CABG. Hunt, Hendrata, & Myles (2000)¹² found mixed results with the MOS SF-36 and a combined quality of life questionnaire: despite significantly improved physical function 12 months after CABG, patients did not perceive a significant improvement in their general health. This finding raises the question, do physical function and health-related quality of life mean the same thing to the individual?

Though these studies may shed some light on patient recovery and symptoms over time, the tools used were not validated to measure functional status, but rather health-related quality of life. The results are unclear whether measuring physical function (functional status) and measuring health-related quality of life is the same thing when dealing with patient perspective on their recovery status-post open heart surgery. Without using a validated tool designed to measure functional status, significant functional gains cannot be certain to occur in that preoperative to early postoperative (~ 6 weeks) phase or are back to baseline by 12 months postoperative. With the previous studies' limitations, particularly related to non-specific tools used and ill-defined usage, the aim of this mixed-method study was to determine if changes in functional status, as measured by the LLFDI, are associated with changes in subjects' perceived quality of life?

Methods

This was a mixed-methods study comparing quantitative changes in functional status, as measured by the LLFDI (at preoperative, six weeks and one year postoperative), to qualitative data obtained from a phone interview with these same subjects on their perception of their functional status progress and quality of life at one year postoperative. With these two key pieces of information, the relationship of functional status and quality of life was explored further, to examine how accurately the LLFDI measured both functional status and quality of life in post-open heart subjects.

Study Population

For the quantitative data, this study was a prospective, non-experimental, longitudinal design with repeated measures of the LLFDI using a sample of convenience. Subjects (n= 43) were recruited from Saint Vincent Health Center from June to December, 2010, after a cardiac surgeon informed them non-emergency cardiac surgery was recommended. Inclusion criteria were subjects who were at least 18 years old, able to communicate fluently in English, and underwent elective cardiac surgery which was one of the following: coronary artery bypass graft (CABG) as an initial or redo procedure, valve repair/replacement, or any CABG/valve combination procedure. If elective cardiac surgery became emergency surgery or a subject failed to submit or sufficiently complete their preoperative LLFDI, then they were excluded/ terminated from the study. This study was a collaborative venture between Saint Vincent Health Center and Gannon University Doctor of Physical Therapy Program. Human subject approval was obtained from the institutional review boards of each participating

institution in this study as well as that of Western Michigan University as partial requirements for completion of my doctoral dissertation work. For this study, two time periods of interest were measured, based on gaps in the literature and plausible times when functional status restoration may occur, which were 6 weeks and one year postoperative, as well as preoperative data for comparison.

Seventy-seven individuals met eligibility criteria and were invited to participate in this study. The purpose and procedure of the study was explained and informed consents were obtained in person by the primary investigator. All 77 subjects consented, however, 22 of the subjects failed to return their preoperative LLFDIs and an additional 12 of them were excluded from the study due to insufficiently completed preoperative LLFDIs. The total number of subjects in this study was therefore, $n = 43$. From the subjects with completed preoperative LLFDIs ($n = 43$), the total LLFDIs returned/completed at six weeks postoperative were $n = 34$ (6 returns incomplete, 3 not returned). At one year postoperative, total LLFDIs returned/completed were $n = 38$ (1 return incomplete, 4 not returned). There were a total of 29 complete LLFDI responses at all three time points.

Measurement: Late-Life Function and Disability Instrument (LLFDI)

The LLFDI is a self-reported questionnaire made up of a 32-question Function component and a two-part Disability component with 16 questions each on frequency and limitation.^{6,11,23} The higher the Function score, the more functionally able/active one is in performing routine physical activities. The higher the Disability scores, the less disabled one is in social life tasks. This tool has standardized instructions for subjects to answer all 48 questions using a 0 to 5 Likert scale. Each question carries a different weight,^{6,11,23}

therefore; raw scores must be transformed to 0-100 scaled scores using the LLFDI computer program.

Statistical Analysis (Quantitative Data)

The preoperative LLFDI data served as a baseline to compare to 6 week and 1 year postoperative scores. Repeated measures analyses (repeated measures ANOVA or Friedman's ANOVA) were conducted to determine functional status changes from preoperative to 6 weeks postoperative to one year postoperative, as based on LLFDI (using Disability Limitation, Disability Frequency, and Function Total) scores. Any significant main effects found in mean LLFDI changes were further analyzed for specific interactions using post-hoc tests with Bonferroni adjustment. All quantitative data were analyzed using the statistical package SPSS 18.0.0 (SPSS Inc., Chicago, IL). Data were considered significant at $p < 0.05$.

Qualitative Design

The qualitative component of this mixed-method study was based on a phenomenological psychological approach using constant comparative method. Constant comparative method is a qualitative approach to analyzing iterations of data coding in order to develop an integrated theory on a phenomenon.²⁴ This theoretical form, in the end, can be merely discussion on several categories or yield an overarching hypothesis on a theme, as in a propositional theory.²⁴

Study Population (Qualitative Design)

The subjects in this study are the same from the quantitative component of this study (and the very same from paper #1), recruited prospectively from a sample of convenience. Subjects included in this study must have: 1) returned their completed preoperative LLFDIs, and 2) undergone non-emergency initial or redo open heart surgery with sternotomy that involved either coronary artery bypass grafting (CABG), valve repair or replacement, or a CABG/valve combination procedure. Subjects were excluded/eliminated from the study if: 1) non-emergency cardiac surgery became emergency surgery, 2) subjects failed to submit or sufficiently complete their preoperative LLFDI, or 3) subjects expired prior to their one year postoperative anniversary. The study was approved by the human subjects review committees at Western Michigan University and Saint Vincent Health Center.

Measurement: Phone Interview

Subjects were contacted by phone approximately one year after their open heart surgery to participate in a one-time phone interview. The phone interview consisted of 10 structured, yet open-ended questions (Table 2.5) about subjects' perceived postoperative recovery, past and present functional status, and change in quality of life as a direct result of the cardiac surgery. These structured questions were developed based on gaps in the literature and on the operational definition of functional status for this study, in so far as the researcher was able to obtain aspects of physical activities and limitations, limitations related to cardiac disease or complications since surgery, perception of symptoms, psychological perception of quality of life, and social support. The primary researcher

asked every subject the same questions, in the exact same order. The questions were pre-typed in columns in an Excel spreadsheet and the researcher used a hands-free headset to communicate with the subject while recording all answers in Excel. The researcher verbally restated what was recorded as the subject's response, after each question was answered. Any corrections needed were retyped immediately and read back to the subject for verification of accuracy. The total time for each interview to be conducted ranged from 14 to 35 minutes, and averaged 22 minutes per subject.

Statistical Analysis (Qualitative Design)

In the phenomenological tradition, qualitative data was collected by obtaining in first-person, the lived-experience of open heart surgery by former patients, with an attempt to capture central psychological themes from the experience as a whole. Qualitative data was analyzed using a constant comparative analysis method to identify patterns and themes through a process of coding data.²⁴ Data on subjects' incidents were compared and similar ones were grouped into categories (open coding).²⁵ Strategies were then used to make connections between categories (axial coding). Finally, the core category (central phenomenon) was selected and used to relate to all the other categories (selective coding).²⁵

Statistical Analysis (Mixed-methods)

Additionally, the relationship between LLFDI and quality of life was analyzed for overlapping themes using a mixed-methods approach. Change in functional status scores, preoperative to six weeks postoperative to one year postoperative were compared to the

phone interview responses for any trends between the two sets of data. In particular, we looked for subsets in which all aspects of their functional status improved from a quantitative standpoint, and examined what was unique about them from a qualitative perspective. Likewise, we also examined if there was a subgroup that did not improve in all three areas of functional status, and explored their qualitative data to ascertain if there was an overarching theme in regards to their perceived quality of life. Ultimately we wanted to determine if the quantitative functional status data could be explained by the qualitative responses in the subjects' perceived quality of life one year status-post heart surgery.

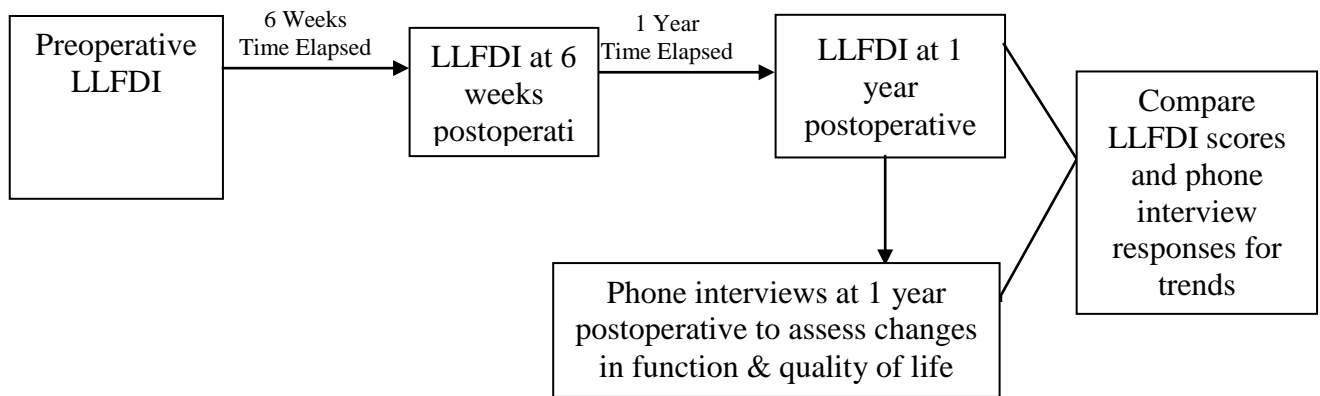


Figure 3.1. Overview of study design.

Results

Baseline Demographics and Distribution

The study data were very similar to the data used to validate the LLFDI tool originally.^{4,19} Both samples, as seen in Table 3.1, were similar in gender make-up (28%

female/ 72% male in preoperative phase of study; 23% female/ 77% male in LLFDI validation sample) and in percentage of subjects in their 60s and 70s (65% in the preoperative study; 68% in LLFDI validation). The mean age in the study was 66.3 ± 9.74 and patients undergoing coronary bypass in 2010 was 64.9. Eighty-six percent of the subjects (n=37) underwent an elective CABG procedure, 9% (n=4) underwent elective valve repair or replacement surgery, and 5% (n=2) underwent a CABG/valve combination procedure. All cardiac procedures were performed on cardiopulmonary bypass pump.

Table 3.1

Study Demographics versus LLFDI Validation Demographics

Study Demographics			LLFDI Demographics		
Preoperative	N	% of Total	L LFDI Development	N	% of Total
Gender			Gender		
Female	12	28%	Female	34	23%
Male	31	72%	Male	116	77%
Race/ Ethnicity			Race/ Ethnicity		
Caucasian	41	95%	Caucasian	126	84%
Hispanic	1	2%	Hispanic	8	5%
African Amer.	1	2%	African Amer.	11	7%
Age			Age		
40-49	1	2.3%	40-49	X	0%
50-59	9	20.9%	50-59	X	0%
60-69	17	39.5%	60-69	41	27.3%
70-79	11	25.6%	70-79	61	40.7%
80-89	5	11.7%	80-89	40	26.7%
90+	8	5.3%	90+	8	5.3%
Median	66		Mean age for CABG	64.9	
SD	9.739		(STS, 2010)		
Mean	66.35				
Mode	54, 61, 62, 66				

Descriptive statistics conducted on each LLFDI variable at each time period revealed skew & kurtosis values which supported the assumptions of normality in 7 out of 9 variables. To be certain, because 2 variables (Disability Frequency at one year postoperative and Function Total at one year postoperative) were heavily skewed and kurtotic, and sample size was small, equivalent non-parametric test was also run, which still revealed roughly the same significances as the parametric test. Therefore, although some assumptions of normality were violated, normality was assumed as ANOVA is robust and a more powerful design than the non-parametric equivalent tests to conduct the data analyses for the quantitative aspect of the methodology.

Group Means

At preoperative, group means for the three LLFDI components of functional status were: M=62.34 (SD= 8.90) for Function Total, M=51.80 (SD=6.20) for Disability Frequency, and M=75.65 (SD= 14.93) for Disability Limitation, which is consistent with the “moderate to slight limitation” classification^{13,14} (Table 3.2). Mean difference preoperative to six weeks postoperative and six weeks to one year was not significant for any of the LLFDI components. Group means at one year postoperative (based on significant mean difference preoperative to one year postoperative) were: M=65.82 (SD=10.99) for Function Total and M=57.79 (SD=12.48) for Disability Frequency, which is consistent with the “slight limitation” classification^{13,14} (Table 3.2).

Table 3.2

Four Levels of Functional Limitation
(Based on converted mean LLFDI scaled 0-100 scores)^{18,19}

Classification	Total Function	Disability Frequency	Disability Limitation
Severe Limitation	41.7	44.3	55.4
Moderate Limitation	53.2	49.5	63.5
Slight Limitation	65.6	53.6	73.8
No Limitation	75.6	58.1	82.5

Repeated Measures ANOVA

Repeated measures ANOVA was conducted on the three time measures and each of the three LLFDI components for functional status (n=29) (Table 3.3). Repeated measures ANOVA sphericity assumption was met and Function Total was significantly affected by time, $F(2, 56) = 3.232$, $p = .047$, which meant that patients' ability to perform routine activities significantly changed over time (Table 3.4). Preoperative Total Function scores ($M = 62.34$, $SD = 8.90$) were not significantly different from 6 week postoperative scores ($M = 62.97$, $SD = 8.70$) but were significantly lower than one year postoperative scores ($M = 65.82$, $SD = 10.99$), as revealed by post hoc tests using Bonferroni adjustment (M difference = +3.48, $SE = 1.48$, $p = .026$).

