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THE COGNITIVE AND FUNCTIONAL IMPACT OF OPEN HEART SURGERY: A PILOT STUDY INCLUDING THREE COMMON PROCEDURES (CORONARY ARTERY BYPASS GRAFT, HEART VALVE REPLACEMENT, AND LEFT VENTRICULAR ASSIST DEVICE)

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

by

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Dedications

to Michael,

for enduring love and quick-witted humor that revitalizes and sustains me through all my

endeavors

to my parents,

for unwavering love and support, and for "stereo parents" that brightens up every day

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Activities of daily living	ADL
American Occupational Therapy Association	AOTA
Cardiopulmonary bypass	CPB
Cardiovascular disease	CVD
Cognitive Disabilities Model	CDM
Coronary artery bypass graft surgery	CABG
Heart valve replacement	HVR
Hospital Anxiety and Depression Scale	HADS
International classification of functioning, disability, and health	ICF
Instrumental activities of daily living	IADL
Kettle Test	KT
Left ventricular assist device	LVAD
Montreal Cognitive Assessment	MoCA
Occupational Therapy	OT
Occupational Therapy Practice Framework: Domain & Process	OTPF
Physical Self Maintenance Scale	PSMS
Virginia Commonwealth University Health	VCUH
World Health Organization	WHO

Abstract

THE COGNITIVE AND FUNCTIONAL IMPACT OF OPEN HEART SURGERY: A PILOT STUDY INCLUDING THREE COMMON PROCEDURES (CORONARY ARTERY BYPASS GRAFT SURGERY, HEART VALVE REPLACEMENT, AND LEFT VENTRICULAR ASSIST DEVICE)

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This study investigated the impact of open heart surgery (Coronary Artery Bypass Graft, Heart Valve Replacement, or Left Ventricular Assist Device placement) on cognition, functional performance, and mood in the three months following surgery. The Montreal Cognitive Assessment (MoCA), Kettle Test (KT), Physical Self Maintenance Scale (PSMS), and Hospital Anxiety and Depression Scale (HD) measured global cognition, functional cognition, functional performance, and mood states, respectively.

Thirteen male participants (ages 38 – 75) completed assessments at four time points -- when they were scheduled for surgery, within one week prior to surgery, before hospital discharge after surgery, and three months after surgery. ANOVA analyses were

conducted on overall raw mean scores taken at these time points. Correlational analysis compared changes in cognition and functional performance of daily activities for this group. Effect size estimations and power analyses were conducted to estimate sample sizes needed for adequately powered subsequent study. Two measures (KT and PSMS) were adequately powered at 95% for the study sample. Functional cognition as measured by the KT improved significantly after surgery and surpassed baseline within three months after surgery. Functional performance as measured by the PSMS declined significantly after surgery but returned to baseline within three months after surgery. Global cognition as measured by the MoCA did not change, was not correlated with other measures, and was below norms at all time points. Mood states as measured by the HADS did not change and were above norms at all time points.

This study had a small sample, only male participants, and one pooled group that did not allow for group comparisons. Two measures were self-reported, which may have impacted results due to responses biases. Despite these limitations, this is one of the first studies to track and compare both cognitive and functional performance changes over time. As such, this study may help practitioners and researchers improve and prioritize assessment and treatment options for individuals with cognitive and functional performance deficits after open heart surgery.

Chapter One: Introduction

This dissertation provides evidence that open heart surgery is accompanied by declines in the functional performance of daily activities and functional cognition and that these factors improve over time. The study sought to compare functional cognition and the functional performance of daily activities among three common open heart surgery groups (coronary artery bypass graft [CABG], heart valve replacement [HVR], and left ventricular assist device [LVAD] placement). This chapter provides an overview of the problem of cognitive decline after open heart surgery. This chapter continues with a discussion of the purpose of the study, specific aims, hypotheses, the theoretical framework, and the rationale for this study.

The annual occurrence of new myocardial infarctions in American adults is ~605,000 and ~371,000 patients had inpatient coronary artery bypass surgery in 2014 (Benjamin et al., 2018). More than five million adults are diagnosed with heart valve disease per year (Nikomo et al., 2006) and roughly 102,425 adults had valve replacement surgery in the United States in 2013 (Benjamin et al., 2018). The prevalence of heart failure in American adults is ~6.5 million, the number of LVAD placements has increased from 98 in 2006 to 2423 in 2014, and the proportion of LVAD placements as destination therapy is 45.7% (Benjamin et al., 2018). Destination therapy refers to LVAD placement for the rest of the patient's life expectancy rather than as a bridge to heart transplantation.

Open heart surgery is a life-saving procedure for patients who need CABG, HVR, or LVAD placement, but it also carries a risk of cognitive injury. During these surgeries, the heart is stopped and blood is temporarily circulated through the body by a cardiopulmonary bypass (CPB) machine. Cognitive injury during CPB has been attributed to embolization, microembolism, longer time on CPB, and arterial hypotension during prolonged CPB (Benedict, 1994); and recently has been attributed to inflammatory substances from the vasculature that disrupt the blood brain barrier (Abrahamov et al. 2017).

Cognitive deficits have been reported as sequelae to each of the three primary open heart surgery procedures. CABG surgery leads to an improvement in cardiac function, but between 30 and 60% of this population may also develop deficits in cognitive function (Knipp et al., 2017; Newman, Kirchner, et al., 2001; Van Dijk et al., 2002). Research suggests that patients have more cognitive deficits after HVR surgery compared to patients after CABG surgery, possibly due to more particulate air emboli from the valve itself (Zimpfer et al., 2002), or due to increased cerebral air microembolism from the open cardiac chambers during surgery (Hudetz et al., 2011). Research on cognitive function in patients after LVAD has identified a postoperative cognitive decline in attention, working memory, problem solving (Fendler et al., 2015), executive function (Fendler et al, 2015; Komoda, Drews, Sakuraba, Kubo, & Hetzer, 2005), slower mental processing speed, and deficits in verbal and visual memory functions (Petrucci et al., 2006). One study found an initial improvement in cognitive function for patients undergoing long term LVAD support six months after surgery, but a decline at twelve months (Slaughter, Sobieski, Gallagher, Dia, & Sliver, 2008). A later

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study found that age and destination therapy were associated with cognitive decline in 21% of patients by one year after LVAD implantation; however, 44.5% had no significant change, and 34.5% experienced an improvement (Fendler el al., 2015).

Researchers have tracked cognitive changes after open heart surgery and found that deficits may last as long as five years (Newman, Grocott, et al., 2001; Tully, Baker, Knight, Turnbull, & Winefield, 2009), caregivers recognize deficits more readily than patients themselves (Kastaun et al., 2016), and these deficits are associated with poor satisfaction with the performance of activities of daily living (ADL; Phillips-Bute et al., 2006). Historically research literature has focused on cognition and function separately. Little is known about the relationship between cognitive dysfunction and everyday functional performance after open heart surgery.

Significance

The estimated direct and indirect cost of cardiovascular disease (CVD) for 2014 was $329.1 billion (Benjamin et al., 2018) which is expected to increase to ~$918 billion by 2030 (Mozzaffarian et al., 2015). CVD accounts for ~836,546 American deaths every year (Benjamin et al., 2018). Per the Heart Disease and Stroke Statistics – 2018 Update, a report form the American Heart Association (Benjamin et al, 2018), prevalence of CVD in adults >=20 in the 2014 US population is as follows: males (36.6%), females (37.4%), White males (37.7%), White females (35.1%), Black males (46.0), Black females (47.7%), Hispanic males (31.3%), and Hispanic females (33.3%). 2014 National US data for mean length of stay was as follows: all cardiac surgeries (6.3 days), CABG (9.3 days), HVR (9.7 days), and LVAD (20 days; Benjamin et al., 2018).

CABG surgery leads to an improvement in cardiac function, but deficits in cognitive function may also develop in over one-third of the population receiving this surgery (Knipp et al., 2017; Newman, Grocott, et al., 2001; Van Dijk et al., 2002). Cognitive function follows a similar course for patients after HVR with early postoperative decline followed by recovery after three months (Knipp et al., 2017). Cognitive decline also occurs in patients after LVAD placement and is linked to destination therapy and older age (Fendler et al., 2015).

The types of cognitive deficits present after open heart surgery are typically determined by tabletop neuropsychological test batteries (Keith et al., 2002; Newman, Grocott, et al., 2001; Simoni et al., 2014; Van Dijk et al., 2002). While neuropsychological testing reveals much about cognitive deficits, it is costly and time-consuming. Recommendations have been made to develop and use brief screening tools to effectively reveal cognitive deficits in patients after open heart surgery and to identify at risk patients preoperatively (Benedict, 1994; Evered, Silbert, & Scott, 2016; Petrucci et al., 2006). Establishing the efficacy of screening tools for open heart surgery patients may provide clinicians with more efficient and economical assessment measures to drive therapy for these patients.

Patients report dissatisfaction with activities of daily living performance after CABG surgery (Phillips-Bute et al., 2006), but the type of ADL or instrumental activities of daily living (IADL) affected or to what extent has not been reported. Two studies compared CABG and ADL, but neither identified specific ADL deficits or looked at changes over time (Keizer, Hijman, van Dijk, Kalkman, & Kahn, 2003; Lagercrantz, Lindblom, & Sartipy, 2010). One study found significant changes in everyday functional

performance over six-months in patients 60 years and older after CABG as tracked by the Functional Independence Measure, but did not indicate which ADL were impacted (Niemeyer-Guimaraes, Cendoroglo, & Almada-Filho, 2015). This makes it difficult to accurately determine what supports patients may need to perform their daily functional activities in the weeks and months following surgery.

Studies on functional performance after HVR reported on rates of autonomy (Chaturvedi et al., 2010; Kirsch et al. 1998; Shapira et al., 1997), limitations with ADL (Heijmeriks, Pourrier, Dassen, Prenger, & Wellens, 1999; Huber, Goeber, Berdat, Carrel, & Eckstein, 2007), and use of the Functional Independence Measure to predict discharge location (Ryomoto et al., 2017). Similar to studies on CABG, HVR studies did not look at changes over time with pre- and post-operative assessments, did not consistently provide specifics on which elements of ADL/IADL were deficient, or did not compare pre- and post-operative assessments to determine change over time.

Studies on LVAD and ADL described independence levels after surgery, reported on concerns with ADL performance, reported on activity levels, or provided activity and home recommendations. Studies that addressed independence, reported on return to independence with ADL after implantation (Mehta, Silber, Boehmer, Christensen, & Pae, 2006) and the importance of independence and perceived control with ADL in LVAD recipients (Hallas, Banner, & Wray, 2009). Studies that reported on ADL identified sleeping concerns (Dew et al., 2000), sleeping and showering difficulties (Shapiro, Levin, & Oz, 1996), and bathing and dressing limitations (Rose et al., 2001). One study reported solely on levels of activity during daily life after LVAD placement compared to healthy subjects, but did not identify any ADL/IADL (Granegger et al., 2016). Several

studies provided recommendations on activity restrictions, activity accommodations, home requirements or modifications (Hobson, 1994; Holmes, 2003; Givertz, 2011), and resumption of ADL/IADL (Stahovich, Chillcott, & Dembitsky, 2007; Givertz, 2011). These studies lacked consensus on specific ADL/IADL definitions, did not consistently address all areas of ADL/IADL, did not measure changes in ADL/IADL over time, and did not compare changes in ADL/IADL with cognitive function.

Comparing research reports on cognitive function after open heart surgery can be challenging as these studies do not measure similar time points before and after surgery, or consistently measure changes over time. Likewise, studies on ADL/IADL address different time points before and after surgery and do not measure similar performance activities. Recent studies, however, have begun to report functional performance changes measured over time, as this study does. Researchers have not yet fully explored possible relationships between cognitive change and everyday functional performance after open heart surgery. This study seeks to address that gap in the literature.

Theoretical Framework

The International Classification of Functioning, Disability, and Health (ICF) provides a standardized language and conceptual framework to design and measure health and disability (World Health Organization [WHO], 2001). The ICF conceptualizes functioning as body function, body structures, activities, and participation and the positive dynamic interaction between a person's health and their environmental and personal factors (WHO, 2001). The ICF further conceptualizes disability as impairment, activity limitations, and participation restrictions and the negative interaction between a

person's health and their environmental and personal factors (WHO, 2001). The American Occupational Therapy Association (AOTA) adopted the language of the ICF when they updated the Occupational Therapy Practice Framework: Domain & Process (OTPF) in 2002, and kept this language in both the 2nd (AOTA, 2008) and 3rd editions (AOTA, 2014). The adoption of the ICF language by the occupational therapy (OT) profession reflects the desire to collaborate with other disciplines using a common language and fosters exploration into how OT practice models are aligned with ICF language (Petterson, Petterson, & Frisk, 2012).