The sphericity assumption was violated for Disability Frequency, but using Greenhouse-Geisser correction, repeated measures ANOVA revealed significant differences over time for Disability Frequency, $F(1.53, 42.70) = 5.49$, $p = .013$, $\epsilon = .763$, indicating subject participation in social life tasks significantly changed over time (Table 3.4). Specifically, preoperative Disability Frequency scores ($M = 51.80$, $SD = 6.20$) were significantly lower than one year postoperative scores ($M = 57.79$, $SD = 12.48$), which

indicated that social task participation significantly increased from preoperative to one year postoperative (M difference = +5.98, SE=2.19, p=.033 (Table 3.3) as revealed by post hoc pairwise comparison tests using Bonferroni adjustment.

Table 3.3

Functional Status (LLFDI)—Group Mean Changes Over Time

Variable	Time	Mean	Std. Deviation	LLFDI Limitation Classification ^{18,19}	Sig.
Function total	Preoperative	62.3424	8.90171	Moderate to Slight	
N=29	6 Weeks Postoperative	62.9655	8.70044	Moderate to Slight	
	1 Year Postoperative	65.8210	10.98957	Slight	
(PreOp to 1 Year PostOp)	M Difference	+ 3.4786	1.48 (SE)		.026*
Disability Frequency	Preoperative	51.8141	6.20402	Moderate to Slight	
N=29	6 Weeks Postoperative	52.9041	8.17441	Moderate to Slight	
	1 Year Postoperative	57.7921	12.48259	Slight	
(PreOp to 1 Year PostOp)	M Difference	+ 5.978	2.19 (SE)		.033*
Disability Limitation	Preoperative	75.6497	14.93365	Slight	
N=29	6 Weeks Postoperative	75.6317	15.57000	Slight	
	1 Year Postoperative	81.6524	15.44953	Slight	
(PreOp to 1 Year PostOp)	M Difference	+ 6.0207	2.55 (SE)		.075

* p < .05 denotes statistical significance

The higher the mean score = the more functional, less disabled the individual

Disability Limitation was not significantly affected by time ($p=.098$), which meant that capabilities in performing social life tasks did not significantly change preoperatively to postoperatively (Table 3.4).

Table 3.4

Main Effect of Time on Functional Status (each LLFDI Component)

Variable	Sphericity Test	Df	F	Sig
Functional total	Sphericity Assumed	(2, 56)	3.232	.047*
Disability Frequency	Greenhouse Geisser	(1.53, 42.70)	5.494	.013*
Disability Limitation	Sphericity Assumed	(2,56)	2.423	.098

1. Did you go back to your own home when you got discharged from the hospital after your heart surgery? If so, who did you go home to and what kind of help did you have there?
2. Before surgery, what other medical issues limited your mobility and how did they affect your quality of life?
3. Did you have any lingering complaints after surgery and do you have any still?
4. How does your physical endurance seem now, compared to how it was before you had open heart surgery (much better, a little better, same, little worse, much worse?) choose one and then elaborate why?
5. How would you describe your current activity level?
6. What kind of physical activities do you do, besides necessary things around the house? [The frequency and duration of each activity was asked and documented as well.]
7. Any physical tasks you cannot do since the open heart surgery (and you could do before the surgery)? What are they?
8. One year later, now looking back: Was it worth it to you to undergo open heart surgery? Why or why not?
9. Currently are there other medical issues not related to your heart [You don't have to state what they are], which are also impacting your mobility and your quality of life?
10. One year later, how has your quality of life changed since you underwent open heart surgery?

Figure 3.2. Structured phone interview questions at one year postoperatively.

Perceived Quality of Life...One Year Later

Twenty-three subjects responded to phone calls made approximately one year status-post their open heart surgery and the first analysis on subjects' incidents were compared and similarities were grouped into categories (Table 3.5). Ninety-one percent (21/23) returned to their own home, and 15/23 specifically to their spouse's care. Seventy percent of the subjects had premorbid issues, which limited mobility and quality of life to some extent. Of those subjects, 44% had low back pain and 38% had joint arthritis. Of the 70% that had lingering complaints postoperatively, the majority (n=9) was related to chest incision pain, numbness, or hypersensitivity and next most common at thirteen percent (n=2), was lingering atrial fibrillation/flutter. All but three of the subjects (87%), reported their physical endurance was at least the same, if not better than before surgery and 91% (21/23) stated an improved current activity level which ranged between "moderate/good" and "fantastic." Examining current activities, subjects fell into at least one of four categories: walking regularly (n=9), routinely participating in recreational activities (n=10), taking part in a structured exercise program (n=7); or returning to work at least part time (n=5). Thirty percent (n=7) stated they were now limited in some way that they were not previously, as a result of the surgery. Most commonly, these subjects either had decreased left arm strength or reduced walking distance (both n=3). When asked in the interview if surgery was worth going through, interestingly, five subjects (22%) were "on the fence" and one subject adamantly said no, despite the common response given of, "I wouldn't still be here if I hadn't had it done." There were also five subjects who had current medical issues impacting their quality of life, but none were cardiac or orthopedic related. When asked how quality of life had

changed since surgery, nine subjects (39%) reported no difference/stayed same, but 14 reported changes physically (noted in task), psychologically (emotional insight given), and/or symptomatically (lessened cardiopulmonary symptoms).

Table 3.5
Quality of Life - Open Coding Responses

Questions	Coded Categories (n=23)	
1. Return Home with Whom	Home with someone (21); Home w/spouse -15; Home w/children, friends/neighbors checking - 5	Not home right away (2)
2. PreOp Med Issues	Yes (16): Low back pain - 7 CVA - 2 SOB - 2 Arthritis - 6 Dialysis -1	None (7)
3. Lingering Complaints	Yes (16): Chest incision (sore, numb, hypersensitive) - 9 A fib/flutter - 2	None (7)
4. Physical Endurance	Same or better (20): Same - 4; little better - 6; lot better -10	Lost some (3)
5. Current Activity Level	Moderate to very good (21)	Low/decreased (2)
6. Kinds of Activities	Walking - 9 Functional or Recreational activities -10	Structured Ex program - 7 Returned to work - 5
7. Tasks Cannot Do Now	Yes (6): Can't lift as much (LUE weakness) - 3 Can't walk as far - 3 Balance -1 Decreased LUE ROM -1	Nothing (17)
8. Was it Worth it	Yes (17/23): "Would be dead otherwise" - 10 "Definitely worth it" - 7	No (1/23); On the fence - 5
9. Current Med Issues	Yes (5/23): Colon CA -1 Dysphagia -1 Prostate issues -1 Hernia -1 Weight loss-1	None (18/23)
10. How has QOL changed	Changed for the better (14): Physically/task-related - 9 Psychologically/Emotionally - 5 Cardiopulmonary symptoms - 3	Same/not changed (9); "Only did it for my wife"- 2 "Surgery didn't help"- 1 "Can't say it was"- 1

Axial Coding

Making connections between categories within the overall sample, revealed that the majority of subjects in this population (n=16; 70%) had notable preoperative medical issues which affected quality of life and lingering postoperative complaints primarily from the chest incision or arrhythmia. Eighty-seven percent (20/23) returned home for recovery with some kind of support and despite varied degrees of activity and endurance now, the consensus (74%) reported that surgery was worth going through. How surgery changed their quality of life remained mixed with 61% responding positively to 39% giving neutral or negative feedback. Subjects seemed to interpret change in quality of life, positively or negatively, from a physical (task-related), psychological (emotion driven), or symptom perspective, regardless of activity or endurance level reported.

There was a unique subgroup (n = 4; 17%) who felt quality of life was not better and either doubted or denied surgery was worth going through. In fact, two individuals gave the same response, verbatim, that they only did it for their spouse and if not for them, they would not have gone through with the surgery. Tracing these four individuals' responses across other categories, interestingly all four subjects denied any current or preoperative medical issues, with the exception of long-term dialysis dependence for one, yet nothing that had limited their quality of life. This subgroup routinely participated in functional tasks (farming, yard work, baking); one also participated in a structured exercise routine involving machines; and one returned to work part-time. All four subjects rated their current activity level between "okay" and "very good," but in contrast, only 2/4 felt their physical endurance was good or very good, while the other two reported that their endurance had decreased and got "tired quicker," despite their

activity reported above. Finally, all four subjects returned home for recovery with some kind of support (three had spousal support; one had their children's support); however, on follow-up questioning, none of them had any additional support network in place, which was in sharp contrast to the other 19 subjects.

There was one other subgroup (n=6; 26%) who clearly had postoperative complications that lingered (5/6) and tasks they could not do currently that they could do before surgery (all 6) that warranted further exploration. Since two of the subjects were part of the first subset, they were removed from this data analysis to avoid overlapping results. This subset of four reported continued problems with left chest area numbness/pain and one still had limited use of the left arm. Additionally, three of the subjects had current medical issues which were being investigated by doctors and which negatively impacted their quality of life. Despite these issues, current physical endurance ranged from "good" to "tremendously improved" for all four subjects and activity level ranged from "good" to "pretty good," with the exception of one admitting that they were not yet back to where they were before surgery. Additionally, when asked what kind of activities this subset did currently, all four individuals participated in routine functional or recreational activities and three (75% of subset; 43% of sample) participated in a structured exercise routine involving machines. Whether surgery was worth it, seventy-five percent of this subgroup (n=3) reported with almost identical responses, that they would not still be here if they had not had the surgery, and the fourth was extremely thankful for the procedure. How surgery changed their quality of life varied somewhat with one subject having responded "no real influence on it," but the other three responded

favorably with resolved cardiopulmonary symptoms, physical (task-related) changes noted, or psychological (emotional) insight gained.

Mixed Comparison Analysis

In comparing LLFDI trends to phone interview responses, all but four (83%) of the entire study population (19/23) demonstrated improvement in at least one of the following categories of functional status: disability frequency, disability limitation, or function total. Of the four subjects that showed no improvement in any area of functional status according to the LLFDI, three of the four subjects were of the subset who felt quality of life was not better and either doubted or denied surgery was worth going through.

There was another subset (n=10) from the LLFDI data, who improved in all three areas of functional status, from preoperative to one year postoperative and who also demonstrated unique characteristics from their phone interviews. This subgroup was much like the subset n= 6, having both preoperative medical issues (60%) and lingering postoperative complications (60%) as well as tasks they could not do now that they could before surgery (20%). However, when asked their current activity level, 8 out of 10 reported anywhere from “good” to “fantastic” and 9 out of 10 rated current physical endurance as “better” to “much better” with the only outlier reflecting that they didn’t realize how bad it [endurance] was until after surgery. This subset was unanimous in reporting surgery was worth having and 5 out of 10 conveyed that they would not still be here if they had not gone through with it. The question asking how surgery changed their quality of life, produced positive responses in all three areas (physically, psychologically,

symptomatically). Upon closer examination using the constant comparative method, another nuance discovered was the frequent reference to family, their support and love, and a renewed ability to enjoy them in some fashion. This reference was followed up again with the initial question of who they returned home with initially. Eight out of ten returned home to some kind of support, and of the two outliers, one went to transitional care short term and another to rehab for 2 weeks before both went home alone, however, all 10 individuals in this subset had an extensive support network in place.

Discussion

Recovery from cardiac surgery appears to be a lengthy process as demonstrated by this study. Participation in social life tasks (Disability Frequency) and routine physical activities (Function Total) significantly improved from preoperative to one year postoperative, but not from preoperative to 6 weeks postoperative. These findings are consistent with prior longitudinal studies that explored functional status changes after CABG surgery,^{9,23} but unique to them because this study included preoperative data with which to compare. Cardiac surgery entails a major operation, typically including sternal precautions for 6 weeks, supporting the reasons why patients did not report significant improvement at only six weeks after surgery. The qualitative data further confirmed this truth with the extent of lingering postoperative complaints reported, ranging from two to three months postoperatively to still remaining one year later.

Based on the results of the LLFDI measurements, subjects overall resumed but did not surpass their baseline (preoperative) functional status levels at one year postoperatively. Qualitative data helped provide added support for this timeline with

consistent comments that at seven and even eleven months post-surgery, subjects still reported functional limitations with resuming life as before. At 12 months, however, subjects were now “doing construction 4-5 hours a day and walking about 3 miles, 3-4 times/week” and “walking the dog daily, walking the beach about 3 miles, and back to working full-time as a hairdresser.” This finding was relatively consistent with some of the other research which indicated functional recovery by 12 months post-cardiac surgery.^{5,12} This study further added to the body of knowledge by using a validated tool (LLFDI)¹⁶ specifically designed to measure function and disability over time. With the reality that individuals heal at different rates and some subjects were still not back to baseline one year postoperatively, future research using the LLFDI may want to be explored extending the postoperative time to 18 months.

The results also revealed that subjects’ limitation in social life tasks (Disability Limitation) did not prove to be significant at any of the time periods and was not influenced by gender or age (influence of gender and age discussed in more detail in the first paper). LaPier & Mizner (2009)¹⁸ published a study which calculated the LLFDI minimally detectable changes for the three functional status components and calculated the Disability Limitation component as being 16.7, which was a result of high standard deviation measurements. The Disability Limitation minimally detectable change measurement is in high contrast to the 7.8 minimally detectable change for the Disability Frequency component and 4.3 for the Function Total component (at 95% confidence interval), per the LaPier & Mizner study.¹⁸ Given the wide variance in responses for Disability Limitation, the change needed to exceed the level of measurement error in order to detect meaningful change in Disability Limitation was not likely to be reached

with this small sample size. Furthermore, unlike the frequency to which one participates in social life tasks (Disability Frequency), as found in this sample, which recorded participation in a variety of different personal and social activities, Disability Limitation refers to one's capability in participating. These subjects demonstrated great variety in their physical capabilities at one year postoperatively, as confirmed by the interview responses on activity level and physical endurance, which helps to explain the wide range of scores around the mean, reaffirmed in their quantitative data on Disability Limitation. This variance, however, may have inflated the risk of a type II error and reduced the overall power.