The ICF and OTPF both use mental functions (global and specific) when describing personal health factors, and activities and participation when exploring their dynamic interactions (WHO, 2001; AOTA, 2014). The population of adults undergoing open heart surgery may have impairments in mental functions and limitations or restrictions in activities and participation. Occupational therapists seek to improve the occupational performance outcomes of full engagement and participation in activities of interest to the client (AOTA, 2014). The OT process and ICF classifications align with each other through a common language in the shared goal of enhancing and improving participation in client chosen activities.

Models or theoretical frameworks are used to promote engagement and participation in fulfilling occupations during the OT process (AOTA, 2014). This process incorporates cognitive models to explain and guide intervention when personal factors include mental function impairments (AOTA, 2013). An ICF functioning-based approach has been used to look at patients' functionality after completing inpatient cardiac rehabilitation and this approach found that the ICF functional data was aligned with the

patients' clinical course (Racca et al., 2015). Beyond this one study, which primarily focused on movement, exercise, and cardiopulmonary function, past research has not provided a theoretical framework to specifically address the impairments in mental functions and the relationship to activity limitations and participation restrictions in this population.

This study used constructs from the Cognitive Disabilities Model (CDM; McCraith, Austin, and Earhart, 2011) to frame and guide operational definitions of cognition and the relationship to functional performance abilities. The three constructs used were functional cognition, global cognitive deficit, and global functional abilities. For the purpose of this study, the corresponding variables were operationally defined as global cognition, functional cognition, and functional performance. The CDM has explored functional cognition in other populations such as dementia, traumatic brain injury, and severe mental illness (Allen, Earhart, & Blue, 1992). This study not only investigated the presence of functional cognition deficits, but also examined ADL/IADL performance over time and examined post-operative cognitive deficits after open heart surgery through the lens of the CDM. The third chapter discusses the CDM in more detail.

Purpose Statement

The purpose of this study was to determine whether cognition and functional performance of daily activities are affected by open heart surgery, whether cognition and function change over time, and whether there is a correlational relationship between any change in cognition and function. As a pilot study, another aim was to determine effect sizes and sample sizes necessary for adequately powered subsequent studies.

Research Questions

       This study was designed to provide evidence in support of the following questions, assessed at two times before surgery, within three days before discharge after surgery, and at three months after surgery:

1. Is there a change in global cognition among adults who undergo open heart surgery (CABG, HVR, and LVAD) over time as measured by the Montreal Cognitive Assessment (MoCA)?

2. Is there a change in functional cognition among adults who undergo open heart surgery (CABG, HVR, and LVAD) over time as measured by the Kettle Test (KT)?

3. Is there a change in self-reported functional performance of ADL/IADL among adults who undergo open heart surgery (CABG, HVR, and LVAD) over time as measured by the Physical Self Maintenance Scale (PSMS)?

4. Is there a change in self-reported level of anxiety and depression among adults who undergo open heart surgery (CABG, HVR, and LVAD) over time as measured by the Hospital Anxiety and Depression Scale (HADS)?

5. Are there correlations between global cognition, functional cognition, the self-reported functional performance of ADL/IADL, and self-reported level of anxiety and depression among adults who undergo open heart surgery (CABG, HVR, and LVAD) over time as measured by the MoCA, KT, PSMS, and HADS?

6. What are the estimated effect sizes and sample sizes necessary for adequately powered subsequent study using these measures?

Rationale

Cognitive deficits are a frequent sequel to open heart surgery. Typical post-operative cardiac recommendations request neuropsychological batteries for determining cognitive deficits, but more recent research recommends the use of simple screening tools (Liimatainen et al., 2016; Murkin, Newman, Stump, & Blumenthal, 1995; Gaviria, Pliskin, & Kney, 2011). This study used quick screening tools to satisfy this recommendation. Previous research indicates that patients are dissatisfied with everyday functional performance post-operatively (Kaustan et al., 2016; Phillips-Bute et al., 2006), but these studies did not report the level of ADL/IADL performance after surgery. This study used a self–report questionnaire to examine the patients perceived level of ADL/IADL function. Anxiety and depression are common to open heart surgery patients and may influence both cognition and functional abilities (Vingerhoets, de Soete, & Jannes, 1995). Depression and anxiety symptoms have been reported in adults before and after CABG surgery and a relationship appears to exist between age and anxiety; younger adults (<60 years) appear to have higher levels of anxiety before surgery that declines significantly after surgery, whereas adults 60 and older have lower rates that do not change over time (Krannich et al., 2007). This study incorporated a self-report questionnaire addressing anxiety and depression levels to examine the level of these emotional states among the study subjects.

The overriding aim of this study was to measure and compare the cognitive and functional challenges experienced by adults after open heart surgery. The OTPF (3rd ed.) affirms that therapists need the best available evidence (AOTA, 2014) to improve outcomes related to occupational performance for patients and their families, and in this

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case, specifically after open heart surgery. This study addresses that need by examining any change in cognition and functional performance of daily activities to provide evidence for improved post-surgical assessment and intervention.

Summary

The risk of cognitive and functional decline after open heart surgery is of concern to patients and to the occupational therapists and other clinicians who work with them. It is crucial to examine the challenges patients may experience in the days, weeks and months following surgery. Occupational therapists and other clinicians need effective and efficient tools to prioritize and implement post-operative plans that better help clients resume their daily routines. Studies are needed to provide support for evidence-based assessments to address cognitive function and functional abilities among people undergoing open heart surgery.

In this study, adult volunteers age 18 or older undergoing elective open heart surgery at Virginia Commonwealth University Health (VCUH) were recruited through a consecutive convenience sample. This study followed a quasi-experimental repeated measures design, using a pre/post-test cognitive, functional performance abilities, and mood assessment series (O_1 O_2 X_1 O_3 O_4). The participants were screened with the MoCA, KT, PSMS, and HADS at O_1 pre-test (at an outpatient clinic one month to two weeks prior to surgery), O_2 pre-test (at an outpatient clinic within one week before surgery), O_3 post-test (within three days from hospital discharge), and O_4 post-test (at an outpatient clinic three months after surgery). The pre- and post-test cognitive and functional performance abilities screening tools were used to measure and compare any changes over time for this open heart group after surgery. The study analyses utilized

repeated measures ANOVA to track changes in mean scores, and comparisons determined whether or not cognition correlated over time with functional performance abilities using Pearson correlation coefficients. The analyses also estimated effect and sample sizes to provide justification for adequately powered subsequent study.

This chapter provided an overview of the purpose, research questions, significance and impact, theoretical framework, and sources of data for the scope of this dissertation. Chapter Two reviews the literature in relation to open heart surgical groups, exposes the gaps in what we know about possible relationships between cognitive change and functional abilities within these groups, reveals problems with past research methodology, examines prior cognitive measures for these groups, and provides a theoretical model to frame cognition and functional abilities for patients after open heart surgery. Chapter Three presents the methodology for this dissertation grounded in and guided by the proposed theoretical framework, and the data analysis plan. Chapter Four presents the results of the statistical analysis and Chapter Five provides a discussion of the conclusions drawn and implications for practitioners and for further research.

Chapter Two: Review of the Literature

This chapter reviews evidence regarding the cognitive and functional performance changes experienced by open heart surgery patients, comparing the impact of three open heart surgery procedures. Research has focused on both cognition and function after open heart surgery, but these variables have been measured separately. As discussed below, recommendations for comparisons have begun to emerge in the last few years.

Three common open heart surgeries are coronary artery bypass graft (CABG), heart valve replacement (HVR) and left ventricular assist device (LVAD) placement. All three appear to impact cognition and functional performance. On-pump is a term that refers to the use of a cardiopulmonary bypass (CPB) procedure. CPB is utilized during open heart surgeries. During CPB, blood is rerouted through a heart-lung machine to be oxygenated and pumped to maintain perfusion of the body.

Intraoperative measures intended to protect the brain during surgeries include hypothermia, anticoagulants, and filters to reduce microemboli. Off-pump CABG surgery has historically been considered as an option to reduce cognitive dysfunction. Comparisons between on and off-pump CABG surgery have not shown this to be an effective or significant option in reducing cognitive impact (Rankin et al., 2003; Samuels, 2006; Shroyer et al., 2017). Off-pump CABG has been shown to have lower graft patency rates with increased risk of graft failure and lower five year survival rates

(15.2%) as compared to on-pump CABG (11.9%; Ernest et al., 2006; Samuels, 2006; Shroyer et al., 2017).

Opinions differ as to the prevalence and functional impact of postoperative cognitive decline. Risk factors associated with increased lingering cognitive dysfunction after surgery include age, gender, prior cognitive function, co-morbidity, time on CPB, and decreased cognitive function at hospital discharge (Benedict, 1994; Funder, Steinmetz, & Rasmussen, 2009; Gerriets et al., 2010). While these studies have shown that cognitive function declines more after CABG surgery with increasing age, studies have not clarified the differences regarding other predictive factors between age groups.

Patients appear to have poorer cognitive function after HVR surgery compared to patients after CABG surgery (Zimpfer et al., 2002; Hudetz et al., 2011). Less is known about the cognitive impact of LVAD. A few studies have measured satisfaction with activities of daily living (ADL) on quality of life scales and have variously shown: (1) cognitive decline at one year after on-pump CABG surgery limited expected improvements in quality of life (Phillips-Bute et al., 2006), (2) no greater improvement in quality of life occurred between patients after on- or off-pump CABG surgery (Tully et al., 2008), and (3) quality of life gains were limited when associated with decreased cognitive function after on-pump CABG surgery (Funder et al., 2009). Satisfaction with the ability to perform ADL is reportedly low in patients after CABG surgery, but little is known about the correlation between satisfaction and actual performance of ADL or instrumental activities of daily living (IADL).

The Cognitive Impact of Open Heart Surgery

The cognitive impact of CPB. Postoperative cognitive deficits are well documented after open heart surgery and attributed to the effects of CPB. There are varying degrees of incidence reported, differing opinions as to causation, and conflicting reports when comparing cognitive outcomes in adults after on and off-pump CABG, HVR, and LVAD surgeries. Off-pump CABG was developed as a safer alternative to on-pump CABG (with CPB). However, as will be discussed below, research has shown no advantage in CABG with off-pump over on-pump procedures in conserving cognition, and artery grafts appear to be less viable after off-pump CABG. While early research focused on the intraoperative effects of CPB on cognition and how to minimize these effects lower preoperative cognitive levels may also be present in patients with heart failure.

CPB is traditionally conducted and monitored during open heart surgery by anesthesiologists. Gao et al. (2005) discussed techniques used in anesthesia to help preserve cognitive function that include bypass machine advances, new warming techniques, and a "beating-heart" procedure. Preventative pre- and intra-operative risk factors include: hemodynamic stability, hypothermia, minimal invasion, mechanical devices (intra-aortic filter to reduce microemboli), ultrafiltration to trap inflammatory mediators, and leukocyte depletion to reduce oxygen free radical-mediated lung injury (Gao et al., 2005). These protective factors are typically incorporated during CPB and may reduce but not prevent cognitive impact.

Proposed mechanisms of cerebral injury include embolization (from air trapped in the heart and then released when cardioplegia is terminated), microembolism (from

manipulation of the heart and cross-clamping of the aorta that releases atheromatous

material), and arterial hypotension during prolonged CPB (Benedict, 1994), which may

result in neuronal starvation. Memory and attention deficits have been associated with

emboli and poor middle cerebral artery blood flow respectively (Fearn et al., 2001). CPB

may cause microemboli, hypoperfusion, systematic inflammatory response, as well as

atheroembolism to the brain due to surgical manipulation of the ascending aorta (Baba

et al., 2007). A recent study implicates inflammatory substances typically found only in

the vasculature that appear to disrupt the frontal lobe blood brain barrier during CPB

and are associated with attention and executive function deficits (Abrahamov et al.

2017). We know, too, that postoperative cognitive decline appears to occur after other

surgeries and may not be isolated to cardiac surgery alone (Evered et al., 2016).

The cognitive impact of CABG surgery. Studies on patients after CABG

surgery have looked at those on CPB, called on-pump CABG, and those without,

referred to as off-pump CABG. During off-pump CABG, surgery is conducted on a

beating heart without rerouting the blood to a heart-lung machine or CPB. Comparisons

have been made between patients after CABG surgery with non-surgical cardiac groups

(including those with coronary artery disease and heart failure) and healthy controls.

Several studies have compared on and off-pump CABG to determine which provided

the best outcomes.

On-pump CABG surgery. On-pump CABG research has provided insight into

the types of cognitive deficits, proposed injuries to the brain that impact cognitive

function, intraoperative risk factors, and patient characteristics that predict decline

(Fearn et al., 2001; Gao et al., 2005; Baba et al., 2007). To a lesser degree research on

the correlation with quality of life has been explored, while the effect of cognitive decline on ADL is alluded to but not explored or explained (Phillips-Bute et al, 2006). Findings as to the types of cognitive deficits, rates and duration of cognitive decline, and predictors of cognitive decline on patients after on-pump CABG are discussed below, along with recommendations for future research.

Neuropsychological batteries have revealed insights into the types of cognitive deficits that occur after CABG. An early literature review cited deficits in visual attention, visuomotor tracking, and memory (Benedict, 1994). Other studies found a decline in attention, concentration, perceived motor speed and memory for 255 patients (Croughwell et al., 1994) and deficits in attention, recent memory, psychomotor speed, and verbal fluency in 63 patients (Bruggemans, van Dijk, & Huysmans, 1995). Ninety patients subjectively reported cognitive declines in memory, concentration, and sustained attention six-months after CABG surgery (Vingerhoets et al., 1995). In a study of 261 patients, 86% of the variance in cognitive functions after CABG was found to be represented by four cognitive domains: (1) verbal memory and language comprehension (short and delayed), (2) abstraction and visuospatial orientation, (3) attention, psychomotor processing speed, and concentration, and (4) visual memory (Newman, Grocott, et al., 2001).

Varying rates of cognitive decline have been reported in the literature. Toner et al. (1994) examined magnetic resonance imaging (MRI) and neuropsychological test batteries on patients after CABG surgery and noted postoperative deficits in ~1/3 of the patients in verbal and nonverbal memory and attention. Croughwell et al. (1994) reported, similarly, that 38% of patients experienced cognitive declines in attention,

concentration, perceived motor speed, and memory at discharge. Vingerhoets et al. (1995) compared a checklist of subjective complaints and neuropsychological tests on patients six months after CABG, finding that patients reported cognitive declines in memory (46%), concentration (38%), and sustained attention (33%). Newman, Kirchner, et al. (2001) reported a higher incidence of cognitive decline than previous studies, with 53% at discharge, 36% at six weeks, 24% at six months, and 42% at five years; additionally this study found that cognitive function at discharge was significant ($p < 0.001$) for prediction of long-term function.

Lower rates of cognitive decline have been reported in the literature that looked at brain imaging after surgery. Bendszus et al. (2002) incorporated diffusion-weighted magnetic resonance imaging to examine the frontal lobe of the brain in 35 patients after CABG, correlated this data with neuropsychological results, and found no new focal deficits after surgery. While 26% of patients had new ischemic lesions, these were not correlated with impairment in neuropsychological test performance postoperatively. Similarly, Knipp et al. (2004) examined incidence of brain injury in 29 patients after CABG and found new ischemic lesions (45%) were revealed on MRI at discharge as well as impairment in attention, memory and executive function in six out of thirteen tests, but impairments were not associated with the new lesions and five of six functions resolved at six months. Verbal learning, however, remained impaired.

Higher rates of cognitive decline have been reported more recently in the literature. A study of 27 patients found a higher incidence of cognitive decline (48%) after CABG surgery compared to 10% with less invasive percutaneous coronary intervention (Ahlgren, Lundqvist, Nordlund, Aren, & Rutberg, 2003). A subsequent

literature review (Hanning, 2005) found that rates of postoperative cognitive decline were more prevalent in patients after CPB compared to patients after non-cardiac surgery. Boodhwani et al. (2006) found that 59% of 448 patients undergoing on-pump CABG displayed postoperative cognitive dysfunction. Chernov, Efimova, Efimova, Akhmedov, & Lishmanov (2006) reported a cognitive decline in memory and attention postoperatively at 96%, dropping to 55% at six months for a sample of 65 CABG patients.

A noteworthy observation was pointed out by Baumgartner (2007), that several studies neglected to report improvements in cognitive function after CABG, that there must be considerations into the impairment in cognition that may already be present in this population prior to the operation, that long-term or late cognitive declines may be related to pre-operative conditions, and there may be an increased risk for development of dementia in this population. The author commented that the majority of neurocognitive deficits are resolved in this population three months post-operatively as compared to control groups. Tully & Baker (2013) also report a high frequency of pre-surgical neurocognitive impairment among cardiac surgery patients.

Examining predictive factors of cognitive decline and CABG. Predictive factors associated with more severe cognitive deficits after CABG include advancing age, longer time on CPB, and severe heart disease and are associated with cognitive deficits that manifest in areas of visual attention, visuomotor tracking, and memory (Benedict 1994). Croughwell et al. (1994) found baseline cognitive scores, years of education, and increasing arterial-venous oxygen difference as predictors of cognitive impairment. Kilo et al. (2001) determined that CABG predicted short and long-term

cognitive impairment at seven days and four months and that diabetes mellitus and concomitant carotid artery stenosis repair predicted cognitive benefit in the long-term. Post-operative decline, number of microemboli, and degree of improvement at eight weeks were predictors of 43% of variance of change in cognitive function at five years in 107 patients after CABG (Stygall et al., 2003). Persistent a-fibrillation predicted deficits at three years in 104 patients after CABG, and authors concluded that compared to 80 subjects in the nonsurgical control group, CPB caused long-term cognitive deficits (Zimpfer et al., 2004).

In contrast, high education level, abnormal left ventricular function, elevated preoperative serum creatinine, and prolonged stay in intensive care units were identified as independent predictors of cognitive decline, however previously documented predictors (age, time on CPB, diabetes, and peripheral/carotid artery disease) were not significant in a study of 448 CABG patients by Boodhwani et al. (2006). Rosengart et al. (2006) asserted that baseline cognition more accurately predicted long-term decline after CABG in 35 patients when compared to a cognitively matched group of 42 participants. Gerriets et al. (2010) completed neuropsychological assessment preoperatively and postoperatively at two to four days and at three months on 106 patients undergoing CABG and identified visual memory and delayed verbal recognition as the most important domains of long-term cognitive decline. Early neuropsychological bedside testing was suggested as the best predictor of this decline compared to cerebral biomarkers, diffusion-weighted magnetic resonance imaging, age, and intraoperative variables.

Pre- and postoperative predictive factors for cognitive decline. Research for

on-pump CABG has provided insight into preoperative risk factors of cognitive decline

such as age, longer time on CPB, and severe heart disease (Benedict, 1994). Baseline

cognitive scores, years of education, and increasing arterial-venous oxygen difference

have been found to be predictors of cognitive impairment in attention, concentration,

perceived motor speed, and memory at hospital discharge (Croughwell et al., 1994).

Newman, Kirchner, et al. (2001), in a study of 261 patients, found that cognitive function

at discharge predicted long-term function. Post-operative decline, number of

microemboli, and degree of improvement at eight weeks were predictors of 43% of

variance of change in cognitive function at five years in 107 patients (Stygall et al.,

2003). Bokeriia et al. (2007) compared the microembolic load at the left and right middle

cerebral arteries (MCA) in patients after open heart and CABG surgeries and found

verbal memory declines were correlated with increased load at the left MCA and

nonverbal memory declines at the right MCA in patients after open heart surgery. Verbal

memory declines were associated with length of CPB time and not microembolic load in

patients after CABG. Funder, et al. (2009) cited five factors that potentially contribute to

cognitive dysfunction: atherosclerosis, cerebrovascular disease, hypertension, diabetes,

and increasing age.

      CABG versus other patients. Research that compared CABG with other

patients reported incidence and duration of cognitive deficits, predictors of cognitive

decline, and differences in cognitive decline between groups. When comparing patients

after CABG or vascular/thoracic operations, incidence of cognitive dysfunction was

higher in CABG at seven days than other surgeries and remained higher at two months

and was associated with prolonged CPB (Murkin, Martzke, Buchan, Bentley, & Wong, 1995). Neurocognitive testing pre- and postoperatively in 104 patients after CABG compared to an age and gender matched non-surgical control group (n = 80) showed deficits in attention and memory at four months after surgery (Zimpfer et al. 2004).

A few studies showed no difference between comparison groups or an improvement in cognitive function. Rosengart et al. (2006) compared elderly patients (mean age of 65 in control and 67 in CABG and percutaneous coronary intervention [PCI]) undergoing either CABG or PCI to an age and education matched control group, finding no significant differences at baseline and at three weeks in tests of attention, fine motor dexterity, processing speed, language, executive function, verbal learning, and memory. An overall improvement was seen in both CABG and PCI groups at four months. Selnes et al. (2008) compared patients after CABG with nonsurgical cardiac patients measuring eight cognitive domains (verbal memory, visual memory, visuoconstruction, language, motor speed, psychomotor speed, attention, and executive function) at baseline, twelve months and six years, and while cognitive decline occurred in patients after CABG it was not significantly different from non-surgical cardiac patients and not specifically related to CPB. Anastasiadis et al. (2011) determined that after CABG surgery patients on minimal extracorporeal circulation showed significant improvement in complex scanning, executive function, verbal working memory and long-term memory when compared to patients on conventional extracorporeal circulation at discharge and in addition, visuospatial perception showed significant improvement at three months along with the areas noted at discharge.

Off-pump CABG surgery. In an effort to reduce the intraoperative risk factors of on-pump CABG, off-pump CABG emerged and became popular during the 1990s and early 2000s. Researchers found better initial cognitive outcomes for the off-pump procedure, but comparison studies of long-term cognitive outcomes were inconclusive. Additional research with better comparison groups and long-term outcome measures indicated no apparent advantage of off-pump over on-pump in preserving cognition. Furthermore, off-pump CABG seemed to result in less viable artery grafts than on-pump. These studies are summarized below.

On-pump versus off-pump CABG. Studies comparing on- and off-pump CABG surgeries reported rates, duration, predictors, and types of cognitive decline. Initial studies found high rates of decline with lingering deficits at six months and attributed this decline to microemboli. Diegeler et al. (2000) compared intraoperative microemboli in the middle cerebral artery and cognitive function in 40 patients after on and off-pump CABG, and discovered cognitive impairment in 90% of 20 patients after on-pump CABG and none in 20 patients after off-pump CABG, which appeared to be associated with the occurrence of microemboli. Stroobant, Van Nooten, Belleghem, & Vingerhoets (2002) compared 49 patients undergoing on and off-pump CABG and found no significant cognitive differences between groups at either point after surgery compared with baseline cognitive performance, however cognitive declines were present in 59% of both CABG groups and persisted in 11% of the on-pump CABG group at six months, suggesting different patterns of decline and recovery of cognitive functions in on and off-pump CABG. These authors attempted to reduce test re-test effects by using alternative versions of cognitive tests whenever available.

Subsequent studies found lower rates of cognitive decline than initial studies. van Dijk et al. (2002) examined 139 patients after on-pump and 142 patients after off-pump CABG, finding cognitive function declined at three months (on-pump 29% and off-pump 21%) and twelve months post-surgery (on-pump 33.6% and off-pump 30.8%). In a study of 115 patients, van Dijk et al. (2004) reported early cognitive decline in on-pump and off-pump CABG groups (49% off-pump and 57% on-pump) predicted cognitive decline at three months and was more strongly associated with on-pump than off-pump groups. In a study of 140 patients, McKhann et al. (2005) found that on and off-pump CABG groups demonstrated significant differences in verbal memory, visual memory, motor speed, psychomotor speed, attention, and executive function at baseline compared to heart healthy controls. Baba et al. (2007) compared 218 patients after on-pump (n = 129) and off-pump (n = 89) CABG and found cognitive dysfunction was present in 11.2% of the off-pump group and 22.5% of the on-pump group. Stroobant, van Nooten, De Bacquer, Van Belleghem, & Vingerhoets (2008) found no significant differences in cognitive function between on-pump (n = 33) and off-pump (n = 21) CABG patients, but cognitive declines were present in 30% of patients three to five years after surgery in non-verbal immediate memory and attention, speed for visual search, visual attention and mental flexibility.

During this timeframe researchers began suggesting that preoperative cognitive function and other previously unidentified factors may be contributing to cognitive deficits after surgery. van Dijk et al. (2002) suggested that factors other than CPB contribute to cognitive decline, that the off-pump procedure may contribute a new mechanism to decline, and that improved outcomes related to the off-pump procedure

may become clear in long-term follow up studies. Rankin, Kochamba, Boone, Petitti, & Buckwalter (2003), found preoperative deficits, particularly in verbal memory and psychomotor speed, in both groups and asserted that preexisting cognitive deficits in patients with vascular disease might skew post-surgery findings. This study recommended pre-surgical and repeated measures postoperatively to examine the degree of impact on cognition over time. Selnes et al. (2007) suggested that cognitive decline in patients with coronary artery disease may not be attributable to surgical intervention or CPB. Funder et al. (2009) reviewed evidence that cognitive decline exists after cardiovascular surgery and recommended consideration of several preexisting factors, including atherosclerosis, cerebrovascular disease, hypertension, diabetes, and increasing age.