A major strength of this study was in its design, as a mixed-methods approach, which enabled us to fully explore the relationship between functional status and quality of life as well as expose the influencing covariate, social support. What appears to be occurring is a direct relationship between the two variables, in which both functional status and quality of life display improvement in the presence of an extensive support network. Likewise, when functional status was not improved, quality of life was also not perceived to be better and a support network, other than a spouse or grown child, was absent. Social support or lack thereof has been well researched over the years, with Waltz (1986) discovering that there are certain types of people that are more likely to "master adaptive tasks" postoperatively, and those types are ones who are 1) satisfied in life; 2) mutually content in their marriage; or 3) belong to a network.²⁶ Marital status and strength of a marital relationship, although not a concentration of this study, has also been shown to impact physical function and recovery^{26,27} in the CABG population.^{28,29} Waltz determined that social support acts as a "buffer" to stress.²⁶ On the contrary, numerous

studies have found that people who lack a social network or reside alone, are less likely to improve their physical status and are at an increased risk of functional decline.^{27,30-33}

Additionally, Oxman & Hull (1997) discovered certain social support components were more apt to predict depression 6 months after cardiac surgery, and one in particular being those with perceived adequate friend support were less likely to be depressed.³⁴

Incidentally, one of the subjects in this study reportedly lived alone and had “no help but [was] okay,” continued to suffer postoperatively from depression, which was still present at the one year follow-up interview.

Conducting this study at a single site with a sample of convenience (e.g., all on-pump, elective cases) and no control group certainly challenges the ability to generalize findings to this population from a quantitative perspective. The sample size was sufficient, however, for the qualitative component and responses reached saturation for each phone interview question. Furthermore, the nuance of social support influence that was obtained through mixed-methods remains a valid finding. Future studies may want to explore the influence of social support on postoperative functional status changes using the LLFDI and compare different cardiac surgical approaches (e.g., on-pump versus off-pump; minimally invasive versus sternotomy). From a clinical perspective, these findings should be confirmation to the health care profession how essential it is to screen these patients preoperatively regarding information about their social support network, not just for discharge planning purposes, but for potential psychological impact on recovery as well. Since lack of social support may set the stage for certain individuals to develop postoperative depression which can linger, health care providers should be more attune to look for these signs and symptoms. Furthermore, predetermined alternate

discharge arrangements and locations (e.g., home versus skilled nursing facility) may need to be a discussion with the patient who resides alone or has minimal social support.

References

1. Granton J, Cheng D. Risk stratification models for cardiac surgery. *Semin. Cardiothorac Vasc. Anesth.* 2008;12: 167-174.
2. Geissler HJ, Hölzl P, Marohl S, Kuhn-Régnier F, Mehlhorn U, Südkamp M, de Vivie ER. Risk stratification in heart surgery: comparison of six score systems. *Eur J Cardiothorac Surg.* 2000;17: 400-406.
3. Bennett JA, Riegel B, Bittner V, Nichols J. Validity and reliability of the NYHA classes for measuring research outcomes in patients with cardiac disease. *Heart Lung.* 2002;31:262-270.
4. Sorensen EA, Wang F. Social support, depression, functional status and gender differences in older adults undergoing first-time coronary artery bypass graft surgery. *Heart Lung.* 2009;38: 306-317.
5. Barnason S, Zimmerman L, Anderson A, Mohr-Burt S, Nieveen J. Functional status outcomes of patients with a coronary artery bypass graft over time. *Heart Lung.* 2000;29: 33-46.
6. LaPier TK, Howell D. Functional status deficits in patients recovering from coronary artery bypass: An application of evidence-based practice. *Cardiopulm Phys Ther J.* 2002;13: 12-19.

7. Douki ZE, Vaezzadeh N, Zakizad M, Shahmohammadi S, Sadeghi R, Mohammadpour RA. Changes in functional status and functional capacity following coronary artery bypass surgery. *Pakistan J Biol Sci.* 2010;13: 330-334.
8. Ballan A, Lee G. A comparative study of patient perceived quality of life pre and post coronary artery bypass graft surgery. *Aust J Adv Nurs.* 2007;24: 24-28.
9. LaPier TK. Functional status of patients during subacute recovery from coronary artery bypass surgery. *Heart Lung.* 2007;36: 114-24.
10. Mayer C, Ergina P, Morin JF, Gold S. Self-reported functional status as a predictor of coronary artery bypass graft surgery outcome in elderly patients. *Can J Cardiol.* 2003;19:140-144.
11. Rumsfeld JS, MaWhinney S, McCarthy Jr M, Shroyer ALW, VillaNueva CB, O'Brien M et al. Health-related quality of life as a predictor of mortality following coronary artery bypass graft surgery. *JAMA.* 1999;281: 1298-1303.
12. Hunt JO, Hendrata MV, Myles PS. Quality of life 12 months after coronary artery bypass graft surgery. *Heart Lung.* 2000;269: 401-411.
13. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. development and evaluation of the disability component. *J Gerontol.* 2002;57A:M209–M216.

14. Haley SM, Jette AM, Coster WJ, et al. Late Life Function and Disability Instrument: II. development and evaluation of the function component. *J Gerontol.* 2002;57A:M209–M216.
15. Jette AM, Haley SM, Kooyoomjian JT. *Late Life Function and Disability Instrument.* Boston, MA: Trustees of Boston University; 2002.
16. Sayers SP, Jette AM, Haley SM, Heeren TC, Guralnik JM, Fielding RA. Validation of the Late-Life Function and Disability Instrument. *J Am Geriatr Soc.* 2004;52: 1554-1559.
17. Dubuc N, Haley SM, Ni P, Kooyoomjian JT, Jette AM. Function and disability in late life: Comparision of the Late-Life Function and Disability Instrument to the Short-Form-36 and the London Handicap Scale. *Disabil Rehabil.* 2004;26: 362-370.
18. LaPier TK, Mizner R. Outcome measures in cardiopulmonary physical therapy: Focus on the Late-Life Function and Disability Instrument (LLFDI). *Cardiopulm Phys Ther J.* 2009;20: 32-35.
19. Kinney LaPier TL, Waitt M. Using the Late Life Function and Disability Instrument as a self-report outcome measure in patients with cardiovascular disease. *J Cardiopulm Rehabil Prevent.* 2007;27(5):331.
20. Dubuc N, Haley SM, Ni P, Kooyoomjian JT, Jette AM. Function and disability in late life: comparison of the Late-Life Function and Disability Instrument to the Short Form-36 and the London Handicap Scale. *Disability Rehabil.* 2004;26(6): 362-370.

21. Giorgi A. The descriptive phenomenological method in psychology: A modified Husserlian approach. Pittsburg, PA: Duquesne University, 2009.
22. Giorgi A. Sketch of a psychological phenomenological method. In Giorgi A (ed.). Phenomenology and psychological research. Pittsburgh, PA: Duquesne University Press. 8-22, 1985.
23. Artinian NT, Duggan C, Miller P. Age differences in patient recovery patterns following coronary artery bypass surgery. *Am J Crit Care*. 1993;2(6):453-61.
24. Glaser BG, Strauss AL. The Discovery of Grounded Theory: Strategies for Qualitative Research. New York, NY: Aldine de Gruyter, 1967.
25. Strauss A, Corbin J. Basics of Qualitative Research: Grounded Theory Procedures and Techniques. Newbury Park, CA: Sage Publications, 1990.
26. Waltz M. Marital context and post-infarction quality of life: is it social support or something more? *Soc Sci Med*. 1986;22(8):791-805.
27. Mor V, Murphy J, Masterson-Allen S, Willey C, Razmpour A, Jackson ME, Greer D, Katz S. Risk of functional decline among well elders. *J Clin Epidemiol*. 1989;42:895-904.
28. Kulik JA, Mahler HI. Social support and recovery from surgery. *Health Psychol*. 1989;8: 221-238.
29. Kulik JA, Mahler HI. Emotional support as a moderator of adjustment and compliance after coronary artery bypass surgery. *J Behav Med*. 1993;16:45-63.

30. Bowling A, Browne PD. Social networks, health, and emotional well-being among the oldest old in London. *J Gerontol* 1991;46:S20-S22.
31. Liu X, Liang J, Muramatsu N, Sugisawa H. Transitions in functional status and active life expectancy among older people in Japan. *J Gerontol B Psychol Sci Soc Sci*. 1995;50B: S383-S394.
32. Wolinsky FD, Johnson RJ. Widowhood, health status, and the use of health services by older adults: A cross-sectional and prospective approach. *J Gerontol*. 1992;47: S8-S16.
33. Weinberger M, Tierney WM, Booher P, Hiner SL. Social support, stress and functional status in patients with osteoarthritis. *Soc Sci Med*. 1990; 30:503-508.
34. Oxman TE, Hull JG. Social support, depression, and activities of daily living in older heart surgery patients. *J Gerontol B Psychol Sci Soc Sci*. 1997;52B(1):P1-14.

CHAPTER IV

IS PREOPERATIVE FUNCTIONAL STATUS ASSOCIATED WITH POSTOPERATIVE MORTALITY AND MORBIDITY IN ELECTIVE OPEN HEART PATIENTS?

Introduction

Because cardiac surgery has the potential to cause adverse outcomes, a set of risk factors (recent events such as myocardial infarction or unstable angina) as well as medical history (e.g., diabetes, hypertension, prior cardiac surgery) are considered when surgeons estimate likelihood of mortality or morbidity (complications).¹⁻⁵ Physiological factors like body mass index and advanced age have more recently been accepted as additional cardiac surgery variables.⁵⁻⁸ The effects of preoperative functional status have not been adequately evaluated to date.⁸⁻¹² This study aims to examine the relationship between preoperative functional status and postoperative mortality and morbidity in elective open heart patients.

Coronary artery disease is the leading cause of death worldwide.⁵ As patients continue to live longer, the decision becomes less clear on whether the benefits outweigh the risks of undergoing coronary bypass surgery. As part of the cardiac surgery guideline revisions in 2008, patients of advanced age (at least 70 years old) accounted for 50% of cardiac surgeries performed in North America and 78% of the combined major complications (morbidity) and deaths (mortality).⁵ In terms of valve surgery and aortic valve replacement in particular, older adults (≥ 70 years of age) accounted for 30-

40% of the cases turned down for surgical intervention, despite evidence of surgical success in their age group.³ In this same age bracket, more than 25% of these older Americans were functionally limited by cardiovascular disease, according to the United States Census Bureau.⁹

Heart disease, either coronary or valvular in nature, is typically a silent disease which progresses gradually over time. It is not until changes are seen in endurance, physical mobility and/or socialization (one's quality of life), that the impact of the disease becomes evident. Likewise, changes in functional status are gradual over time and affect not only physical, emotional and mental well-being, but may interfere with the recovery process. *Functional status*, as defined for use in this study, is the ability to function physically, perform tasks with both upper and lower extremities, to a degree which provides satisfaction in valued areas of life such as activities of daily living, recreational activities, and interpersonal relationships.

In research, “impaired functional status” has become somewhat synonymous with the term “frailty,” and its association with mortality and morbidity has been studied primarily in the inpatient, non-surgical population. Narain et al studied older adult inpatients with varied diagnoses and concluded that, more than the admitting diagnosis,¹³ decreased functional status was the strongest predictor of 6-month mortality, prolonged length of stay, and readmissions to the hospital. Inouye et al found a strong association between impaired functional status and mortality among older, non-cardiac patients in the hospital setting, which prompted the recommendation for risk adjustment tools to include a functional status variable, especially for older patients.¹⁴ Purser et al determined that there was a strong association between slow gait speed (a dimension of frailty) using a

short walk test (referred to as the 5-m gait speed test), and 6-month mortality in hospitalized patients treated for coronary artery disease, and also recommended adding some frailty component to risk assessments.¹⁵ Cervera et al were one of the few to study the effect of preoperative functional status on mortality in the coronary artery bypass graft (CABG) population, though the definition of impaired functional status was limited to anyone who used assistance or an assistive device to ambulate, or had equipment needs such as dialysis or oxygen.⁹ Interestingly, Cervera et al did not find limited functional status to be a predictor of early morbidity or mortality with CABG patients, however, this was a veteran only population, composed almost exclusively of males.⁹ A large Canadian study by Lee et al examined patients undergoing elective cardiac surgery and concluded those who had higher mortality rates were predominately the ones considered frail (those who had impaired ambulation or limited daily living activities)¹⁰ Lee et al did not compare their “frailty” sub-group to any cardiac risk score for predictive validity, however.