Some studies showed no significant difference in cognition between on- and off-pump surgery. Keizer et al. (2003) compared self reported failures in memory, attention, action, and perception during everyday life tasks using the Cognitive Failures Questionnaire between 36 patients after on-pump CABG and 45 patients after off-pump CABG and showed no difference between the groups in reports of cognitive impairment one year after surgery. However, 112 participants in a healthy control group reported cognitive impairment significantly more often than those who had undergone CABG surgery, a finding that was attributed to the higher likelihood of healthier individuals engaging in more challenging tasks and environments than patients who underwent surgery and being more inclined to be aware of their weaknesses. Sakurai, Takahara, Takeuchi, & Mogi (2005) discovered cognitive declines were present in 22.8% of 192 participants after CABG surgery and that there were no differences in incidence of

cognitive dysfunction between the on and off-pump CABG groups. For this group, age was the only significant predictor. Jensen, Hughes, Rasmussen, Pedersen, & Steinbrüchel (2006) hypothesized that the degree and frequency of cognitive dysfunction would be reduced in off-pump compared with on-pump CABG in elderly, high-risk patients, stratified by age (55 – 65 or > 65), however results on 120 patients revealed no significant difference in neurocognitive decline postoperatively at three months. Ernest et al. (2006) compared cognitive outcomes between 107 patients after on and off-pump CABG and found no advantage in using the off-pump method since there was no significant difference between the groups in cognitive outcomes. In a study of 395 patients, Selnes et al. (2007) found no significant differences in post-surgical cognitive function between on- and off-pump CABG groups compared to baseline, however the off-pump group demonstrated significant declines in verbal and visual memory and visuoconstruction at 36 months compared to twelve months.

McKhann et al. (2005) compared the cognitive function of four groups: on-pump CABG (n = 140), off-pump CABG (n = 72), nonsurgical cardiac controls (n = 99), and heart healthy controls (n = 69). Post-surgery results did not reveal significant differences in cognition between the control groups and CABG subjects over twelve months. Tully et al. (2008) randomized 66 CABG patients to on- and off-pump groups and found declines in cognitive function at six days and six months in both groups, but no significant difference between them. Improvements in quality of life were comparable between on- and off-pump CABG groups (Tully et al., 2008). As these studies show, there is no agreement on which of the two procedures – on- or off-pump CABG surgery – may place patients at greater risk of cognitive injury. Researchers agree, however,

that any cognitive dysfunction related to open heart surgery is associated with a decline in quality of life and increased mortality (Funder et al., 2009). Puskas et al. (2011) demonstrated no significant differences in acute cerebral infarcts between on- (n = 41) and off-pump (n = 35) CABG groups, and suggested patients after off-pump CABG showed better cognitive reasoning and a trend towards better verbal learning than those after on-pump CABG. This study, however, lacked a neuropsychological test at baseline, so results are inconclusive.

We do not yet have a definitive answer to the question of whether off-pump procedures reduce the risk of cognitive injury among open heart surgery patients, but other concerns have led surgeons to question the utility of off-pump procedures. Rankin et al. (2003) studied 43 patients and showed no change in either on or off-pump CABG surgery groups at two and a half months, inferring that off-pump CABG contributes neither a protective nor a detrimental contribution to cognitive function postoperatively. Samuels (2006) argued that the increased risk of graft failure with off-pump procedures obviated any potential reduced risk of cognitive injury. Rates of off-pump CABG declined in the US between 2002 to 2012 from 23% to 17%; and the most recent reports for 2016 indicate off-pump procedure rates at 13.1% for the US and Canada (Shroyer et al., 2017). This decline has been attributed to worse graft patency and shorter long-term survival (Shroyer et al., 2017).

Several authors have suggested non-surgical reasons for cognitive decline after CABG surgery. In a prospective study of patients one year after on- (n = 36) and off-pump (n = 45) CABG and age-matched healthy subjects (n = 112), the control group reported more cognitive failures and may have self-selected due to an interest in their

cognitive function (Keizer et al., 2003). Van Dijk et al. (2004) explained early and late cognitive changes between pre and postoperative tests on 281 patients after on and off-pump CABG as regression to the mean. While in their study no significant difference in cognitive impairment was found between patients one year after on- (n = 47) and off-pump (n = 43) CABG surgery, Jensen, Rasmussen, & Steinbrüchel, (2008) suggested that patients lost to follow-up may have had cognitive impairments or the tests may have lacked sufficient sensitivity to detect a difference between the two groups. In a study of 54 patients with endpoint of three years, Stroobant et al. (2008) added support to the body of evidence that CPB may not be the main cause of cognitive decline in the long-term, suggesting chronic vascular disease as a possible cause. Jensen et al. (2008) found no significant difference in cognitive change between 90 patients (43 on- and 47 off-pump) twelve months after surgery, reporting that age was the strongest predictor of cognitive dysfunction after cardiac surgery.

Summary. Research in off-pump surgery has lead to decreased use of this procedure due to reduced life expectancy, poor graft patency and conflicting evidence on its purported cognitive benefit compared to on-pump surgery. Research continues to support the existence of cognitive decline after either type of surgery, but some evidence suggests no difference between the groups. Similar to other CABG surgery studies, on- versus off-pump CABG research has been criticized for lacking appropriate controls, preoperative baseline testing scores, long-term follow up testing scores, and appropriate comparison groups, so that practice guidelines lack sufficient evidence for any final determination regarding the cause of observed cognitive change.

The cognitive impact of HVR surgery. Research on HVR has compared aortic and mitral valve replacement and also compared heart valve replacement with CABG surgery. Cognitive declines appear to be associated with microemboli, which have also been cited as a cognitive risk factor in CABG surgery. Neuropsychological testing batteries have been conducted using the same recommendations as in CABG and have revealed deficits in some of the same areas of cognition. Studies show that patients appear to have poorer cognition after HVR than after CABG. These findings are discussed below.

The cognitive impact of various HVR procedures. Studies on HVR procedures reported types, rates, predictors of cognitive deficits, and mood states. Knipp et al. (2005) evaluated 29 patients after cardiac valve replacement and observed significant declines in memory, attention and rate of information processing at five days, which recovered at four months. In a study of 100 heart valve surgery patients, Hong et al. (2008) found that 23% had postoperative cognitive decline and that low education levels and higher baseline temperatures were significant predictors of this decline. Grimm et al. (2003) compared neurocognitive function on patients after mechanical mitral valve replacement (n = 20) and mitral valve repair (n = 20). Five different versions of the test were used to minimize learning effects. The authors found that cognition continually declined over a four-month period in the mechanical heart valve replacement group, whereas it remained unchanged in the mitral valve repair group. This effect was attributed to more microemboli produced and present in the mechanical heart valve replacement circulation.

Neurocognitive function and mood states were evaluated by Cicekcioglu et al. (2008) on 25 patients after beating heart mitral valve replacement on CPB without cross-clamping the aorta. Neurocognitive tests showed no neurologic or cognitive decline postoperatively, and anxiety and depression as measured by the Hospital Anxiety and Depression Scale (HADS) were found to be significantly lower postoperatively compared to preoperative tests.

HVR versus non-surgical controls. Deklunder, Roussel, Lecroart, Prat, & Gautier (1998) compared attention and memory in twelve patients with histories of mechanical heart valve transplants, twelve patients with biological porcine prostheses, and twelve non-surgical subjects matched for age and verbal intellectual abilities. Results showed no difference between the groups in attention, but the surgical groups demonstrated significantly lower scores in verbal memory. This study only looked at one point in time and did not indicate when patients had their transplants or prostheses placed. Zimpfer et al. (2006), found that 32 patients after mechanical aortic valve replacement declined cognitively as compared with 28 nonsurgical controls, but these scores normalized to preoperative levels at four months and stayed normal when measured at three years.

HVR versus CABG. Zimpfer et al. (2002) compared postoperative cognitive deficits in 30 patients undergoing HVR with biological prostheses and those undergoing CABG. Results showed no difference preoperatively between the groups, but both groups demonstrated decreased cognitive function at seven days postoperatively, whereas at four months the CABG group returned to normal and the HVR group showed continued or worsened cognitive deficits in concentration, memory, learning

and visuo-motor response speed. This was attributed to the higher number of intraoperative microemboli in HVR versus CABG and implicated the biological valve as a possible source of microemboli. Hudetz et al. (2011) compared 44 adults undergoing CABG with or without valve repair or replacement (n = 22), those undergoing CABG alone using CPB (n = 22), and 22 nonsurgical controls. Results showed significantly longer intensive care unit stay, hospital stay, and 30-day readmission rates in patients after valve with/out CABG versus CABG alone. Overall cognitive function was significantly impaired in valve with/out CABG versus CABG alone. While this study confirmed and extended previous findings that postoperative delirium and cognitive decline are greater in valve with/out CABG versus CABG alone, generalization of results is limited to male veterans one-week postoperatively. Knipp et al. (2017) found significant cognitive deficits in executive function, attention, delayed recall, and digit span for both HVR and CABG patients at discharge after surgery followed by a marked improvement after three months to baseline in all areas.

Summary. Research on HVR procedures has attributed declining cognitive function in areas of memory, attention and information processing to microemboli. Predictors of decline include low education and high baseline temperatures. HVR versus non-surgical controls indicate no difference in attention, a decline in verbal memory, but a gradual return to baseline. Comparison studies of HVR versus CABG and HVR versus non-surgical controls have attributed poorer cognitive outcomes after HVR to microemboli. These studies also lacked preoperative and postoperative testing scores and long-term follow up tests.

The cognitive impact of LVAD. LVADs are increasingly being used as a bridge to later heart transplantation due to an increased incidence of heart failure and limited availability of hearts for transplantation. Though a relatively new procedure, research over the last decade suggests cognitive deficits in the LVAD group after surgery that are comparable to those present in patients who undergo CABG or valve replacement. While studies have compared various combinations of CABG, HVR, healthy controls, and non-surgical groups, there is so far no published research comparing the cognitive or functional impact of LVAD with the other open heart surgery groups.

Risks related to LVAD include cerebral embolism due to thrombus development in conduit and valve connection points, or hemorrhagic stroke due to high levels of anticoagulation. Slaughter et al. (2008) evaluated the frequency and incidence of neurological events in patients undergoing long-term support with LVAD. Results indicated a low incidence of neurologic events in the absence of anticoagulation therapy and improvement in neurocognitive function from six to twelve months on the Trail Making Test, however, the Boston Naming Test and Block Design Test improved after six months but then declined at twelve months. The authors concluded that better patient selection and support on LVAD with antiplatelet therapy alone produces low incidence of neurologic complications.

Microemboli have been detected with the use of CPB and LVAD. Decline in executive function may be due to the chronic effect of microemboli. Komoda et al. (2005) compared men ages 25 - 59 without history of stroke in three groups (heart transplant after mechanical circulatory support with thrombus detected (AH-Thr) or without (AH) and then compared them to a control group after heart transplant without

use of mechanical support (HTx). Results indicated poorer cognitive performance in the AH-Thr group with longer completion time and more perseverative errors, suggestive of frontal lobe damage. No baseline preoperative comparison or long-term tests were reported. Petrucci et al. (2006) compared cognitive function in three groups of patients with heart failure and patients potentially needing cardiac assist devices (outpatients, inpatients requiring inotropic infusion, and in-patients likely to require mechanical cardiac assist devices (MCAD). Results showed fewer deficits in the outpatient group. The MCAD group noted more severe deficits including slower mental processing speed and verbal and visual memory functions compared to the other two groups.

One review that analyzed studies on cognitive changes showed improvements in memory, visual memory, and executive function in patients after LVAD implantation attributed to increased perfusion (Simoni et al. 2014). Fendler et al. (2015) reported the incidence of cognitive decline at 29.2% in the year after LVAD implantation, and older individuals (ages >70 versus <50) and individuals receiving LVAD as destination therapy had worse outcomes.

Summary. It appears that patients with LVAD experience cognitive changes post-surgery similar to that of CABG and HVR patients. The deficits cannot be assumed to be unique to this individual group when considering the deficits linked to other open heart surgeries. Studies have lacked baseline preoperative testing scores, appropriate comparison groups, and long-term follow up testing scores. The use of appropriate comparison groups, preoperative and postoperative testing, and the implementation of a functional measure and brief cognitive screening tool may strengthen the results of future studies.

Recommendations for tracking cognitive function after open heart surgery.