From a clinical perspective, cardiac surgeons have universally accepted risk score assessment systems^{5,16,17} such as the EuroSCORE¹⁷ or Parsonnet score¹⁷ to predict mortality and morbidity risk. The Society of Thoracic Surgeons (STS) risk scoring model is the national standard used in the United States.⁸ Despite their wide use and acceptability, risk score systems produce only modest mortality predictions, statistically speaking, and perform poorly in predicting morbidity, as they were not originally intended or designed to detect morbidity risk.^{8,12,16,17} Cardiac risk models do not take into consideration patients’ functional status as part of the risk stratification calculation^{5,8,17} despite the fact that the most recent American College of Cardiology valve treatment

guideline revision in 2012 acknowledged that frailty (a.k.a. “impaired functional status” in research) may be an important outcome predictor in high-risk populations especially.³

STS made a recommendation in May, 2011, that preoperative functional measures such as gait speed be added to the STS database for adult patients pending cardiac surgery, in order to aid in stratifying risk.^{8,18} This recommendation was based on findings from a multicenter study in the USA and Canada lead by Afilalo et al which concluded that slow gait speed utilizing a 5-m distance demonstrated a 2-3 fold increase in STS-predicted mortality or major morbidity. Going beyond the 5-m walk test, Sundermann et al found some significant associations in their more comprehensive frailty assessment and its predictive validity with respect to early and 1-year mortality as well as morbidity in elective cardiac surgery patients.¹¹⁻¹² The comprehensive assessment of frailty (CAF) tool by Sundermann et al, however, is laborious to conduct for clinicians, and as yet, has not shown to be superior to cardiac risk score assessments.¹¹ There has been limited preoperative functional data collected to date since the STS announcement and no standardized approach taken with this recommendation to evaluate its impact on mortality and morbidity risk.^{8-12,18,19}

The gold standard for measuring physical function and capacity has been the six-minute walk test but it only accounts for the “physical” component.^{20,21} The Late-Life Function and Disability Instrument (LLFDI) is a self-reported questionnaire specifically targeting a wide variety of physical activities (function) and social life tasks (disability status), which defines one’s functional status.²² This outcome tool was designed to assess community-dwelling and ambulating 75 to 90 year old adults, and its use has been validated on patients with cardiovascular disease and post-cardiac surgery.^{21,23-26} The

LLFDI correlated significantly with the six-minute walk test, but also with the 4.5m walk test, Short Physical Performance Battery, Timed Up and Go, and the Short Form 36 (all widely accepted functional measures) in its concurrent validity, reliability, precision, and responsiveness with diverse patient populations.²⁷⁻³⁰ More comprehensive and perhaps more unique than any of the above tests mentioned, the LLFDI also indicates aspects on recreational participation and community socialization which significantly impacts one's quality of life and makes this an appropriate tool to use with the cardiac surgical population.

As of 2010, the risk-adjusted mortality rate for isolated CABG was 2.1%¹ and 2.6% for isolated AVR³ per the 2012 updated guidelines, yet admittedly these models fail to include potentially influential risk factors such as impaired functional status.³ While the LLFDI has been proven valid and reliable as a tool to measure functional status in a comparable population, to date, there have not been any published studies exploring its predictive validity with respect to mortality and morbidity.³⁰

Methods

Study Design

A non-experimental design using a prospective cohort of subjects undergoing elective cardiac surgery from Saint Vincent Health Center between June and December 2010 was assembled. Preoperative baseline data was obtained to calculate mortality and morbidity risk and follow-up postoperative data was abstracted at one year to calculate actual mortality and morbidity events. Regression analysis was conducted to assess the

relationship between the LLFDI preoperative score (independent/predictor variable) to the STS mortality and morbidity risk scores (dependent/outcome variables).

Participants

Subjects included in this study were at least 18 years old, able to communicate fluently in English, and underwent one of the following elective cardiac surgeries: initial or redo coronary artery bypass graft (CABG), valve repair/replacement, or any valve/CABG combination procedure. If elective cardiac surgery became emergency surgery or a subject failed to submit or sufficiently complete their preoperative LLFDI form, they were excluded/ terminated from the study. Consecutive subjects were screened after they were scheduled to undergo cardiac surgery which involved CABG, valve repair/replacement, or valve and CABG combination surgery. Eligible subjects were asked to complete a LLFDI questionnaire preoperatively and this served as the predictor variable for this study. This study was approved by the human subjects review committees at Saint Vincent Health Center and Western Michigan University.

Measures

Late-Life Function and Disability Instrument (LLFDI)

In this study, functional status was measured using only the Functional component of the LLFDI tool. The Disability component focuses more on recreational tasks and community socialization than the daily movements and limitations asked in the Function component.²²⁻²⁴ Since both the Function and Disability components each have strong validity and reliability, they can be used as stand-alone tests.^{21-24,29} The Function component is made up of (32) questions using a 0 to 5 Likert scale that start with asking,

“How much difficulty do you have?” on routine physical actions and daily activities such as making a bed or walking up a flight of stairs.^{22,24} The higher the Function score, the more functionally able/active one is. Each question carries a different weight,^{21-24,29} therefore, the raw scores were converted to 0-100 scaled scores using an accompanying LLFDI computer program.

STS Risk Calculator

The specific demographic and clinical patient information found in Table 4.1 has been identified by the STS to collectively constitute the significant mortality and morbidity risk predictors in cardiac surgery,^{13,14,16,17,31} and is the same information used to calculate these two outcome variables for this study. The STS cardiac risk score calculator data version 2.81 was developed in 2007 and allows health care workers and researchers to estimate individual mortality and morbidity risk for cardiac surgery by entering individual clinical data points based on these predicted risks.⁴ With assistance from the STS data abstractor (someone who locates and receives information from medical records and prepares the *data* for a requester), preoperative clinical data were derived from chart reviews prospectively to determine the initial mortality risk, which was calculated using the STS risk calculator version 2.81. The STS-mortality risk (in percentage) is based on 24 covariates³ (“Preoperative data” column in Table 4.1), individually weighed, and involves mathematical formulas for deriving the end calculations which are all proprietary information of STS.⁴ The STS risk calculator version 2.81 also provides a combined “mortality or morbidity risk” estimate (in percentage) from the same calculation method used to estimate mortality risk. For this

study, the morbidity risk was calculated by subtracting the estimated “mortality risk” score from the “mortality or morbidity risk” score, since STS does not directly estimate morbidity on its own.

Actual adverse events, which comprise the basis for morbidity risk according to the STS, is a composite based on any of the following 5 major complications (found in “Postoperative Data” in Table 4.1): stroke (permanent neurologic event >24 hours as confirmed by diagnostic testing), renal failure (new requirement for dialysis or creatinine level at 3-fold increase from preoperative level), prolonged ventilation (>24 hours or reintubation required), deep sternal wound infection (requiring operative intervention and antibiotic therapy with positive cultures), and need for reoperation (due to major bleeding), as well as postoperative death (all-cause by 30 days and by one year-postoperative).^{4,5,8} The frequency of major complications (a.k.a. adverse events, bolded in Table 4.1 under “Postoperative Data”) were calculated in this study and compared against the individual’s predicted morbidity risk score as estimated by the LLFDI.

Because mortality and morbidity data is often extended beyond the patients’ hospitalization, including postoperative data at 30 days and as far out as one year,^{16,31} retrospective data abstraction was also used to capture this trend. The additional postoperative clinical data (entire “Postoperative Data” column in Table 4.1) were abstracted prospectively from chart reviews during the subject’s hospitalization and again retrospectively one year post-surgery, in order to calculate actual complications (morbidity events stated above), any readmissions within 30 days, as well as any listing of death (checked in medical records and obituary searches statewide). Data from the subjects’ medical records (Table 4.1) were accessed and extracted using McKesson

Electronic Medical Record Systems and MIS medical records and compiled on a disc. All information was transferred onto an Excel spreadsheet, de-identified, and verified for accuracy against the hardcopy, which was then destroyed.

Table 4.1

Data Abstracted for STS Risk Estimates and Actual Postoperative Events

Preoperative	Postoperative
Specific cardiac procedure	Intubation > 24 hours (and re-intubation)
Age	Deep sternal infection
Gender	Neurologic event (confirmed by brain CT or MRI)
Ethnicity	Postoperative bleeding (if return to surgery)
Ejection fraction % (EF)	Mortality (≤ 30 -days and all-cause at 1-year)
NYHA Class/heart failure	Creatinine within 72 hours (compared to pre-op level)
Creatinine level	Blood products required (type and amount)
Body Mass Index (height/weight)	Total cross-clamp time on bypass pump
Number of vessel disease	Adverse arrhythmia (pacemaker or defibrillator required)
Cardiac presentation/symptoms	Any comorbidities (new diagnoses/progression)
Myocardial Infarction history	Total postoperative length of stay
Cerebral and peripheral vascular disease	
Prior coronary intervention (timeframe)	
Hypertension (history/management)	
Immun Arrhythmia (atrial fibrillation type ocompromise history)	
Inotrope meds or Balloon Pump use preoperatively	
Endocarditis (presence/management)	
Diabetes (history/management)	
Cardiovascular surgery incidence (previous CAB or valve)	

Data Analysis

All data were analyzed using the statistical package Stata 14 (StataCorp, College Station, TX). Study demographics were collected (Table 4.2) on gender, age, and

race/ethnicity as well as preoperative functional status (measured by the LLFDI Function Total score), and surgical mortality and morbidity risk as based on the STS risk calculator scores (in percentage). Descriptive statistics on the sample demographics were examined for frequency distribution and assumptions of normality. Ordinary least square regression was conducted to estimate mortality and morbidity risk using preoperative functional status (LLFDI Function Total) as the explanatory variable. Negative binomial regression was conducted to estimate the frequency and probability of adverse events (major complications) utilizing the LLFDI. Data were considered significant at $p < 0.05$.

Results

Baseline Demographics and Variable Distribution

The study cohort consisted of 43 subjects with completed preoperative LLFDIs for analysis (Figure 4.1). Subjects ranged from 45 to 83 years with a mean age of 66 ± 9.7 years; 28% were female and 95% were Caucasian (Table 4.2). All 43 subjects were alive 30 days postoperative; however, one (2.3%) subject had died within one year post-surgery. Eighty-four percent of the cohort underwent coronary bypass graft surgery (initial or redo), but for analysis purposes, all cardiac surgical procedures were combined, including valve surgeries, which made up 16% (repair, replacement, or in combination with bypass surgery).

Functional status, mortality and morbidity risk scores were assessed for normality, however; both mortality and morbidity risk scores evidenced significant departure from normality when Shapiro-Wilk test was conducted. Quantile-normal plots were generated to determine best fit for transformation and log transformation was determined for both

outcome variables. After the necessary variables were transformed, all the assumptions of normality were met for analysis purposes.

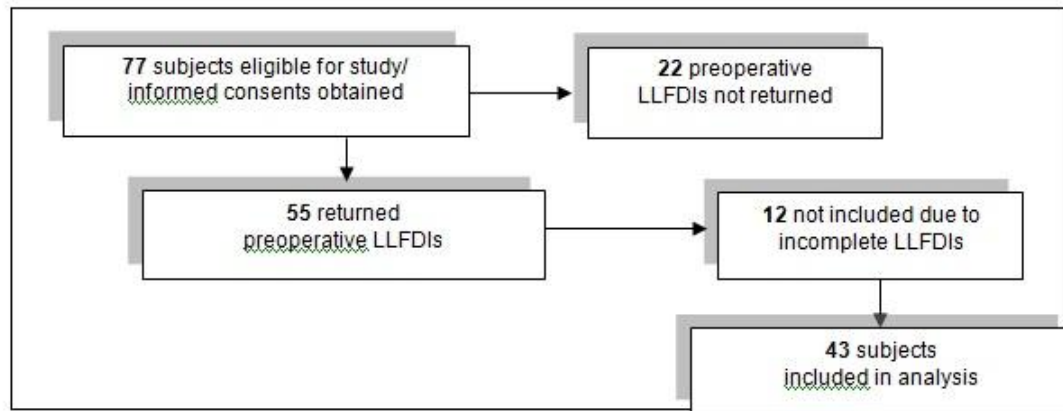


Figure 4.1. Late-Life Function and Disability Instrument (LLFDI) data flow diagram.

Table 4.2

Patient Characteristics (based on n=43)

Patient Characteristics (based on n=43)		LLFDI demographics (based on n=150)
Gender	Female 12 (28%)	23%
	Male 31 (72%)	77%
Age	Range 45 – 83 years	64.9*
	M = 66.35 (SD 9.74)	
Race/Ethnicity	Caucasian 41 (95%)	84%
	Hispanic or Latino 1 (2%)	5%
	African American 1 (2%)	7%
Surgical Approach	CABG— on pump 30 (72.1%)	---
	CABG— off pump 5 (11.6%)	---
	CABG - both types combined, 35 (83.7%)	---
	Valve replacement /repair or with CABG 8 (16.3%)	---
Preoperative Functional Status	LLFDI Function Total (score range 0-100) M = 61.39 (SD 9.41)	M = 62.9 (SD 13.0)
Mortality Risk (%)	M = 1.47 (SD 1.31)	n/t
Morbidity Risk (%)	M = 10.23 (SD 4.27)	n/t

LLFDI = Late-Life Function and Disability Instrument

* mean age for bypass surgery (STS, 2010)

n/t = not tested

Regression Analysis

The regression of mortality risk on functional status was found to be significant, $F(1, 41) = 4.96$, $p = .032$, providing an adjusted $R^2 = 0.086$. Function Total yielded a significant negative association with mortality risk, $\beta = -0.328$. Regression diagnostics indicated that normality of residuals and homoscedasticity assumptions were met. Analysis to detect influential observations using Cook's distance revealed the presence of two potentially influential cases. Both cases were deleted and the analysis was rerun. The equation for mortality (Table 4.3) was found to be significant, $F(1, 39) = 4.75$, $p = 0.035$, with an adjusted $R^2 = 0.086$, and Function Total yielded a significant negative association with mortality risk, $\beta = -0.329$.

Table 4.3

Bivariate Least Squares Regression Analysis: Mortality Risk ($N=41$)

Variable	<i>B</i>	SE B	β	<u>Adjusted R^2 †</u>
Functional Total	-0.044	0.013	-0.469*	0.086
* $p < 0.05$; ** $p < 0.01$				
† Adjusted R^2 was based on reverse transformation of the dependent variable				

The equation for morbidity risk was not significant, $F(1, 41) = 2.66$, $p = 0.11$, providing an adjusted $R^2 = 0.038$. Function Total yielded a significant negative association with morbidity risk, $\beta = -0.247$. Normality of residuals and homoscedasticity assumptions were met. Analysis for the presence of influential observations using Cook's distance revealed one potentially influential case. The regression equation for morbidity following deletion of this observation (Table 4.4) was found to be significant, $F(1, 40) =$

4.89, $p = 0.033$, with an adjusted $R^2 = 0.087$ and Function Total yielded a significant negative association with morbidity risk, $\beta = -0.328$.

Table 4.4

Bivariate Least Squares Regression Analysis: Morbidity Risk ($N = 42$)

Variable	<i>B</i>	SE B	β	<u>Adjusted R^2 †</u>
Functional Total	-0.014	0.006	-0.328*	0.087
* $p < 0.05$; ** $p < 0.01$				
† Adjusted R^2 was based on reverse transformation of the dependent variable				

Results for the negative binomial regression analysis appear in Table 4.5.

Estimation of the counts for postoperative complications as estimated by Function Total failed to reach significance (Wald $\chi^2 = 0.34$, $p = .56$), which provided a pseudo $R^2 = .009$. Consequently, probabilities for frequencies of adverse events (major complications) could not be reliably calculated.

Table 4.5

Negative Binomial Regression Analysis: Frequency of Complications ($N=43$)

Variable	<i>B</i>	SE B	Pseudo R^2
Functional Total	-0.031	0.053	0.009
* $p < 0.05$; ** $p < 0.01$			

Discussion

Preoperative functional status, as measured by LLFDI Function Total, yielded significant findings in predicting both mortality and morbidity risk in elective cardiac surgery. Although the LLFDI outcome measure has been widely used with the cardiac population (eg, cardiac rehab post-bypass surgery, coronary heart disease, congestive heart failure),^{26,30,32} to date, this is the only known research study to have explored the predictive validity of the LLFDI in terms of mortality and morbidity risk in elective cardiac surgery patients.³⁰ What is not known is how much of the variance for mortality or morbidity risk can be accounted for by LLFDI preoperative Function Total. With such a small sample size, comparing the LLFDI is infeasible against such an exhaustive list of cardiac surgery risk factors that includes every possible influencing variable.^{5,8,9} A larger sample in the future would help detect if clinically relevant effects occurred and may strengthen the overall power of this study.

Despite the overall significance found with the LLFDI, there were two cases deemed the exception as they were flagged as unduly influencing the mortality risk results due to their individual functional scores: one was unexpectedly high and the other was extremely low. Consequently, the LLFDI was a poor predictor of mortality risk in these two cases. As stated earlier, there are numerous potential variables that can influence cardiac surgery complications and mortality. It is essential to isolate as many of the key influencing variables as possible when using surgical risk predictor tools such as STS, otherwise calculating the estimate may be flawed, and on elective procedures especially, accuracy is paramount. In an attempt to examine the effect of the LLFDI

alone, there certainly could have been another unexplained covariate(s) acting or anomalies occurring within the accounted STS variables.

The LLFDI overestimated morbidity in one case and consequently was a poor predictor of morbidity risk in this one case. Interestingly, this case was one of the two cases that was also problematic with regard to mortality risk. Overall, results of the regression analysis were an accurate reflection of the association between the variables in the vast majority of the cases. Furthermore, finding a significant association between the LLFDI Function Total and STS morbidity risk, as well as LLFDI Function Total and STS mortality risk, suggests that the STS cardiac risk score may need to be refined.

This study had limitations with attrition rate from obtaining consents to receiving preoperative LLFDIs of 29% (n=22). One explanation may have been that subjects were met briefly and typically after they just received news of needing cardiac surgery without much time to process all of the information. Unfortunately, there is only a small window of time (roughly two hours) to approach these potential subjects in person after all of their consults and tests have been completed and before they are discharged. This issue could potentially be improved in future studies by conducting a follow-up call at home 1-2 days after the initial contact and prior to surgery.

Conducting this study at a single site with a sample of convenience (i.e., elective, primarily on-pump cases) without a control group certainly challenges the ability to generalize findings to the cardiac surgery population. Closer examination of the data revealed that all but five of the participating subjects that underwent CABG surgery (n=35), were performed on-pump, and of the eight subjects who underwent valve repair or replacement, three of the valve procedures was a combination valve/CABG surgery.

Additionally, two of the valve cases were mitral valve surgeries, which naturally carry higher mortality risk, however; all of these sub-groups were too small to do any comparative studies on mortality and morbidity influence. Regardless of the cardiac surgery performed, however, preoperative diminished functional status, as measured by the Late-Life Function and Disability Instrument, is associated with an increased risk of mortality and morbidity in patients undergoing elective cardiac surgery. The risks and benefits of cardiac surgery should be weighed carefully and include a patient's preoperative functional status, especially in the case of an elective procedure.

References

1. Hillis L, Smith PK, Anderson JL, et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: executive summary. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2011; 58(24):2584-2614.
doi:10.1016/j.jacc.2011.08.008.
2. Roger VL, Go AS, Lloyd-Jones DM, et al. American Heart Association. Heart disease and stroke statistics 2011 update: A report from the American Heart Association. *Circulation*. 2011; 123: e18-e209. doi:10.1161/CIR.0b013e3182009701.

3. Holmes DR, Mack MJ, Kaul S, Agnihotri A, Alexander KP, Bailey SR, et al. ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement. *J Am Coll Cardiol*. 2012; 59(13): 1200-1254.
 4. Society of Thoracic Surgeons. (2015). STS Adult Cardiac Surgery Database. About the STS risk calculator (version 2.81).
<http://riskcalc.sts.org/stswebriskcalc/views/About%20the%20STS%20Risk%20Calculator%20v2%2081.pdf>. Updated 2015. Accessed November 25, 2015.
-
5. Shahian DM, O'Brien SM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1—coronary artery bypass grafting surgery. *Ann Thorac Surg*. 2009; 88:S2–22.
 6. van Straten AH, Bramer S, Soliman Hamad MA, et al. Effect of body mass index on early and Late mortality after coronary artery bypass grafting. *Ann Thorac Surg*. 2010; 89:30–7.
 7. Bakaeen FG, Chu D, Huh J, Carabello BA. Is an age of 80 years or greater an important predictor of short-term outcomes of isolated aortic valve replacement in veterans? *Ann Thorac Surg*. 2010; 90:769 –74.
 8. Afilalo J, Eisenberg MJ, Morin JF, et al. Gait speed as an incremental predictor of mortality and major morbidity in elderly patients undergoing cardiac surgery. *J Am Coll Cardiol*. 2010; 56:1668-1676.
-

9. Cervera R, Bakaeen FG, Cornwell LD, Wang XL, Coselli JS, LeMaire SA, Chu D. Impact of functional status on survival after coronary artery bypass grafting in a veteran population. *Ann Thorac Surg.* 2012; 93:1950–1955.

10. Lee DH, Buth KJ, Martin BJ, Yip AM, Hirsch GM. Frail patients are at increased risk for mortality and prolonged institutional care after cardiac surgery. *Circulation.* 2010; 121:973–8.
11. Sündermann SH, Dademasch A, Praetorius J, et al. Comprehensive assessment of frailty for elderly high-risk patients undergoing cardiac surgery. *Eur J Cardiothorac Surg* 2011; 39:33–7.
12. Sündermann SH, Dademasch A, Seifert B, et al. Frailty is a predictor of short- and mid-term mortality after elective cardiac surgery independently of age. *Interact CardioVasc Thorac Surg.* 2014; 18(5):580-585.
13. Narain P, Rubenstein LZ, Wieland GD, Rosbrook B, Strome LS, Pietruszka F, Morley JE. Predictors of immediate and 6-month outcomes in hospitalized elderly patients. The importance of functional status. *J Am Geriatr Soc.* 1988; 36:775-783.
14. Inouye SK, Peduzzi PN, Robison JT, Hughes JS, Horwitz RI, Concato J. Importance of functional measures in predicting mortality among older hospitalized patients. *JAMA.* 1998; 279:1187-1193.

15. Purser JL, Kuchibhatla MN, Fillenbaum GG, Harding T, Peterson ED, Alexander KP. Identifying frailty in hospitalized older adults with significant coronary artery disease. *J Am Geriatr Soc*. 2006; 54:1674–81.
 16. Granton J, Cheng D. Risk stratification models for cardiac surgery. *Semin Cardiothorac Vasc Anesth*. 2008; 12:167-174.
 17. Geissler HJ, Hölzl P, Marohl S, Kuhn-Régnier F, Mehlhorn U, Südkamp M, de Vivie ER. Risk stratification in heart surgery: comparison of six score systems. *Eur J Cardiothorac Surg*. 2000; 17:400-406.
 18. Society of Thoracic Surgeons. (2015). Using gait speed to measure frailty. <http://www.sts.org/news/using-gait-speed-measure-frailty>. Updated 2015. Accessed January 11, 2016.
 19. Wilson CM, Kotsuca SR, Boura JA. Utilization of a 5-meter walk test in evaluating self-selected gait speed during preoperative screening of patients scheduled for cardiac surgery. *Cardiopulm Phys Ther J*. 2013; 24(3):36-43.
 20. Enright PL. The Six Minute Walk Test. *Respir Care*. 2003;48(8):783-785.
-
21. LaPier TK, Mizner R. Outcome measures in cardiopulmonary physical therapy: focus on the Late Life Function and Disability Instrument (LLFDI). *Cardiopulm Phys Ther J*. 2009; 20:32-35.
 22. Jette AM, Haley SM, Kooyoomjian JT. *Late Life Function and Disability Instrument*. Boston, MA: Trustees of Boston University; 2002.

23. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. development and evaluation of the disability component. *J Gerontol.* 2002; 57A: M209– M216.
24. Haley SM, Jette AM, Coster WJ, et al. Late Life Function and Disability Instrument: II. development and evaluation of the function component. *J Gerontol.* 2002; 57A:M209–M216.
25. LaPier TK, Waitt M. Using the Late Life Function and Disability Instrument as a self-report outcome measure in patients with cardiovascular disease. *J Cardiopulm Rehabil Prevent.* 2007; 27(5):331.
26. LaPier TK. Utility of the Late Life Function and Disability Instrument as an outcome measure in patients participating in outpatient cardiac rehabilitation: a preliminary study. *Physiother Can.* 2012 Winter; 64(1):53-62.
27. Sayers SP, Jette AM, Haley SM, Heeren TC, Guralnik JM, Fielding RA. Validation of the Late-Life Function and Disability Instrument. *J Am Geriatr Soc.* 2004; 52:1554-1559.
28. Denkinger MD, Igl W, Coll-Planas L, et al. Evaluation of the short form of the Late-Life Function and Disability Instrument in geriatric inpatients: validity, responsiveness, and sensitivity to change. *J Am Geriatr Soc.* 2009; 57(2):309–14.
29. Dubuc N, Haley SM, Ni P, et al. Function and disability in late life: Comparison of the Late- Life Function and Disability Instrument to the Short-Form-36 and the London Handicap Scale. *Disability Rehabil.* 2004; 26:362-370.

30. Beauchamp MK, Schmidt CT, Pedersen MM, Bean JF, Jette AM. Psychometric properties of the Late-Life Function and Disability Instrument: A systematic review. *BMC Geriatr*. 2014; 29(14):1-12.
31. Bennett JA, Riegel B, Bittner V, Nichols J. Validity and reliability of the NYHA classes measuring research outcomes in patients with cardiac disease. *Heart Lung*. 2002; 31:262-270.
32. LaPier TK, Howell D. Functional status deficits in patients recovering from coronary artery bypass: An application of evidence-based practice. *Cardiopulm Phys Ther J*. 2002; 13:12-19.

CHAPTER V

CONCLUSION

Three-Paper Summary

The aim of this three-paper dissertation was to explore how patients' preoperative functional movements and limitations, known as functional status, influenced recovery after elective open heart surgery. Functional status is complex and multi-factorial in nature so for this research proposal, *functional status* was defined as an individual's ability to do activities within his/her regular environment, an ability that may be limited by physical disabilities due to cardiac disease, perception of symptoms, or extend to a variety of environmental, social and psychological factors.¹ For all three studies, functional status was measured using the *Late-Life Function & Disability Instrument* (LLFDI)²⁻⁴ as this is a functional status outcome tool with strong validity and reliability⁵⁻⁸ specifically targeting a wide variety of physical activities and social life tasks²⁻⁴ and has been used on the cardiac surgery population.⁹⁻¹⁰ Paper one utilized repeated measures to examine functional status changes over time and based on gaps in literature, specifically explored both the early recovery phase (6 weeks postoperative)¹¹⁻¹⁴ as well as late recovery (one year postoperative) phase.¹⁵⁻¹⁷ Paper two employed a mixed-method approach using a structured phone interview format to examine changes in self-perceived quality of life one year after open heart surgery and its interaction with functional status changes (LLFDI scores). Paper three applied ordinary least squares and negative

binomial regression to chart review data gathered retrospectively, in order to examine the association between preoperative functional status (LLFDI score) and mortality and morbidity risk, as based on calculated Society of Thoracic Surgeons (STS) risk scores.¹⁸

Summary of Paper One and Recommendations for Clinical Practice

The average length of stay in the hospital after open heart surgery is 5 days and the average time for the sternal incision to close and heal is two weeks, but how long for patients to return to or surpass their prior functional level remains unclear.¹⁸⁻¹⁹ With paper one, change in functional status was examined in a longitudinal design study, to focus on the early recovery phase, to assess if patients indicate improved functional status as early as 6 weeks postoperative, as well as the late recovery phase, to determine if prior functional levels are restored, surpassed, or worse by one year postoperative.