Cognitive assessments typically utilize a battery of neuropsychological tests to reveal deficits and detect changes over time. Researchers have used a variety of neuropsychological batteries, observation, patient/family questionnaires, and brain and artery imaging to explore cognitive decline and the effects of CPB on these groups (Bendszus et al., 2002; Bokeriia et al., 2007; Newman, Grocott, et al., 2001; Toner et al., 1994). Areas of cognitive deficits are clearly defined by these tests, however the tests are lengthy and take time to complete. Recommendations have been made to develop and use brief screening tools to effectively reveal deficits in patients after open heart surgery (Benedict, 1994; Liimatainan et al., 2016; Petrucci et al., 2006). Vingerhoets et al. (1995) discovered that patients reporting declines in cognition had significantly higher levels of depression and anxiety states, and thus, personality and mood state instruments were recommended for pre and postoperative evaluations to explore the influence on subjective reports after open heart surgery. Hanning (2005) recommended utilization of sensitive tools with high test-retest reliability. Chernov et al. (2006) recommended the use of alternate versions of neuropsychological tests to reduce test-retest effects.

In order to assess cognitive change after open heart surgery, Benedict (1994) proposed the following considerations: (1) test within two weeks postoperatively and again several months later, (2) attend to possible re-test effects during the neuropsychological examinations, (3) use brief tests to minimize patient fatigue/frustration, ensure full participation, and help reduce attrition rates, (4) randomize patients to groups, (5) use standardized procedures, and (6) repeat

neuropsychological examinations to support return to normal employment and activities of daily living.

In summary, a number of studies have noted cognitive change related to open heart surgery. Critiques of research on cognition and function after surgery have identified poor controls, lack of long-term follow up testing, lack of preoperative baseline testing, and lack of or inappropriate comparison groups. Testing scores at discharge are considered primary predictors of cognitive decline in the long term. Pre- and postoperative testing at discharge and at least three to four months after surgery and assessment of mood states have been recommended for future studies.

Functional Performance Abilities after Open Heart Surgery

CABG and ADL. As discussed above, post CABG cognitive deficits may be present one to five years after surgery and have been correlated with decreased satisfaction in ADL skills (Phillips-Bute et al., 2006). While this reveals a potentially debilitating impact, information is lacking on the type of ADL and the associated level of reduced independence experienced while performing ADL after open heart surgery. While there is evidence that quality of life and ADL skill are related, we do not know how cognitive impairment after cardiac surgery impacts ADL, and if there is a difference over time among surgical groups.

Research on everyday task performance after CABG is scarce and lacks discriminative functional measures as compared to the many studies on post-CABG cognition. Lagercrantz et al. (2010) conducted a retrospective study of 141 patients who had an intensive care unit stay of more than ten days after cardiac surgery, examining survival, functional status, and quality of life, as measured by the Karnofsky

performance scale (KPS) and the Short Form-36 (SF-36) questionnaire. Sixty-five percent of patients had a score of 80 or more on the KPS, indicating they could perform everyday activities without assistance, and 13% had a score of 50 or less, indicating they required considerable assistance with everyday activities. Limitations included no preoperative scores, only one follow-up at approximately two years with no postoperative score near discharge, and a general lack of specifics on ADL/IADL levels.

Cognition and function after CABG. Ahlgren et al. (2003) conducted the only study that correlated measurable cognitive decline to a specific IADL functional performance task, and concluded that CABG may influence cognitive functions necessary for safe driving skills relating to attention and traffic behavior. However, the small sample, non-randomization, and potential differences in non-matching comparison groups limited generalization.

HVR and ADL. Research on HVR and ADL has focused on the impact of surgery on quality of life, autonomy, and everyday function in adults 75 or older. Extant studies do not agree on ADL/IADL definitions or use similar measures. Additionally, they do not fully address participation in and/or change in the ability to perform ADL/IADL over time. The few studies that refer to ADL/IADL are discussed below.

Studies that report on quality of life after HVR had a wide range of post operative assessment points including two and six months (Heijmeriks et al., 1999), between two to 55 months (Shapira et al., 1997), at 2.2 years, 3.6 years and 3.5 years (Chaturvedi et al., 2010), and at five years (Kirsch et al., 1998). All of these studies lacked preoperative measures and with the exception of two studies, only completed one postoperative assessment point, which does not allow for comparison over time.

These studies reported varying rates of quality of life, autonomy, and function. Shapira et al. (1997) found that at follow-up, 96% lived at home and 92% could bathe and dress independently. Kirsch et al. (1998) found across all groups (HVR, CABG and HVR/CABG combined), 63.6% of long-term survivors were fully autonomous after five years. This study did not define autonomy or indicate the autonomy measure they used. Heijmeriks et al. (1999) stated there were similar improvements in both groups two months after surgery with further improvements at six months when comparing quality of life of 200 open heart surgery patients 75 years old or older with 200 younger open heart surgery patients otherwise matched for gender and procedure (coronary, valvular, or coronary/valvular surgery). Huber et al. (2007) reported little or no limitations with ADL for 85% of patients after CABG, 79% of patients after HVR, 76% for patients after CABG/HVR combined, and 81% for all patients combined after surgery. This suggests that CABG patients fare better in functional performance than HVR, and HVR patients fare better than those with CABG/AVR combined surgeries. Chaturvedi et al. (2010) used a combined Barthel index and Karnofsky performance scores (autonomous, semiautonomous, or dependent) on 300 octogenarians after cardiac surgery. 63.9% of subjects were "autonomous", 31.7% were "semiautonomous", and 4.3% were "dependent" at 2.2 years after surgery. At 3.6 years 64.9% were autonomous, 28.1% semiautonomous, and 6.9% were dependent. The results are limited as they are from one institution without preoperative assessment of functional status.

Cognitive decline and the influence on daily living has typically been perceived better by caregivers than patients themselves in the year after surgery; however patients appear to recognize cognitive failures during daily tasks more readily than

previously reported in the literature (Kastaun et al. 2016). Kotajrarvi et al. (2017) compared frail versus non-frail adults before and after HVR and found that frail adults had poorer physical and mental functions, physical well-being, and quality of life than non-frail adults but improved more in these areas after surgery. One study found the preoperative Functional Independence Measure cut off score of 64 points was an effective measure of frailty and predictor of discharge home after HVR, based only on the level of abilities to walk, stand, or swallow (Ryomoto et al., 2017). This study did not report any ADL/IADL abilities.

Summary. As noted above, studies of ADL/IADL function related to CABG, HVR and ADL either lack pre-operative or post-operative tests and/or comparisons over time. Follow up test times vary and the studies lack comparison of functional assessment over time and display responder bias. The varying use of unclear functional measures limits consensus on functional impact among these studies. Most of these studies on HVR reported assessment results years after surgery. While this information suggests that ratings on quality of life, autonomy, and function are high years after surgery, immediate and short-term needs are absent from the literature and there are no time point comparisons over time.

LVAD and ADL. Research on LVAD and ADL addresses either the level of assistance needed with ADL after device placement, recommendations for safety with ADL/IADL participation after device placement, or changes in activity levels. Similar to CABG and HVR, the studies do not address all areas of ADL/IADL or use comparable tools, nor do they measure changes in functional abilities over time. These studies are discussed below.

Studies that examine psychological factors that play a role in quality of life after LVAD placement report decreased satisfaction due to medical complications, difficulty lying on side to sleep, abdominal pain caused by movement of the device, fears of infection or bleeding along the drive line, difficulty showering, confinement to the hospital, boredom, and feeling like a burden instead of a help to their families (Shapiro et al., 1996). Study results on self-reported questionnaires from LVAD inpatients using quality of life assessment in areas of physical functional status reported concerns with sleep and rest related to position of the driveline and noise during sleep (Dew et al., 2000) and limitations, either a little or a lot, in bathing or dressing (Rose et al., 2001). One case study on a patient after LVAD (Mehta et al., 2006) reported a return to complete independence with daily activities, however no return to work, because the employer was reluctant to accept the person back into the factory. One recent study reported that adults increased their daily life activity levels after LVAD, but reached only 53% of activity levels compared to healthy subjects (Graneggar et al., 2016). However, this study measured daily life activity levels only by wrist acceleration and identified no ADL/IADL.

A limited number of studies focus on participation in ADL/IADL after LVAD surgery or on the impact that cognition may have on functional abilities. Quality of life is clearly impacted as evidenced by poor satisfaction with daily activities after surgery in all of these surgical groups, but the specific activities are not clearly or consistently identified by any ADL/IADL measures, nor do they measure changes in functional abilities over time or attempt correlations between cognition and functional performance.

Summary

Open heart surgery appears to be a factor in cognitive decline for open heart surgery patients. The impact of open heart surgery on changes in functional performance areas over time and whether there is a corresponding occurrence between cognition and function after open heart surgery remains unclear. There is little extant research addressing the impact of open heart surgery on everyday functional performance of ADL/IADL or relating cognitive change to functional change after surgery.

The current study addresses gaps in the literature by exploring both cognition and everyday functional performance. As such, it is one of the first to assess and compare changes in both cognition and ADL/IADL among open heart surgery patients using pre- and post-surgery assessments. Chapter Three describes the research methodology. Chapter Four presents the results of the statistical analyses, Chapter Five discusses conclusion drawn from the findings and implications for practitioners and further research.

Chapter Three: Research Methodology

This study compared changes in cognition and everyday functional performance among patients undergoing three common open heart surgery procedures. Global cognition, functional cognition, functional performance, and mood states were assessed at two time points prior to surgery, immediately post-surgery and three months after surgery. That data was analyzed to assess change over time and to explore the impact of surgery on the participants' cognitive and functional ability. This chapter includes pertinent information regarding the study rationale, design, statistical analyses of data, and a description of the study's participants, measures and procedures.

Approval

The Institutional Review Board at Virginia Commonwealth University approved this study, continuing review and the initial and subsequent Informed Consent forms. Copies of the approval letters and Informed Consent forms are included in Appendix A.

Design Rationale

Chapter Two summarized prior research on cognition and functional performance after open heart surgery, discussed problems and evidence gaps associated with prior studies and provided recommendations from study authors on how to address these issues. This study incorporated these recommendations in the following ways by: measuring pre- and post-operative changes in cognition over time, expanding the research focus to include self reports of ADL/IADL performance, identifying the specific

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ADL/IADL that may be impacted by surgery, measuring changes in these functional changes over time, and exploring correlations between cognition and functional performance.

Theoretical Model

The Cognitive Disabilities Model (CDM) is an occupational therapy practice model that was developed to promote engagement in occupations for individuals with cognitive impairment. The model emphasizes the relationship between cognition and function and asserts that assessment of functional cognition provides "an estimate of an individual's functional cognitive capacities at a given moment in time" (McCraith et al., 2011). The CDM defines functional cognition as "a neutral term that connotes an individual's cognitive and functional strengths and limitations, or functional cognitive capacities" and asserts that "a measure of functional cognition suggests identification of both cognitive impairments and remaining cognitive abilities" (McCraith, et al., 2011). The CDM further acknowledges that functional cognitive capacity may change over time for an individual with a cognitive impairment and the process of serial assessment allows clinicians to identify these changes. The CDM was used in this study as a lens to examine cognitive function after open heart surgery. This study design incorporated the CDM's theoretical basis for serial assessment of functional cognitive changes through repeated measures and met the statement of consensus on assessment of neurobehavioral outcomes after cardiac surgery (Murkin, Newman, et al. 1995). A panel of experts from multiple disciplines that included psychology, neuropsychology, neurology, anesthesia, cardiovascular surgery, and epidemiology drafted these guidelines on issues relevant to research in this area as displayed in Table 1.

Table 1

Design Rationale

Consensus Guidelines for assessment of neurobehavioral outcomes after cardiac surgery (Murkin, Newman, et al. 1995)	Study Design Components to Meet Recommendations
"need to be assessed at a time prior to operation to provide accurate baseline information;	(1) preoperative baseline assessments of global cognition, functional cognition and functional performance abilities using the MoCA, KT, and PSMS;
individual change in performance from baseline to a time after the operation is essential to any evaluation of the impact of the operation associated with it;	(2) postoperative assessments of global cognition, functional cognition and functional performance abilities using the MoCA, KT, and PSMS;
because of time constraints and the physical limitations in performing neuropsychological assessment in the context of cardiac operation, care must be taken to select appropriate tests;	(3) the use of brief screening assessments for global cognition, functional cognition and functional performance abilities; the MoCA took up to 10 minutes, the KT took from 10-20 minutes, and the PSMS took up to 5 minutes. Additionally, the MoCA and PSMS only required the physical effort necessary to complete pen/paper tasks and the KT only required the physical effort necessary to prepare two hot beverages;
performance of neurobehavioral tests can be influenced by mood states and mood state variations . . . and it is important that mood state assessments be performed concurrently with the neuropsychological assessments;	(4) the use of an anxiety and depression assessment concurrently with the other assessments to address mood states. The HADS took up to 5 minutes to complete with pen/paper;
selection of the tests should take into consideration cognitive domain, sensitivity/reliability, time taken to perform, degree to which learning may occur, availability of parallel versions, physical effort to perform, and overall balance of the cognitive domains assessed	(5) the MoCA, PSMS, KT and HADS were considered for the constructs measured, sensitivity/reliability/validity, the brief time to administer, the availability of multiple versions for the MoCA, the minimal physical effort to perform them, and the scope of cognitive domains assessed by the MoCA, which was enhanced by the functional cognitive components of the KT;

Table 1. *Continued*

neurobehavioral dysfunction is highest in the immediate postoperative period, care must be taken to perform at least one assessment when performance is more stable . . . at least three months postoperatively; and	(6) assessments were planned for in hospital after surgery and for three months postoperatively;
cognitive testing can be associated with improvement in performance on repeated testing . . . study designs incorporating procedures to minimize practice effects is encouraged"	(7) the use of alternative test forms were incorporated whenever available to minimize any practice effects; and (8) a double pre-test was incorporated to reduce threats from maturation or regression.