Patients who underwent elective open heart surgery demonstrated significantly improved functional status from preoperatively to one year postoperatively, both in performing their routine tasks and in participating more frequently in social activities, but it is a long healing process with changes primarily occurring after six weeks postoperatively. These findings may assist cardiac patients in what to expect for recovery so they can make a more informed decision. Although functional status changes did not seem to differ by gender, patients in the 70 years or older age group demonstrated significantly lower scores on their ability to perform routine activities than their 60 to 69 and < 60 years old counterparts. Advanced age is a predictive variable already taken into consideration on most cardiac risk score models (see Appendix C).¹⁹⁻²⁰

Summary of Paper Two and Recommendations for Clinical Practice

Functional status and quality of life appear to be directly related and improve in the presence of an extensive support network. When social support is minimal or absent, however, individuals should give careful consideration of all the risks and benefits for such an extensive surgery as coronary bypass, especially in the case of an elective procedure. Furthermore, social support plays a key role in recovery, and its absence may set the stage for certain individuals to develop postoperative depression which can linger.

Social support or lack thereof has been well researched over the years, with Waltz (1986) discovering that there are certain types of people that are more likely to “master adaptive tasks” postoperatively, and those types are ones who are 1) satisfied in life; 2) mutually content in their marriage; or 3) belong to a network.²¹ From a clinical perspective, these findings should be confirmation to the health care profession how essential it is to screen these patients preoperatively regarding information about their social support network, not just for discharge planning purposes, but for potential psychological impact on recovery as well. Predetermined alternate discharge arrangements and setting may need to be a discussion with the patient who resides alone or has minimal social support.

Besides the mental well-being and emotional benefit that a social network appears to provide, the second paper demonstrated that there was a direct association between functional status and patients’ perceived quality of life, influenced by social support or lack thereof. This finding is supported in other research. In fact, those who lack a social network or reside alone, on the contrary, are less likely to improve their physical status and are at an increased risk of postoperative depression²² and functional decline.²³⁻²⁷

Although cardiac rehabilitation is recommended to all post-surgical patients²⁸, only 22% attended [2010-2011 Saint Vincent patient data], which is not far below the national average of 31% post-CABG attendees (even lower still that attend are Medicare beneficiaries, at 12%).²⁹⁻³⁰ Interestingly, Ashton and Saccucci reported functional status was not significantly different based on patients' participation in cardiac rehabilitation, but the influence of social support was not part of their study.¹²

Summary of Paper Three and Recommendations for Clinical Practice

Preoperative diminished functional status, as measured by the LLFDI, is associated with an increased risk of mortality and morbidity in patients undergoing elective cardiac surgery. Although the LLFDI outcome measure has been widely used with the cardiac population (eg, cardiac rehab post-bypass surgery, coronary heart disease, congestive heart failure),^{8,10,13} to date, this is the only known research study to have explored the predictive validity of the LLFDI in terms of mortality and morbidity risk in elective cardiac surgery patients.⁸ What remains unknown, however, is how much of the variance does functional status account for the increased risk of postoperative mortality or morbidity risk, in relation to all the other known cardiac risk factors.^{19,31,32} Thus, until additional studies are conducted (and ones with larger samples) to compare functional status against all the key influencing variables that make up a cardiac risk stratification score, current surgical risk predictor tools such as STS may provide a flawed estimate. As a result of this study, it is recommended that a patient's preoperative functional status be carefully considered among all the risks and benefits of cardiac surgery, especially in the case of an elective procedure. From a clinical perspective, this

may better assist patients and surgeons alike so they can work together to make a more informed decision.

Study Limitations

Conducting this study at a single hospital with a sample of convenience (i.e., elective, primarily on-pump cases) without a control group certainly challenges the ability to generalize findings to the cardiac surgery population. A significant attrition rate (29%, $n = 29$) occurred right after initial consents were obtained and resulted in a small sample size for the study. This may have been due to the timing of receiving this information, which coincided with news of needing and having scheduled major cardiac surgery, and the small window of time (roughly two hours) to approach these patients with the details of participating in the research before they were discharged from hospital. Although there was a total sample size of $n = 43$, as based on preoperative LLFDIs returned, there was only 29 completed LLFDIs for all three time periods and the relatively small n impacted the statistical power of the study and limited the ability to reach minimally detectable change (MDC) levels with the LLFDI tool. Furthermore, creating sub-groups for comparison from $n = 29$ were too small for meaningful analyses, beyond basic descriptive statistics. This reality was most evident in the third paper, where the patient sample was compromised of a majority of CABG cases and lent itself to only a handful of valve cases, too few to dichotomize for further meaningful analyses. Different cardiac surgical procedures, however, carry different mortality and morbidity risks (mitral valve surgery naturally carries a higher mortality risk regardless of age or

gender).^{19, 28} Combining dissimilar morbidity and mortality rates was a constraint of the study.

Implications for Future Research

Although this three-paper study added to the body of knowledge on the topic of functional status and elective open heart surgery recovery, there are several implications for future research to explore. This repeated-measures study was one of the first to explore changes in functional status from preoperative to as early as 6 weeks postoperatively (often not captured in studies), and as far out as one year postoperatively using an outcome tool specifically designed to measure functional status and one that has been tested on patients with cardiovascular disease.^{2-4,9,15} However, future studies should capture more time points between 6 weeks and one year, in order to get past the period of sternal precautions and ascertain when recover truly takes place. Data should also be collected 12 – 24 months postoperative, to better determine when (or if) patients surpass their baseline functional status levels. Additionally, cardiac rehab participation should be treated as a covariant, due to its potential to influence functional status results.

The nuance of social support influence that was obtained through mixed-methods remains a valid finding and future studies may want to explore the influence of social support on postoperative functional status changes using the LLFDI and compare different cardiac surgical approaches (eg, minimally invasive versus sternotomy; on-pump versus off-pump). Future research should also address the psychological impact of open heart surgery, specifically the propensity toward postoperative depression observed

in certain individuals, in order to gain a better understanding and perhaps some solutions (eg, preventative counseling) for the psychological issues patients may anticipate in their lengthy recovery.

Preoperative functional status appears to be negatively associated with mortality and morbidity risk in elective open heart surgery patients. Additional studies are warranted, however, and ones with larger samples, to compare preoperative functional status against all the key influencing variables that make up cardiac risk stratification scores. This should provide a more accurate estimate of calculating mortality and morbidity risk in elective cardiac surgery patients with surgical risk predictor tools such as STS.

Clinical Relevance

This research is relevant to cardiac surgeons, the patients and their loved ones, who are each trying to balance the risks and benefits of an elective surgical procedure from a different vantage point, in order to recommend or make the most informed decision. Other key stakeholders are the health care providers from various disciplines who assist in the patient's care and recovery post-surgery through outpatient rehabilitation: Hospitalists/internists; pharmacists; nurses; respiratory therapists; dieticians; physical therapists; case managers; as well as the hospital administration and board of directors who must look at surgical success in terms of complications (morbidity) and unexpected deaths (mortality) in order to contain costs. This research also has the potential to be relevant to future patients, in possibly assisting them in what to expect for recovery so they too can make a more informed decision. To think more

broadly, is the overall relevance of preoperative functional status as one of the potential predictor variables for increased mortality and morbidity risk in open heart surgery and yet in current day clinical practice it fails to be included among any cardiac risk stratification calculation. This begs the question that if future research with large sample sizes continues to explore the association between preoperative functional status and postoperative mortality and morbidity risk in elective open heart surgery patients, then perhaps the predictor variables for the cardiac risk stratification calculation models need to be redefined.

References

1. Bennett JA, Riegel B, Bittner V, Nichols J. Validity and reliability of the NYHA classes for measuring research outcomes in patients with cardiac disease. *Heart Lung*. 2002; 31:262-270.
2. Jette AM, Haley SM, Kooyoomjian JT. *Late Life Function and Disability Instrument*. Boston, MA: Trustees of Boston University; 2002.
3. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. development and evaluation of the disability component. *J Gerontol*. 2002; 57A:M209– M216.
4. Haley SM, Jette AM, Coster WJ, et al. Late Life Function and Disability Instrument: II. development and evaluation of the function component. *J Gerontol*. 2002; 57A:M209–M216.

5. Sayers SP, Jette AM, Haley SM, Heeren TC, Guralnik JM, Fielding RA. Validation of the Late-Life Function and Disability Instrument. *J Am Geriatr Soc.* 2004; 52:1554-1559.
6. Denkinger MD, Igl W, Coll-Planas L, et al. Evaluation of the short form of the Late-Life Function and Disability Instrument in geriatric inpatients: validity, responsiveness, and sensitivity to change. *J Am Geriatr Soc.* 2009; 57(2):309–14.
7. Dubuc N, Haley SM, Ni P, et al. Function and disability in late life: Comparison of the Late-Life Function and Disability Instrument to the Short-Form-36 and the London Handicap Scale. *Disability Rehabil.* 2004; 26:362-370.
8. Beauchamp MK, Schmidt CT, Pedersen MM, Bean JF, Jette AM. Psychometric properties of the Late-Life Function and Disability Instrument: A systematic review. *BMC Geriatr.* 2014; 29(14):1-12.
9. LaPier TK, Waitt M. Using the Late Life Function and Disability Instrument as a self-report outcome measure in patients with cardiovascular disease. *J Cardiopulm Rehabil Prevent.* 2007; 27(5):331.
10. LaPier TK. Utility of the Late Life Function and Disability Instrument as an outcome measure in patients participating in outpatient cardiac rehabilitation: a preliminary study. *Physiother Can.* 2012 Winter; 64(1):53-62.
11. Ballan A, Lee G. A comparative study of patient perceived quality of life pre and post coronary artery bypass graft surgery. *Aust J Adv Nurs.* 2007; 24: 24-28.

12. Barnason S, Zimmerman L, Anderson A, Mohr-Burt S, Nieveen J. Functional status outcomes of patients with a coronary artery bypass graft over time. *Heart Lung*. 2000; 29:33-46.
13. LaPier TK, Howell D. Functional status deficits in patients recovering from coronary artery bypass: An application of evidence-based practice. *Cardiopulm Phys Ther J*. 2002; 13:12-19.
14. LaPier TK. Functional status of patients during subacute recovery from coronary artery bypass surgery. *Heart Lung*. 2007;36:114-24.
15. LaPier TK, Mizner R. Outcome measures in cardiopulmonary physical therapy: Focus on the Late-Life Function and Disability Instrument (LLFDI). *Cardiopulm Phys Ther J*. 2009; 20:32-35.
16. Douki ZE, Vaezzadeh N, Zakizad M, Shahmohammadi S, Sadeghi R, Mohammadpour RA. Changes in functional status and functional capacity following coronary artery bypass surgery. *Pakistan J Biol Sci*. 2010; 13:330-334.
17. Hunt JO, Hendrata MV, Myles PS. Quality of life 12 months after coronary artery bypass graft surgery. *Heart Lung*. 2000; 269:401-411.
18. Society of Thoracic Surgeons. (2015). STS Adult Cardiac Surgery Database. About the STS risk calculator (version 2.81).
<http://riskcalc.sts.org/stswebriskcalc/views/About>

[%20the%20STS%20Risk%20Calculator%20v2%2081.pdf](#). Updated 2015. Accessed November 25, 2015.

19. Shahian DM, O'Brien SM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1—coronary artery bypass grafting surgery. *Ann Thorac Surg*. 2009; 88:S2–22.
20. Bakaeen FG, Chu D, Huh J, Carabello BA. Is an age of 80 years or greater an important predictor of short-term outcomes of isolated aortic valve replacement in veterans? *Ann Thorac Surg*. 2010; 90:769–74.
21. Waltz M. Marital context and post-infarction quality of life: is it social support or something more? *Soc Sci Med*. 1986;22(8):791-805.
22. Oxman TE, Hull JG. Social support, depression, and activities of daily living in older heart surgery patients. *J Gerontol B Psychol Sci Soc Sci*. 1997;52B(1):P1-14.
23. Mor V, Murphy J, Masterson-Allen S, Willey C, Razmpour A, Jackson ME, Greer D, Katz S. Risk of functional decline among well elders. *J Clin Epidemiol*. 1989;42:895-904.
24. Bowling A, Browne PD. Social networks, health, and emotional well-being among the oldest old in London. *J Gerontol* 1991;46:S20-S22.
25. Liu X, Liang J, Muramatsu N, Sugisawa H. Transitions in functional status and active life expectancy among older people in Japan. *J Gerontol B Psychol Sci Soc Sci*. 1995;50B: S383-S394.