This study met the aforementioned recommendations for cognitive assessment after open heart surgery in order to supplement our understanding of the impact of open heart surgery on global cognition, functional cognition, everyday functional performance abilities, and mood states. Additionally, the primary analysis of the feasibility objective was estimation of effect size for power analysis and sample size justification for subsequent study of this population and variables.

Study Design

This quasi-experimental study used a one group double pre-test and double post-test model. The addition of a second pre-test prior to the first was implemented to reduce threats from maturation by: describing pre-treatment differences; revealing threats from regression if the group was atypically lower or higher between pre-tests; and more precisely estimating correlations between observations due to a clearer estimate of the correlation between non-treatment points in time (Shadish, Cook, & Campbell, 2002). This study design incorporated the use of repeated measures, in

order to assess the change in global cognition, functional cognition, functional performance abilities, and mood states over time. The use of this design afforded comparison of changes on assessments within one month and one week before surgery (1st pre-test to 2nd pre-test), with surgery (2nd pre-test to 1st post-test), and within three days before discharge and three months after surgery (1st post-test to 2nd post-test). Power analysis and sample size estimation set the stage for any future study (Moore, Carter, Nietert, & Stewart, 2011; Jairath, Hogerney, & Parsons, 2000).

Determination of Variables

The dependent variables were global cognition, functional cognition, functional performance of ADL/IADL, and mood state variables of anxiety/depression as measured respectively by the MoCA score, KT score, PSMS score, and HADS scores. The variables global cognition, functional cognition, and mood states, as measured by the MoCA, KT, and HADS scores respectively, also served as independent variables when comparing the simultaneous occurrence of functional performance. The main independent variable in this study was open heart surgical group (CABG, HVR, and LVAD). Additionally, pre-morbid conditions (i.e. diabetes, hypertension, dyslipidemia) and operative factors (i.e. CPB time, cross clamp time, postoperative ventilation hours) were tracked and obtained and reported with demographics in Chapter Four.

The main dependent variables in this study were global cognition, functional cognition, functional performance, and mood states. Functional cognition is a main construct of the CDM, which asserts, "a measure of functional cognition suggests identification of both cognitive impairments and remaining cognitive abilities" (McCraith et al., 2011). As mentioned previously, the CDM defines the construct functional

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cognition as "an individual's cognitive and functional strengths and limitations, or functional cognitive capacities" (McCraith et al., 2011). Functional cognition was a continuous variable measured by the KT. Functional cognition was operationally defined for this study as cognitive skills and processing imbedded in the context of a functional task.

The construct "global cognitive deficit", as defined by the CDM, occurs "when the brain's global capacity to function is impaired" (McCraith et al., 2011). Global cognition was a continuous variable measured by the MoCA. Global cognition was operationally defined for this study as cognitive skills and processing.

According to the CDM, "global functional abilities" is a construct that reflects "the integrated, global functioning of the brain and is observed as patterns of behavior across various activities" (McCraith et al., 2011). Functional performance was a continuous variable as measured by the self-report PSMS. Functional performance was operationally defined for this study as the ability to perform ADL/IADL.

The mood state variables in this study were anxiety/depression. Preoperative mood states of anxiety and depression are predictors of postoperative mood and related to deficits in attention and memory (Andrew, Baker, Kneebone, & Knight, 2000). Mood states was a continuous variable measured by the self-report questionnaire HADS. Responses were measured on a scale of zero to 21 with higher scores indicating an increased state of distress. This variable examined changes in mood states over time.

The main independent variable in this study was open heart surgical group. While there was no treatment provided in this study, comparisons were made to determine if there was a difference in global cognition, functional cognition, functional

performance, and mood states for adults undergoing the three open heart surgery procedures of CABG, HVR, or LVAD placement over time. The three surgical groups were pooled into one open heart surgical group.

Findings from the repeated measures assessment were analyzed and the resulting means were used to estimate effect size for power analysis and sample size. The software Nquery was used to estimate sample sizes of a one-group repeated measure ANOVA for subsequent study considerations at 80%, 90%, and 95% power.

Participant Selection

Recruitment. This study recruited patients from Virginia Commonwealth University Health (VCUH) Ambulatory Care Clinic who were scheduled for elective open heart surgery involving one of the following procedures: (1) coronary artery bypass graft (CABG) surgery, (2) single heart valve surgery (HVR; aortic or mitral), or (3) left ventricular assistive device (LVAD) placement surgery. Recruitment for this study was open from October 2015 through February 2017. Enhanced compensation became available in May 2016 after approval by the committee and from the IRB. Adult patients ages 18 + were recruited by the study team. The original goal was to recruit 36 participants, twelve in each surgical group. There are no studies of this type to estimate an effect size; thus as a feasibility study, a sample size of at least n = 12 for groups with continuous variables was considered appropriate for single center studies in planning of larger studies. This was based on increased precision of CI width from n of five to 10 compared with an n of 10 to 15, and diminishing benefits in precision beyond an n of 15 (Moore et al., 2011). Over the course of the study, it became apparent that this sample would not be achieved. Even group sizes were required for appropriate statistical

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comparative analysis in the proposed study. In discussions with the dissertation committee, it was agreed that the actual recruited sample of thirteen total participants would be pooled into one open heart surgery group. The original analysis was changed to appropriately analyze the combined, uneven group sample size. The final sample size for this study was five CABG, six HVR, and two LVAD subjects that were pooled into one group as previously discussed.

Inclusion/Exclusion. Volunteers age 18 or older scheduled for elective open heart surgery were recruited through non-probability, consecutive convenience sampling. Exclusion criteria were based on functional capacity factors that could bias measurement or for geographic residency that could impact retention and follow up. Volunteers were excluded from participation if they had a clinical diagnosis of dementia, stroke or brain injury with residual cognitive deficits, intellectual disability, visual impairment that impeded safe preparation of hot beverages, or inability to use at least one hand for writing and preparation of hot beverages. Volunteers were also excluded for residence location outside the city of Richmond or adjacent counties of Henrico, Hanover or Chesterfield.

Description of the settings. The initial pre-test, 2nd pre-test, and three month post-test assessments all occurred at a VCU Health Ambulatory Care Clinic visit, and the discharge 1st post-test assessments occurred in hospital within three days before discharge. The KT required an unoccupied room with an electrical outlet, running water, and a stable table or counter for the kettle and supplies. The care clinic environment had a consistent staff room with a table, sink, countertop, and electrical outlet. The

hospital rooms consistently had a sink with a side counter, electrical outlet, and a stable bedside table.

Personnel and Materials

The surgeon, nurse practitioner, and clinic nurses prescreened and provided recruitment flyers (see Appendix B) to potential participants identified as needing one of the elective open heart surgical procedures (CABG, HVR, or LVAD). The researcher then approached potential participants, obtained consent, completed demographic forms, conducted the pre-test and post-test assessments, entered data into SPSS, and ran the analyses.

The MoCA, PSMS, and HADS only required the printed assessment forms and pen/pencils to fill them out. The KT required a table for the items, a working electrical outlet for the kettle, and running water. Data analysis was conducted using the statistical software SPSS v. 24.0 and NQuery Advisor ©, Version 7.0 (2007).

Procedures

The researcher obtained testing booklets, assessment materials/supplies, and a consistent room in the ambulatory care clinic and inpatient units for testing. At consent the researcher obtained the participants' addresses, phone numbers and email for future contact, and the date and time of their scheduled elective surgery. Fifteen volunteers consented to participate in the study. One volunteer consented to participate, signed the consent forms and planned to return to complete the initial assessments at the next scheduled clinic visit. At the next visit, this individual chose to withdraw from the study before completing the initial assessment due to concerns about ongoing transportation. The timetable for assessments is displayed in Table 2.

Table 2.

Timetable for Assessments

Time	Assessments
1st Pre-test: outpatient (Within 1 month to 2 weeks prior to surgery in outpatient clinic)	Consent and Initial Assessment (Demographics Form, MoCA, KT, PSMS, and HADS)
2nd Pre-test: outpatient (Within 1 week prior to surgery in outpatient clinic)	Pre-surgery Assessment (MoCA, KT, PSMS, and HADS)
1st Post-test: inpatient (Within three days before discharge at hospital)	Post-surgery Discharge Assessment (MoCA, KT, PSMS, and HADS)
2nd Post-test: outpatient (three months after discharge in outpatient clinic)	Post-surgery Follow-up Assessment (MoCA, KT, PSMS, and HADS)

Initial assessment. Fourteen volunteers were assessed within one month prior to surgery in the ambulatory care clinic at VCUH. At that time the volunteers signed the consent and demographics form. The volunteers were screened for enrollment through observation of vision and dexterity needed to fill out the demographics form and by the responses on the form. Once the volunteers met inclusion the 1st pre-test assessments were conducted, including the MoCA, KT, PSMS, and HADS. Following completion of the initial assessments, fourteen volunteers who met the inclusion criteria were invited to continue with the study. Before leaving, the researcher scheduled the next pre-test appointment, which was held within one to seven days before surgery.

2nd pre-test. Thirteen participants were assessed at the ambulatory care clinic within one week before surgery. At this time the 2nd pre-test assessments were conducted, including the MoCA, KT, PSMS, and HADS. Prior to ending the session, the researcher confirmed the date and time of their surgery, anticipated discharge date, and informed volunteers that progress notes would be monitored remotely to determine when they were approaching discharge and that their next assessment would be scheduled within three days before discharge. One volunteer was unable to complete the rest of the study at this point and her information was not included in the data analysis.

Post-test at discharge. Following surgery, the participants were assessed in their inpatient hospital room after surgery, prior to their discharge home. Progress notes were monitored for a definitive date of discharge, and once clearly set the researcher contacted the participant to complete the assessments. At this time the researcher conducted the 1st post-test assessments including the MoCA, KT, PSMS, and HADS. Prior to leaving, the researcher reconfirmed contact information and scheduled the three-month assessment date and time to coincide with the participant's ambulatory care clinic visit. The researcher called one week before the three-month visit to confirm the appointment.

Three-month post-test. The participants were assessed at a scheduled visit in the ambulatory care clinic at their surgical follow up appointment. At this time the researcher conducted the 2nd and final post-test assessments including the MoCA, KT, PSMS, and HADS. This three-month follow up visit concluded the participants' involvement in the study. Participants were given a $25.00 gift card as a token of

gratitude for their time. Additionally, a raffle was drawn after the completion of the study and one additional participant received a $50.00 gift card.

Measures

Assessment tools included:

Demographics form. This form captured demographic information about each participant, including gender, age, education level, race, community dwelling status, brief medical history, and open heart surgical group category. This form is presented in Appendix C.

Global cognition measure. This variable was defined as cognitive skills and processing, and measured by the Montreal Cognitive Assessment.

Montreal Cognitive Assessment. A widely used screening tool for detecting cognitive impairment, the MoCA consists of thirteen tests in eight cognitive domains: visuospatial/executive function, naming, memory, attention, language, abstraction, delayed recall and orientation. This test consists of three pen/paper tasks (connecting numbers/letters in series, copying a drawing, and drawing a clock), immediate and delayed recall of five words, forward/backward repetition of digits, sentence repetition, timed generation of words beginning with a given letter, verbalizing what is similar about two words, and stating the date, place and city. The scoring ranges from zero to 30, with the following classifications: (>26) normal cognition, (23 – 26) mild cognitive impairment, (17 – 22) moderate cognitive impairment, and (<= 16) severe cognitive impairment, which is suggestive of dementia (Nasreddine et al., 2005). One point is typically added to the total score for individuals with twelve or less years of education.

After open heart surgery, neuropsychological assessment indicates individuals may experience deficits in visual perception, attention, short-term memory, mental processing speed, decision-making, and executive functioning (Keith et al., 2002; Newman, Grocott, et al., 2001; Van Dijk et al., 2002). While informative, neuropsychological batteries are lengthy and not efficient for pre- and post-testing because they can take several hours to complete. The MoCA is a tool that screens for the deficits typically found in this population. While the MoCA has not yet been used for assessment on the population that has had open heart surgery, it has been applied to other disorders successfully. The MoCA has proven accurate as a screening tool for mild cognitive impairment in populations with Alzheimer's disease (Nasreddine et al., 2010), chronic heart failure (Athilingam et al., 2011; Cameron et al., 2010; & Harkness, Demers, Heckman, & McKelvie, 2011), stroke (Toglia, Fitzgerald, O'Dell, Mastrogiovanni, & Lin, 2011), dementia (Kasten, Bruggemann, Schmidt, & Klein, 2010; Smith, Gildeh, & Holmes, 2007), cardiovascular disease without dementia (McLennan, Mathias, Brennan, Russell, & Stewart, 2010), Parkinson's disease (Hoops et al. 2009), Multiple Sclerosis (Waspe, Vorobeychik, & Beauregard, 2008), and Huntington's disease (Videnovic et al., 2010).

While the Mini-Mental State Examination (MMSE) has been shown to discriminate between moderate and severe cognitive impairment, the MoCA is more sensitive to mild cognitive impairment (MCI) in patients with advanced heart failure (Gaviria et al., 2011). The MMSE and MoCA both identify deficits in language, memory recall, and orientation in patients with chronic heart failure, but the MoCA is also able to recognize deficits in concentration, visuospatial ability, and executive function (Cameron

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et al., 2010). The MoCA screens the primary areas of cognitive deficit revealed by neuropsychological batteries, and may prove useful in screening for patients with postoperative cognitive dysfunction after open heart surgery. Repeated testing may reveal persistent deficits and identify patients that require further neuropsychological assessment. The MoCA meets the standards of the consensus statement for cognitive assessment after cardiac surgery (Murkin, Newman, et al., 1995), because it is brief, has multiple versions for pre-test and post-test use, a wide scope, and it requires minimal physical effort by the participant. The three versions of the MoCA allow for the use of randomized versions during pre-tests and post-tests, in order to reduce any learning effects by repeated use of the test.

The MoCA provides a useful screening tool for detecting patients with mild cognitive impairment (MCI). The validity of the MoCA was established for use in detecting MCI with high test-retest reliability and good content validity when compared to the MMSE (correlation coefficient = 0.92, P < .001), good internal consistency (Cronbach's alpha = 0.83), a sensitivity of 90% to detect MCI with cutoff score <26 compared to 78% on MMSE, and a specificity of 87% as compared to 100% on MMSE (Nasreddine et al., 2005).

The MoCA has excellent test-retest reliability with internal consistency of .83 across items (Nessaradine et al., 2005). The MoCA demonstrates sensitivity (90%) and specificity (78%) for MCI in outpatients with heart failure (Harkness et al., 2011). The MoCA demonstrates 90% sensitivity in patients with heart failure compared to 18% sensitivity on the Mini Mental Status Exam (MMSE) with a cutoff score of <24 (Nasreddine et al., 2005). The MoCA detects the presence of cognitive impairment as

demonstrated by >70% of patients with heart failure scored <26 on MoCA (Harkness et al., 2011). Normative data from a population-based sample of subjects with cardiovascular disease stratified by age and education, without applying the one-point correction for <12 years of education, suggest a more appropriate cutoff score as (< 24) for impairment (Rossetti, Lacritz, Cullum, & Weiner, 2011).

Athilingam et al. (2011) found the MoCA was more effective than the MMSE in revealing different degrees of cognitive impairment on patients with heart failure. The MoCA (score $\leq$26) demonstrated 54%of patients had MCI, 17% had moderate cognitive impairment (score $\leq$22), whereas only 2.2% of these same patients showed a cognitive decline using the MMSE. The MoCA revealed deficits in delayed recall, visuospatial/executive function, language, immediate memory, attention, and abstraction; however compared to the MoCA the MMSE only revealed deficits in language (Athilingam et al., 2011). Gaviria et al. (2011) reiterated support for use of the MoCA, as opposed to the MMSE, due to its sensitivity in detecting mild cognitive impairment and executive function. Furthermore they recommended use of the MoCA as a brief assessment on patients with advanced heart failure rather than lengthy neuropsychological batteries that take several hours to conduct and encouraged conducting a comprehensive neuropsychological battery pending abnormal results on the MoCA (Gaviria et al., 2011).

McLennan et al. (2010) explored the predictive value of cognitive impairment on limitations in IADL in adults with cardiovascular disease who did not have dementia. Gender, cognitive status, age, cardiovascular disease burden, and non-cardiovascular disease burden were associated with the likelihood of assistance needed for $\geq$ 1 daily

activity. The likelihood increased with each additional cardiovascular diagnosis present and each lower point on the MoCA. A score of <23 on the MoCA was associated with 7.7 times more likely to need assistance with everyday activities. Cognitive assessments in patients with cardiovascular disease were recommended, as subtle changes in cognitive scores were the primary predictor of needing assistance with daily tasks (McLennan et al., 2010).

In 2011, McLennan, Mathias, Brennan, & Stewart, continued investigating the MoCA for sensitivity and specificity in detecting amnestic MCI and multiple-domain MCI in patients with cardiovascular diseases or risk factors when compared to the Neuropsychological Assessment Battery Screening Module. Cognitive impairment was found in 72.1% of the population with scores <26 and performance declined with age. The MoCA demonstrated 100% sensitivity detecting amnestic MCI and 83% specificity detecting multiple-domain MCI, however specificity was low for ruling out amnestic MCI (29.2%) and multiple-domain MCI (29.6%). With adjusted cutoff scores of <24, sensitivity remained the same, however, specificity improved to 50% for amnestic MCI and 52.0% for multiple-domain MCI. These results were similar to other studies and recommendations were made to cautiously use the MoCA in populations that have low prevalence of cognitive impairment. Additionally, the authors encouraged using the MoCA as a repeated measure rather than one time screening tool as a single point assessment of cognition has limited clinical relevance (McLennan et al., 2011).

In summary, several researchers have made recommendations for a brief screening tool to reduce fatigue and to identify patients at risk for and in need of more in depth neuropsychological testing. The MoCA addresses the areas of change revealed

by neuropsychological testing in previous studies of patients with cognitive deficits after CABG, HVR, and with LVAD. Additionally, the MoCA has multiple test forms to reduce learning the test in repeated use and can be performed in 10 minutes, making this test convenient and non-fatiguing for those tested. These characteristics support and meet recommendations for cognitive screening improvement noted in many of the studies cited above.

Functional cognition measure. This variable was defined as cognitive skills and processing embedded in the context of a functional task and measured by the Kettle Test.

Kettle Test. Designed to screen for the impact of cognitive impairment in a functional context, the KT (Harman-Maeir, Armon, & Katz, 2005) measures areas of attention and working memory, executive function, and functional performance. Test subjects are asked to complete a common kitchen task, specifically preparing two hot beverages. During the KT the examiner observes the participant preparing two hot beverages and rates the participants' performance on the amount of assistance and/or cueing needed to complete the thirteen steps of the activity. Thirteen steps of performance are assessed: (1) opening the water faucet, (2) filling the kettle with about two cups of water, (3) turning off the faucet, (4) assembling the kettle, (5) attaching the electric cord to the kettle, (6) plugging the electric cord in an electric socket, (7) turning on the kettle, (8) assembling the ingredients, (9) putting the ingredients in the cups, (10) picking up the kettle when the water boils, (11) pouring the water into the cups, (12) adding milk, and (13) indication of task completion. Items of the test are scored on a 4-point scale (0 – intact performance, 1 – slow and/or trial & error, 2 – received general

cues, 3 – a) received specific cueing, b) incomplete or deficient performance, or 4 –

received physical demonstration or assistance. Scoring ranges from zero – 52 and

higher scores correspond with poorer performance.

The KT has strong convergent validity on patients with stroke as demonstrated

on correlation with MMSE ($r = 0.478$), Clock Drawing Test ($r = 0.566$), Star Cancellation

subtest of the Behavioral Inattention Test ($r = .578$), and Functional Independence

Measure (FIM) cognitive scale ($r = 0.659$; Hartman-Maeir, Harel, & Katz, 2009). Test-

retest reliability is excellent for rater-pairs ($r = 0.851$, $p = 0.001$; $r = 0.916$, $p = 0.000$) at

two hospitals on patients after acute stroke (Hartman-Maeir et al., 2009). The KT has

excellent ecological validity with significant correlation to ADL on the FIM Motor Scale (r

$= .759$), and adequate correlation with the Routine Task Inventory Safety Rating Scale

($r = .571$) and IADL scale ($r = .505$; Hartman-Maeir et al., 2009). The KT has not been

tested with any cardiovascular populations, and the KT and MoCA have never been

compared or used concurrently. This study served as novel uses for both of these

purposes.

Functional performance measure. This variable was defined as the level of

ability to perform ADL/IADL and measured by the Physical Self-Maintenance Scale.

Physical Self-Maintenance Scale. A self-rating survey of everyday functional

performance, the PSMS uses a five-point scale to query independence or dependence

in six ADL items and a three, four, or five-point scale for eight IADL items (Lawton &

Brody, 1969). The ADL tasks include: (1) toileting, (2) feeding, (3) dressing, (4)

grooming, (5) physical ambulation, and (6) bathing. The IADL tasks include: (1) ability to

use the telephone, (2) shopping, (3) food preparation, (4) housekeeping, (5) laundry, (6)

mode of transportation, (7) responsibility for own medication, and (8) ability to handle finances. The rating an individual self-reports on this scale reflects their highest self-reported level of functional performance on the current day (Lawton & Brody, 1969). Total independence on any item in either ADL or IADL is rated as a one. Each subscale ranges either one to three, one to four, or one to five depending on the task. Total dependence is rated as a three, four, or five, and scores for each item are combined for a total score. Scoring ranges from six to 30 for ADL and eight to 32 for IADL, a lower score indicating a higher level of independence (total combined ADL/IADL scores range from 14 to 62). The PSMS screens for current performance and when used over time can document self-reported improvements or declines in performance of ADL/IADL. The rating scale demonstrates that a higher score reflects more assistance to complete an ADL/IADL. The PSMS does not measure all areas of function as defined by the OTPF (AOTA, 2014). It does not ask about the ADL tasks of swallowing/eating, personal device care, and sexual activity, or the IADL tasks of care of others, care of pets, child rearing, religious/spiritual activities and expression, and safety/emergency management.

Reliability has been established through a Guttman scale reproducibility coefficient of 0.96 for ADL and 0.93 for IADL, test-retest reliability for ADL as 0.94 and for IADL as 0.88 (Lawton & Brody, 1969); Edwards, (1990) established intraclass correlation coefficients for ADL as $r = 0.96$, IADL as $r = 0.99$, test-retest reliability coefficient for ADL = 0.56, IADL = 0.93, and total ADL/IADL = 0.91. Validity of the PSMS was established with two nurses rating 36 patients, which produced a Pearson correlation of 0.91 (Lawton & Brody, 1969). Correlation was high (0.70) between the

Functional Independence Measure (FIM) and ADL on the PSMS, but low between the FIM and IADL (0.33), and FIM and total ADL/IADL (0.50; Edwards, 1990).

Mood state measure. This variable was defined as the level of anxiety and depression and measured by the Hospital Anxiety and Depression Scale.

Hospital Anxiety and Depression Scale. Consistent with recommendations by Murkin, Newman, et al., (1995) in the consensus statement for cognitive assessment after cardiac surgery, which stated that mood state assessment should be completed concurrently with cognitive assessments, the HADS was administered to examine the amount of anxiety and depression subjects reported. The HADS is a fourteen-item self-rating scale, comprised of seven questions related to anxiety and seven questions related to depression. Each response is rated on a four-point scale of zero to three.

The HADS asks the participant to rate their most immediate response on a Likert scale to fourteen questions (seven for anxiety and seven for depression) about their feelings over the last week. An anxiety question, for example, states, "worrying thoughts go through my mind", and the responses and the rating scale are: (3) a great deal of the time, (2) a lot of the time, (1) from time to time, but not often, or (0) only occasionally. A depression question, for example, states, "I have lost interest in my appearance", and the responses and the rating scale are: (3) definitely, (2) I don't take as much care as I should, (1) I may not take quite as much care, or (0) I take just as much care as ever. This variable was a continuous score zero – 21 and resulted in separate scores for anxiety and depression, with higher scores indicating a higher degree of distress. The total score was interpreted as follows: (0 – 7) normal, (8 – 10), borderline, and (11 – 21) abnormal.