26. Wolinsky FD, Johnson RJ. Widowhood, health status, and the use of health services by older adults: A cross-sectional and prospective approach. *J Gerontol.* 1992;47: S8-S16.
 27. Weinberger M, Tierney WM, Booher P, Hiner SL. Social support, stress and functional status in patients with osteoarthritis. *Soc Sci Med.* 1990; 30:503-508.
 28. Hillis L, Smith PK, Anderson JL, et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: executive summary. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2011; 58(24):2584-2614.
doi:10.1016/j.jacc.2011.08.008.
 29. Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. *Circulation.* 2007; 116:1653–1662.
 30. Centers for Disease Control and Prevention (CDC). Receipt of outpatient cardiac rehabilitation among heart attack survivors—United States, 2003. *MMWR Morb Mortal Wkly Rep.* 2008;57:89 –94.
 31. Afilalo J, Eisenberg MJ, Morin JF, et al. Gait speed as an incremental predictor of mortality and major morbidity in elderly patients undergoing cardiac surgery. *J Am Coll Cardiol.* 2010; 56:1668-1676.
-

32. Cervera R, Bakaeen FG, Cornwell LD, Wang XL, Coselli JS, LeMaire SA, Chu D. Impact of functional status on survival after coronary artery bypass grafting in a veteran population. *Ann Thorac Surg*. 2012; 93:1950–1955.
-

Appendix A

Late-Life Function and Disability Instrument—Function Component (p.1)

How much difficulty do you have....? (Remember this is without the help of someone else and without the use of any assistive walking device.)	None	A little	Some	Quite a lot	Cannot do
F1. Unscrewing the lid off a previously unopened jar without using any devices	5	4	3	2	1
F2. Going up & down a flight of stairs inside, using a handrail	5	4	3	2	1
F3. Putting on and taking off long pants (including managing fasteners)	5	4	3	2	1
F4. Running 1/2 mile or more	5	4	3	2	1
F5. Using common utensils for preparing meals (e.g., can opener, potato peeler, or sharp knife)	5	4	3	2	1
F6. Holding a full glass of water in one hand	5	4	3	2	1
F7. Walking a mile, taking rests as necessary	5	4	3	2	1
F8. Going up & down a flight of stairs outside, without using a handrail	5	4	3	2	1
F9. Running a short distance, such as to catch a bus	5	4	3	2	1
F10. Reaching overhead while standing, as if to pull a light cord	5	4	3	2	1
F11. Sitting down in and standing up from a low, soft couch	5	4	3	2	1
F12. Putting on and taking off a coat or jacket	5	4	3	2	1
F13. Reaching behind your back as if to put a belt through a belt loop	5	4	3	2	1
F14. Stepping up and down from a curb	5	4	3	2	1
F15. Opening a heavy, outside door	5	4	3	2	1
F16. Rip open a package of snack food (e.g. cellophane wrapping on crackers) using only your hands	5	4	3	2	1
F17. Pouring from a large pitcher	5	4	3	2	1
F18. Getting into and out of a car/taxi (sedan)	5	4	3	2	1

Appendix B

Late-Life Function and Disability Instrument—Function Component (p.2)

How much difficulty do you have....? (Remember this is without the help of someone else and without the use of any assistive walking device.)	None	A little	Some	Quite a lot	Cannot do
F19. Hiking a couple of miles on uneven surfaces, including hills	5	4	3	2	1
F20. Going up and down 3 flights of stairs inside, using a handrail	5	4	3	2	1
F21. Picking up a kitchen chair and moving it, in order to clean	5	4	3	2	1
F22. Using a step stool to reach into a high cabinet	5	4	3	2	1
F23. Making a bed, including spreading and tucking in bed sheets	5	4	3	2	1
F24. Carrying something in both arms while climbing a flight of stairs (e.g. laundry basket)	5	4	3	2	1
F25. Bending over from a standing position to pick up a piece of clothing from the floor	5	4	3	2	1
F26. Walking around one floor of your home, taking into consideration thresholds, doors, furniture, and a variety of floor coverings	5	4	3	2	1
F27. Getting up from the floor (as if you were laying on the ground)	5	4	3	2	1
F28. Washing dishes, pots, and utensils by hand while standing at sink	5	4	3	2	1
F29. Walking several blocks	5	4	3	2	1
F30. Taking a 1 mile, brisk walk without stopping to rest	5	4	3	2	1
F31. Stepping on and off a bus	5	4	3	2	1
F32. Walking on a slippery surface outdoors	5	4	3	2	1

Appendix C

Late-Life Function and Disability Instrument—Function Component (p.3)

Questions for those who use a walking device

When you use your cane, walker, or other walking device, how much difficulty do you have...?	None	A little	Some	Quite a lot	Cannot do
FD7. Walking a mile, taking rests as necessary	5	4	3	2	1
FD8. Going up & down a flight of stairs outside, without using a handrail	5	4	3	2	1
FD14. Stepping up and down from a curb	5	4	3	2	1
FD15. Opening a heavy, outside door	5	4	3	2	1
FD26. Walking around one floor of your home, taking into consideration thresholds, doors, furniture, and a variety of floor coverings	5	4	3	2	1
FD29. Walking several blocks	5	4	3	2	1
FD30. Taking a 1 mile, brisk walk without stopping to rest	5	4	3	2	1
FD32. Walking on a slippery surface, outdoors	5	4	3	2	1

Appendix D

Late-Life Function and Disability Instrument—Disability Component (p.1)

	Disability Frequency					Disability Limitation				
	How often do you...?					To what extent do you feel limited in ...?				
	Very Often	Often	Once in a while	Almost never	Never	Not at all	A little	Somewhat	A lot	Completely
D1. Keep (Keeping) in touch with others through letters, phone, or email.	5	4	3	2	1	5	4	3	2	1
D2. Visit (Visiting) friends and family in their homes.	5	4	3	2	1	5	4	3	2	1
D3. Provide (Providing) care or assistance to others. This may include providing personal care, transportation, and running errands for family members or friends.	5	4	3	2	1	5	4	3	2	1
D4. Take (Taking) care of the inside of your home. This includes managing and taking responsibility for homemaking, laundry, housecleaning and minor household repairs.	5	4	3	2	1	5	4	3	2	1
D5. Work (Working) at a volunteer job outside your home.	5	4	3	2	1	5	4	3	2	1
D6. Take (Taking) part in active recreation. This may include bowling, golf, tennis, hiking, jogging, or swimming.	5	4	3	2	1	5	4	3	2	1
D7. Take (Taking) care of household business and finances. This may include managing and taking responsibility for your money, paying bills, dealing with a landlord or tenants, dealing with utility companies or governmental agencies.	5	4	3	2	1	5	4	3	2	1
D8. Take (Taking) care of your own health. This may include managing daily medications, following a special diet, scheduling doctor's appointments.	5	4	3	2	1	5	4	3	2	1

Appendix E

Late-Life Function and Disability Instrument—Disability Component (p.2)

	Disability Frequency					Disability Limitation				
	How often do you...?					To what extent do you feel limited in ...?				
	Very Often	Often	Once in a While	Almost never	Never	Not at all	A little	Somewhat	A lot	Completely
D9. Travel (Traveling) out of town for at least an overnight stay.	5	4	3	2	1	5	4	3	2	1
D10. Take (Taking) part in a regular fitness program. This may include walking for exercise, stationary biking, weight lifting, or exercise classes.	5	4	3	2	1	5	4	3	2	1
D11. Invite (Inviting) people into your home for a meal or entertainment.	5	4	3	2	1	5	4	3	2	1
D12. Go (Going) out with others to public places such as restaurants or movies.	5	4	3	2	1	5	4	3	2	1
D13. Take (Taking) care of your own personal care needs. This includes bathing, dressing, and toileting.	5	4	3	2	1	5	4	3	2	1
D14. Take (Taking) part in organized social activities. This may include clubs, card playing, senior center events, community or religious groups.	5	4	3	2	1	5	4	3	2	1
D15. Take (Taking) care of local errands. This may include managing and taking responsibility for shopping for food and personal items, and going to the bank, library, or dry cleaner.	5	4	3	2	1	5	4	3	2	1
D16. Prepare (Preparing) meals for yourself. This includes planning, cooking, serving, and cleaning up.	5	4	3	2	1	5	4	3	2	1

Appendix F

Structured Phone Interview Questions

1. Did you go back to your own home when you got discharged from the hospital after your heart surgery? And if so, who did you go home to and what kind of help did you have there?
2. Before surgery, what other medical issues limited your mobility and how did they affect your quality of life?
3. Did you have any lingering complaints after surgery and do you have any still?
4. How does your physical endurance seem now, compared to how it was before you had open heart surgery? (much better, a little better, same, little worse, much worse) choose one and then elaborate why.
5. How would you describe your current activity level?
6. What kind of physical activities do you do, besides necessary things around the house? [The frequency and duration of each activity was asked and documented as well.]
7. Any physical tasks you cannot do since the open heart surgery (and you could do before the surgery)? What are they?
8. One year later, now looking back: Was it worth it to you to undergo open heart surgery? Why or why not?
9. Currently are there other medical issues not related to your heart [You don't have to state what they are], which are also impacting your mobility and your quality of life?
10. One year later, how has your quality of life changed since you underwent open heart surgery?

Appendix G

Society of Thoracic Surgeons Risk Factors

Risk Factor	1990	1999	Absolute Change	Relative % Change
Demographics				
Patient age (y)				
Mean	63.7	65.1	1.4	
Median	65	66		
Gender				
Female (%)	25.7	28.7	3.0	11.6
Unknown (%)	0.0	0.4		
Race				
Non-Caucasian (%)	5.6	10.2	4.6	82.1
Unknown (%)	17.7	4.7		
Comorbidities				
Body surface area (m ²)				
Mean	1.90	1.95	0.05	
Median	1.92	1.96		
Unknown (%)	41.0	2.3		
Diabetes mellitus				
Yes (%)	21.4	32.7	11.3	52.7
Unknown (%)	17.6	2.6		
Renal failure				
Yes (%)	3.0	4.6	1.6	51.8
Unknown (%)	18.0	3.6		
Hypertension				
Yes (%)	50.7	68.9	18.2	35.9
Unknown (%)	14.1	2.1		
Pulmonary hypertension				
Yes (%)	0.8	3.0	2.2	275.0
Unknown (%)	38.4	14.7		
Cerebrovascular accident				
Yes (%)	3.8	7.1	3.2	84.9
Unknown (%)	31.4	3.4		
COPD				
Yes (%)	8.2	14.0	5.8	71.0
Unknown (%)	31.2	14.4		
Previous interventions				
Prior cardiac operations				
Yes (%)	10.6	8.4	-2.2	-21.0
Unknown (%)	1.2	2.4		
Cardiac status				
Cardiogenic shock				
Yes (%)	1.3	4.4	3.1	243.0
Unknown (%)	24.1	3.6		
MI timing				
0-21 days	16.2	23.7	7.5	46.3
> 21 days	20.5	21.9	1.4	6.8
Unknown (%)	22.3	3.4		
Unstable angina				
Yes (%)	55.8	43.2	-12.6	-22.6

NYHA class IV				
Yes (%)	13.2	23.1	9.9	75.0
Unknown (%)	57.2	14.7		
Hemodynamics and Cath				
Triple vessel disease				
Yes (%)	55.8	68.5	12.6	22.7
Unknown (%)				
Left main > 50% stenosis				
Yes (%)	15.6	23.4	7.8	50.0
Unknown (%)	30.2	3.4		
Ejection fraction (%)				
Mean	52.7	50.7	-2.0	-3.8
Median	54	50		
Unknown (%)	31.4	13.3		
Operative				
Procedure status				
Elective	67.3	60.8	-6.5	-9.7
Urgent	17.6	32.9	15.3	86.9
Emergent	7.1	5.5	-1.6	-22.7
Salvage	0.6	0.5	-0.2	-28.1
Unknown (%)	7.5	0.4		
CPB and support				
Preoperative IABP				
Yes (%)	4.9	6.5	1.7	33.9
Unknown (%)	6.2	2.6		101

* Trends in all variables were statistically significant (at the $p < 0.0001$ level) over the decade, except salvage status ($p = 0.0003$).

COPD = chronic obstructive pulmonary disease; IABP = intraaortic balloon pump; MI = myocardial infarction; NYHA = New York Heart Association.

surgical intervention in a large, nationwide dataset. We used statistical modeling techniques that permit a longitudinal time trend analysis of the change in surgical risk over time, based on preoperative risk factors. Table 2 illustrates the preoperative risk factor trends during the decade. These trends include increasing age, increased female patient cohort, more comorbidities, more extensive surgical disease, and more patients with abnormal ventricular function. Interestingly, the incidence of emergent and salvage patients declined, in part probably due to the use of coronary stents for acute intervention and for vein graft restenosis, and perhaps due to more aggressive use of preoperative intraaortic balloon pump placement. In summary, this risk profile change resulted in a 30% increase in expected risk during the decade, highly significant for the time trend.

Increased Risk Versus Decreased Mortality

Figure 2 demonstrates a significant decrease in the observed mortality/expected mortality ratio (O/E ratio) for

Appendix H

Informed Consent (Initial)

SAINT VINCENT HEALTH CENTER
Erie, Pennsylvania
CONSENT TO BE IN A RESEARCH STUDY AND AUTHORIZATION FOR
USE/DISCLOSURE
OF HEALTH INFORMATION

TITLE OF STUDY: Is preoperative functional status a predictor of postoperative mortality, morbidity and quality of life in open heart patients?

PRINCIPAL INVESTIGATOR: Kate Reynolds, PT, MPT, CCS

Subject's Name _____

Address _____

Date of birth _____ MR# _____ Phone _____

INTRODUCTION

You are being asked by Kate Reynolds, PhD graduate student at Western Michigan University and PT at Saint Vincent Health Center, to be in a research study, at Saint Vincent's, 232 West 25 Street, Erie, PA 16544, (814) 452-5000. The study is supported in part by the Western Michigan University Interdisciplinary Health Sciences Department.

You should note that this study involves research. Admission guidelines are used to be sure that you have the right medical condition to be in this study. For your own well-being, as well as to be sure the results can help make decisions about other patients with a similar condition, it is important that no exceptions be made to these admission guidelines. This consent describes your role as a subject in the study.

If you refuse to be in this study, your chance to be in a future study will not be affected. Also, you will not lose any medical benefits that you would normally have.

PURPOSE OF THE STUDY: using a standardized outcome measure tool, *Late-Life Function and Disability Instrument* (LLFDI). This questionnaire targets the physical function as well as emotional and mental well-being of a person.

SUBJECTS WHO CAN BE IN THIS STUDY:

To be in this study, you must meet certain criteria. However, even if you meet all the criteria, you might not be selected because of something that would place you at medical risk. To be in this study, you must be/have:

- at least 18 years old,

- able to authorize your own consent (unless you have a legal representative),
- able and willing to follow the instructions given by the investigator,
- able to communicate fluently in English,
- heart surgery to undergo is scheduled and not emergency,
- Dr recommended heart surgery includes coronary bypass grafting (initial or redo), valve repair/replacement, or any combination of the two (including Maze procedure for atrial fibrillation).

WHAT WILL HAPPEN DURING THE STUDY? Informed consents will be distributed to all qualifying participants in person by Kate Reynolds, PT. Kate Reynolds, PT, will also distribute and retrieve the pre-operative questionnaire in person for those participants who will remain hospitalized until the open heart surgery. These patients will be instructed to self-complete the questionnaire with written instructions provided. The patients who will be discharged and later readmitted to undergo the elected open heart surgery will have the pre-operative questionnaire mailed to them with the same written instructions provided and instruction to self-complete and mail back in a provided stamped envelope addressed to the investigators. Questionnaire takes approximately 15 minutes to complete. The same questionnaire will be mailed to each participant 5 weeks after their heart surgery with instruction to self-complete and mail back in a provided stamped envelope addressed to the investigators by 6 weeks post-operative. Follow-up calls by the investigators will be made to those participants that did not return a questionnaire, at which time, participant will be reminded to self-complete and mail back promptly, using the provided stamped envelope addressed to the investigators.

WHAT WILL HAPPEN IF YOU DECIDE NOT TO BE IN THE STUDY?

Your participation in the study is voluntary. You may decide to quit the study at any time without any penalty or loss of benefits. If you decide to quit the study, please call Kate Reynolds, PT, at (814) 452-5978. The study may be stopped by the sponsor, US FDA and other regulatory bodies without your consent for any reason. The investigators can remove you from the study at any time, without your consent and for any reason.

SUBJECTS EXCLUDED OR TERMINATED FROM THE STUDY:

- Elective open heart surgery becomes emergency open heart surgery
- Failure to complete the preoperative or postoperative questionnaire
- Unable to follow or comprehend the instructions
- Unable to self-complete either questionnaire

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

There are no risks or discomforts to this study, other than time taken to complete the questionnaire.

WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THIS STUDY? Your participation in this study may provide insight to the role preoperative functional status plays postoperatively in open heart patients. This study may also help future individuals

when making informed decisions about undergoing elective open heart surgery.

ARE THERE OTHER TREATMENTS AVAILABLE? You do not need to be in this study to receive treatment for your condition. Even if you refuse to be in the study, you will still continue to receive the health care you need. It is your choice to be in the study. You may choose not to have any treatment.

WHAT HAPPENS IF YOU HAVE A BAD EXPERIENCE?

Funds are not available from Saint Vincent Health System or the investigators to pay for lost wages or injuries you might receive as a result of participation in this study. Any bad experience should be reported to Kate Reynolds, PT, Saint Vincent Health Center, at (814) 452-5978.

WHAT ARE THE COSTS OF THIS STUDY?

If you choose to take part in this study, the questionnaire material and any follow-up questionnaires will be provided to you at no cost. All other costs of your treatment including hospitalization, routine tests and treatments will be your responsibility and will be billed to you or your insurance company as if you are not part of this study. However, if your insurance company does not pay, you will be responsible for these charges.

You have the right to know that no investigators or sponsors will receive compensation for conducting this research study.

HOW WILL THE DATA COLLECTED BE KEPT CONFIDENTIAL?

All informed consents and LLFDI questionnaires will be kept in separately marked envelopes and stored in a locked cabinet in the physical therapy department at Saint Vincent Health Center. All questionnaires and consents will be kept for a minimum of five years, after which, such will be destroyed using the Saint Vincent Health Center shredder system.

HOW WILL YOUR HEALTH INFORMATION BE PROTECTED?

Your health information associated with this research study may be protected by Regulations issued by the U.S. Government known as the Health Information Portability Accountability Act (HIPAA) Privacy Rule, 45 C.F.R. Part 164. The information will be kept confidential but may be disclosed (shared) as required by law with your written authorization.

Your health information that may be used or disclosed includes:

- All records concerning tests and treatment which occurs as part of the study.
- Preexisting health information incorporated into these records.

Your health information may be used or disclosed by:

- The principal and co-investigators for the study as listed on the consent form.
- Personnel from the investigators and co-investigators offices.

- Saint Vincent Health Center

Your health information may be disclosed to:

- Saint Vincent Health Center Institutional Review Board (IRB) or another IRB charged with reviewing the study to protect your rights.
- The study's sponsors and investigators.
- Governing agencies involved in overseeing the study.
- Saint Vincent Cardiovascular Surgeons and Physician Assistants

The purpose of disclosing your information associated with this study is to permit those involved in conducting or overseeing the study to:

- Determine its results
- Assess its safety
- Make suggestions for changes

Authorization for disclosure of your information in connection with this study does not have an expiration date.

Your records will be maintained for at least seven years or until the study is completed, whichever is longer.

Please note:

You do not have to agree with this authorization for disclosure of your information, but if you do not, you may not be allowed to participate in the study.

You have the right to revoke (stop) your authorization in writing at any time. To revoke your authorization, you must write to the Principal Investigator's office listed on the consent form:

Primary Investigator's name: Kate Reynolds, PT

Primary Investigator's address: 232 W.25th Street Erie, PA 16541

If you revoke this authorization, you may be required to drop out of the study. Your request to revoke authorization will be acted on as quickly as possible. Any information released before your request for revocation was received may continue to be used. The potential exists for information which is disclosed before the request was made to be subject to re-disclosure by the recipient and no longer protected by the HIPAA Privacy Rule.

WHAT HAPPENS IF YOU HAVE MORE QUESTIONS?

Your questions about the research study will be answered by Kate Reynolds, PT, at (814) 452-5978. If you have questions about your rights as a research subject that you need to discuss with someone else, you can call Saint Vincent Health Center at (814) 452-5717 and talk to an individual in the Research Office.

HOW DO YOU FIND OUT ABOUT NEW INFORMATION?

It is the primary investigator's job to keep you informed about any new findings in the study. New concerns, risks or gains that may affect your choice to stay in the study will be given to you by the primary investigator either over the phone or in a letter as soon as possible after the information is received.

HOW DO YOU FIND OUT ABOUT THE STUDY'S RESULTS?

Any participant interested in receiving the results of the study can check the box listed on the accompanying form, "**Instructions to Participants**", asking for the findings to be sent to them via email or phone call.

SUBJECT'S STATEMENT

I had a chance to ask questions about this study. These questions were answered to my satisfaction.

I realize that being in this study is my choice. I am not under 18 years of age. I know that I may refuse to be in this study or quit the study at any time without penalty or loss of health care. I also know that the primary investigator may decide at any time that I should no longer be in this study. When I sign this consent, I do not lose any of my legal rights for medical or financial help should I become injured because of this study. I have read the information in this consent form. By signing this consent form, I certify that:

- all information I have given in my medical history is true and correct,
- my role in this study has been explained to me,
- I agree to be in this study, and
- I authorize the use and disclosure of my health information as explained within this form.

I was given a copy of this consent form for my own records.

Subject's Signature

Date

Witness to Subject's Signature

Date

Investigator's Signature

Date

This consent document has been approved for use for one year by the Human Subjects

Institutional Review Board (HSIRB) as indicated by the stamped date and signature of the board chair in the upper right corner. Do not participate in this study if the stamped date is older than one year.

2/2007

Appendix I

Consent Letter (Follow-up Research One Year Later)

June 29, 2011

Dear Prospective Participant,

You are invited once again to participate in a research study, following-up one year after your open heart surgery. The study, **“Is Preoperative Functional Status a Predictor of Postoperative Mortality, Morbidity and Quality of Life in Open Heart Patients?”** is conducted by me, Kate Reynolds. I am a Physical Therapist at Saint Vincent Health Center and a PhD student at Western Michigan University and conducted the study before you underwent open-heart surgery. As you might recall, you were mailed a brief questionnaire before surgery (some of you filled it out while in the hospital) and again six weeks after surgery. This study is asking you to complete the exact same questionnaire, now one year after surgery, and will compare all three questionnaire responses for changes in functional status and quality of life over time. From your consent in the first study, I will also review past records of when you had open-heart surgery, to see how other risk factors, besides functional status, influenced your open heart surgery recovery.

If you are willing to participate one last time, please complete the enclosed questionnaire. Self-explanatory instructions are included but if you have any questions about the questionnaire, please contact Kate Reynolds at (814) 452-5978. Completing the questionnaire should take you only about 10 minutes to complete and needs to be done without assistance. However, if you require help in recording your answers, only your answers are to be recorded. There are a total of 48 questions and one section has two columns that both need filled out. After completing your questionnaire, please use the enclosed self-addressed stamped envelope and mail back promptly.

Your participation is completely voluntary. If you choose not to participate, you do not need to return your questionnaire. There are no risks or benefits to you in answer and returning the questionnaire. However, your input may shed light on changes in quality of life and functional status for future patients choosing to undergo open-heart surgery. All information provided by you will be kept strictly confidential and will be used only for the purposes of this study. Any identifying information will be removed from the data and not released to any third party.

If you have any questions regarding the research or your rights as a participant, please contact Saint Vincent Health Center at (814) 452-5601 and talk to an individual in the Research Office.

Sincerely,

Kate Reynolds, M.P.T., C.C.S.
Principal Investigator

Appendix J

Instructions to Participant

Instructions to Participant

Please take the time to fill out this questionnaire now one year after your open heart surgery. Then place the forms and this instruction sheet in the stamped envelope mailed to the researcher, Kate Reynolds.

I appreciate your participation and contribution to this research. If you have any questions, please contact me, Kate Reynolds, at (814) 460-1769.

Please mark any boxes that applied to the completion of the questionnaire:

☐ Physical assistance to mark answers due to _____

☐ Mental assistance to answer questions due to _____

Would you like to be informed of the results of this study?

If yes, please provide me with your email, phone # or home address so that I can contact

you: _____

You will receive the results no later than May, 2012. (Initial results were limited due to minimal feedback so early after surgery).

Thank you again for your time and for participating. Hope you are well on your way to recovery. Happy 1 year anniversary! Sincerely, Kate Reynolds

Appendix K

Saint Vincent IRB Approval Letter

SAINT VINCENT HEALTH CENTER
232 West 25 Street
Erie, Pennsylvania 16544
814/452-5000



June 29, 2011

Ms. Kate Reynolds
145 West 36 Street
Erie, PA 16508

Dear Ms. Reynolds:

On June 29, 2011 expedited approval was awarded to your study, "Is Preoperative Functional Status a Predictor of Postoperative Mortality, Morbidity and Quality of Life in Open-Heart Patients?" and waived the requirement to seek informed consent from participants. Approval was based on the acceptance of a letter that will be provided each participant; a copy of which is enclosed. As previously stated in my letter of June 23, 2011, requirement to obtain informed consent was waived as your research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (45 CFR Part 46.117.c.2).

The Saint Vincent Health Center IRB will be notified of this expedited action at its July 21, 2011 meeting.

Be advised that as the approved clinical investigator, you will be required to present an updated report at the IRB meeting scheduled for May 2012. Any proposed changes in the research protocol affecting the subject must be brought to the attention of the IRB prior to initiation. An exception is any change made in an emergency (life-threatening) situation for the benefit of a subject. You, as the clinical investigator, are required to notify the IRB of all adverse events. Significant adverse events may require you to request an emergency meeting of the IRB.

You may begin the study upon receipt of this letter. Please keep a copy of this letter with the file about the study and share this letter with the sub-investigators of the study. Should you require additional support for your study, please call the Research Office at (814) 452-5601.

Please do not hesitate to contact the IRB office at 452-5601 if you have any additional questions.

Sincerely,

SAINT VINCENT HEALTH CENTER

Olivia C. Purchase
IRB Administrator

C: A. Grimone, Pharm.D.
IRB Chair

Appendix L

Western Michigan University IRB Approval Letters

WESTERN MICHIGAN UNIVERSITY



Human Subjects Institutional Review Board

Date: June 7, 2011

To: Kieran Fogarty, Principal Investigator
Adriane Kate Reynolds, Student Investigator for dissertation

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 11-06-06

This letter will serve as confirmation that your research project titled "Is Preoperative Functional Status a Predictor of Postoperative Mortality, Morbidity, and Quality of Life in Open Heart Patients?" has been reviewed under the **expedited** category of review by the Human Subjects Institutional Review Board.

Before final approval can be given please address each of the following concerns. We expect that you will find the revisions requests to be productive and that you will revise your protocol according to our suggestions or in similar ways. If you think a particular revision is not in the best interest of the human subjects in your study, or you think an entirely different approach to the issue is best, please provide a written explanation and/or call us for consultation.

1. Informed Consent Process section of the protocol outline:
 - It is confusing to have the consent document include the original language when that portion of the study has been completed.
 - Please create a new consent form simply asking to collect the 1 year follow-up data.
 - Also, given that you are using St. Vincent's as your affiliation for consent, please obtain approval from them prior to receiving approval from the HSIRB.
2. The original study was not reviewed by WMU; therefore, we are requesting approval from St. Vincent's first.

In a cover letter to the HSIRB, indicate whether you have made the requested change; addressed the issue in a different way than the one the reviewers suggested; are directing the reviewers to the pages in your protocol that address the issue; or are providing a justification for not making the requested change.

Please submit your cover letter and one copy of the revised protocol with the changes highlighted within the document to the HSIRB, 251 W Walwood Hall (East Campus). **Remember to include the HSIRB project number (above).**

Conducting this research without final approval from the HSIRB is a violation of university policy as well as state and federal regulations.

If there is anything you don't understand about these comments, you are welcome to call the research compliance coordinator (387-8293) for consultation.

Walwood Hall, Kalamazoo, MI 49008-5456
PHONE: (269) 387-8293 FAX: (269) 387-8276

WESTERN MICHIGAN UNIVERSITY

Human Subjects Institutional Review Board

Date: July 19, 2011

To: Kieran Fogarty, Principal Investigator
Adriane Kate Reynolds, Student Investigator for dissertation

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 11-06-06

This letter will serve as confirmation that your research project titled "Is Preoperative Functional Status a Predictor of Postoperative Mortality, Morbidity, and Quality of Life in Open Heart Patients?" has been **approved** under the **expedited** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: July 19, 2012