Poole and Morgan (2006), explored validity and reliability of the HADS in a cardiomyopathy population and established test retest reliability for anxiety with $r = .36$ at 2 weeks $p = .048$ (significant with $p < .05$), and depression with $r = .84$ at 2 weeks $p < .001$. Wang, Chair, Thompson, & Sheila (2009) provide support for excellent test retest reliability ($r – 0.86 – 0.90$) on patients with coronary heart disease (n = 178). The scale performs best with a cutoff score of eight, with the depression subscale sensitivity (100%) and specificity at (87%) and anxiety subscale sensitivity (96%) and specificity (79%); compared to a cutoff score of ten, where depression subscale sensitivity drops to 27% and specificity improves slightly to 79% (Poole & Morgan, 2006). Therefore during analyses the variable will be interpreted as normal (score 0 – 7), and abnormal (8 or above). The self-report of the HADS introduced a social desirability bias through a possible underestimation of feelings on this scale. Participants were allowed to complete the assessment in private before the examiner reentered the room in an attempt to reduce this bias.

Hypotheses

This study compared changes in cognition and functional abilities for participants undergoing open heart surgery. Study hypotheses included:

- H_A1 = There will be a statistically significant change in global cognition as measured by the MoCA in adults who undergo CABG, HVR, and LVAD placement over time.

- H_O1 = There will be no statistically significant change in global cognition as measured by the MoCA in adults who undergo CABG, HVR, and LVAD placement over time.

- H_A2 = There will be a statistically significant change in functional cognition as measured by the KT in adults who undergo CABG, HVR, and LVAD placement over time.

- H_O2 = There will be no statistically significant change in functional cognition as measured by the KT in adults who undergo CABG, HVR, and LVAD placement over time.

- H_A3 = There will be a statistically significant change in the functional performance of ADL/IADL as measured by the PSMS in adults who undergo CABG, HVR, and LVAD placement over time.

- H_O3 = There will be no statistically significant change in the functional performance of ADL/IADL as measured by the PSMS in adults who undergo CABG, HVR, and LVAD placement over time.

- H_A4 = There will be a statistically significant change in mood states as measured by the HADS in adults who undergo CABG, HVR, and LVAD placement over time.

- H_O4 = There will be no statistically significant change in mood states as measured by the HADS in adults who undergo CABG, HVR, and LVAD placement over time.

- H_A5 = There will be positive correlations among global cognition, functional cognition, functional performance of ADL/IADL, and mood states as measured by MoCA, KT, PSMS, and HADS in adults who undergo CABG, HVR, and LVAD placement over time.

- H_O5 = There will be no positive correlations among global cognition, functional cognition, functional performance of ADL/IADL, and mood states as measured by MoCA, KT, PSMS, and HADS, in adults who undergo CABG, HVR, and LVAD placement over time.

Statistical Analysis

The original plan sought to recruit a sample of 36 participants, twelve in each surgical group. In the end, only thirteen participants completed the study, so the original analysis plan was revised. Upon advice of the dissertation committee, participants in the three surgical groups were combined under one open heart surgery category, and data analysis measures were adapted to better accommodate this change for more appropriate analysis with uneven group sizes. For reference purposes, the originally proposed and approved study design and data analysis are included in Appendix D.

The MoCA, KT, PSMS, and HADS assessment tools used in this study provided scores for comparisons at each time point. All data was screened for normality. Data from the assessment tools were entered into the statistical software SPSS v. 24.0 for Mac (2016) to conduct the following calculations:

Descriptive statistics were run to examine and present the demographic data. The results revealed basic similarities and differences in the population.

MoCA, KT, PSMS, and HADS: Mean overall scores from participants were calculated for each of the four administrations of the tests. Repeated measures ANOVA was used to compare change on this assessment across administrations for each individual in the group, with a significance of $p < .05$. Mauchley's test of sphericity was

used to determine whether the assumption of sphericity was violated and if a corrected *F* statistic was needed (Tabachnick & Fidell, 2007).

MoCA, KT, PSMS, and HADS: Mean scores from each participant were calculated across each of the four administrations of the tests. Pearson's Correlation two-tailed significance tests were calculated to produce correlation coefficients to determine if there was relationship between measures.

Effect size: Effect size was estimated to calculate power analysis and generate an appropriate sample size necessary for subsequent study of the population and variables of interest using NQuery Advisor ©, Version 7.0 (2007).

Data analyses provided preliminary data on the study analysis plan, effect size for power analysis, and justification for sample size in any subsequent study. Data analyses were piloted and the resulting means were used to conduct sample size estimates. The software Nquery was used to determine the appropriate formula to estimate effect size of one-way repeated measures ANOVA for each measure. Next, this formula determined the time and group effect sizes for each measure. Then, power analyses were completed to determine the sample size necessary for appropriately powered subsequent study at 80%, 90%, and 95% for each measure.

Summary

Cognitive change after open heart surgery is a frequent problem that may limit participation in everyday functional activities. Evaluating global cognition, functional cognition, functional performance of daily activities, and mood states is important in order for occupational therapists to address the needs of their patients in the days and months after open heart surgery. This chapter has explained the methods used in this

quasi-experimental study to examine and compare change in cognitive and functional

abilities over time after open heart surgery. The original data analysis planned before

the study revision is presented in the appendices. The results of the statistical analysis

as conducted are presented in Chapter Four. Chapter Five will provide a discussion of

the conclusions drawn and implications for practitioners and for further research.

Chapter Four: Results

The primary study objectives were to identify any differences in global and functional cognition in adults who undergo CABG, HVR, and LVAD placement over time, determine differences in the functional performance of ADL/IADL for this group over time, and compare correlations between global cognition, functional cognition, functional performance of ADL/IADL, and mood states for this group over time. Additionally, effect size estimations and power analysis were conducted to estimate sample sizes necessary for adequately powered subsequent study.

As previously noted, the original analysis design was not feasible due to a small sample with uneven group sizes. The overall sample was only thirteen participants (CABG = five, HVR = six, LVAD = two) and rather than splitting them into individual uneven groups, they were pooled into one open heart surgery category. As a pilot study, data analysis was conducted with an emphasis on determining effect size and sample size for future research considerations. The outcomes were evaluated using an ANOVA repeated measures design across four data collection points on total scores and sub scale scores using the Montreal Cognitive Assessment (MoCA), Physical Self Maintenance Scale (PSMS), Kettle Test (KT) and Hospital Anxiety Scale (HADS) measures. Analyses were completed using means calculated from the measures' overall scores. The effect size was determined to recommend appropriate sample size and power analysis considerations for future research. Additionally, analyses were run

on the measures at each time point to see if change in cognition and mood correlated to change in everyday function. Descriptive information and the statistical analysis of tested measures are described in the following sections.

Characteristics of the Participants

Of 23 individuals identified as eligible for the study, fifteen agreed to participate (65.25%). Retention was high for the study (86.7%). One male participant withdrew after consent due to ongoing issues with transportation and concerns over the time commitment, and the lone female participant was not available after the initial assessment. Data from the remaining thirteen participants (all males) were used in the analysis.

Of the thirteen participants who completed the study (See Table Three for demographic information), three identified as Black/African American (two in the CABG and one in the HVR group) and the remaining identified as White. Mean age was 60.15 (*SD* 11.28) with a range from 38 to 75. Mean length of hospital stay for open heart surgery (LOS) was 6.45 days (*SD* 3.751) with a range from three to fourteen days.

The participants were able to complete the four assessments overall within a range of 25 - 35 minutes at each session. Participants were able to complete both of the self-report questionnaires (HADS and PSMS) in five to ten minutes, the MoCA within ten minutes, and the KT in ten to fifteen minutes. The overall total time increased from 40 to 70 minutes for some participants depending upon their preference to drink the beverage they prepared, engage in conversation, or both.

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Table 3

Descriptive Statistics of Demographic Information

	n	*% or Mean (Range)*
Age (years)	13	60.15 (38 - 75)
30 – 39	1	7.7%
40 – 49	1	7.7%
50 – 59	3	23.0%
60 – 69	4	30.8%
70 – 79	4	30.8%
Sex		
Male	13	100%
Race		
White	10	76.92%
Black/African American	3	23.08%
Surgical Group		
CABG	5	38.46%
HVR	6	46.15%
LVAD	2	15.39%
Co Morbidities	13	
Diabetes	4	30.8%
Dyslipidemia	9	69.2%
Hypertension	6	46.2%
Sleep Apnea	4	30.8%
Arrhythmia	5	38.5%
LOS (days)	13	6.45 (3 - 14)
CPB (minutes)	13	146.91 (82 - 224)
Cross Clamp Time (minutes)	13	98.89 (53 - 152)
Lowest Temperature (°C)	13	33.36 (28.8 – 35.4)
Total Hours ICU	13	69.59 (22 - 191)
Total Postoperative Ventilation Hours	13	3.55 (0 - 14)

Change in Global Cognition, Functional Cognition, Functional Performance, and

Mood States

This study sought to compare changes in cognition and everyday

function among patients who underwent three types of open heart surgery. Global

cognition was measured with the MoCA and functional cognition was measured with the

KT. ADL/IADL functional performance was measured with the PSMS. Mood states of

anxiety and depression were measured with the HADS. The MoCA, KT, PSMS and

HADS were conducted at the four time points for assessment in the study.

Confidence intervals were calculated to estimate the range in which the

population parameter is likely to occur. This signifies the results are 95% confident that

the unknown population variables will likely fall between the lower and upper bounds.

The mean scores for each outcome measure are presented in Table 4.

Table 4

Outcome Measures Mean Raw Scores Over Time

Outcome Measure	1st Pretest M [95% CI]	2nd Pretest M [95% CI]	1st Posttest M [95% CI]	2nd Posttest M [95% CI]
MoCA	23.6 [21.7, 24.5]	25.0 [23.7, 26.3]	23.2 [21.1, 25.2]	24.3 [22.9, 25.7]
PSMS	15.7 [13.1, 18.2]	14.7 [14.1, 15.3]	23.9 [19.1, 28.8]	15.2 [13.4, 17.1]
KT	7.7 [5.1, 10.3]	2.1 [1.2, 3.0]	4.0 [2.2, 5.8]	4.4 [1.6, 7.1]
HADS (Anx)	5.0 [3.0, 7.0]	4.6 [3.4, 5.7]	3.8 [2.3, 5.3]	3.4 [.73, 6.0]
HADS (Dep)	3.2 [1.2, 5.2]	2.6 [.73, 4.4]	3.7 [2.2, 5.3]	2.5 [.53, 4.6]

Notes: CI = confidence interval [lower bound, upper bound]; HADS: Hospital Anxiety and Depression Scale (score range = 0 – 21; higher scores indicate higher anxiety and depression; normal = 0 – 7, abnormal = 8 or above); KT: Kettle Test (score range = 0 – 52; higher scores indicate poorer functional performance); MoCA: Montreal Cognitive Assessment (score range = 0 – 30; higher scores indicate better cognition); PSMS: Physical Self Maintenance Scale (score range = 14 – 61; higher scores indicate poorer performance).

Repeated measures ANOVA. Repeated Measures ANOVA comparisons were

conducted for each test to determine whether differences in mean scores were

statistically significant. The results for the repeated measures ANOVA comparing MoCA,

KT, PSMS, and HADS mean raw scores for significant changes are presented in Table

4. Assumption of sphericity is met with a significance value ≥ .05. The results for the HADS Anxiety, HADS Depression, and KT met assumptions of sphericity with significance of .412 (HADS Anxiety), .057 (HADS Depression), and .155 (KT). The results for the PSMS and MoCA demonstrated violation of Mauchley's Test of Sphericity with significance .000 (PSMS) and .020 (MoCA). Therefore Greenhouse-Geisser and Huynh-Feldt transformations were calculated to correct the F statistic for violation of sphericity.

MoCA. Higher scores on the MoCA indicate better cognition. Mean MoCA scores overall were below norms at all time points (>= 26 normal, < 26 mild cognitive impairment [Nasreddine et al., 2005]) but did not vary significantly over time. As noted in Figure 1, on the 30-point MoCA scale, mean scores across the four measurements changed about 2.5 points, with the initial score (T1 = 23.6) climbing to 25 at T2, dropping to the lowest point (23.2) at T3 and rising again to 24.3 at T4.

KT. Lower scores on the KT indicate better functional cognition. Normative data does not appear available for this population, however Hartman-Maeir et al. (2009), demonstrated scores ranging from one – 29 with mean score of 9.34 *(SD* 5.79) for an adult stroke population with an average age of 79.3 (*SD* 5.8). Mean scores for the open heart surgery sample in this study were lower than that score at all time points. As noted in Figure 2, on the 52-point scale, mean scores across the four measurements improved significantly (p = .00) from the lowest point at T1 (7.7) to T2 (2.1), and significantly improved (p = .00) from T1 (7.7) to T3 (4.0). Change in scores from T3 to T4 was not statistically significant.

Mean Change for MoCA Performance Scores

Figure 1. MoCA Performance Score Change.

Horizontal Axis key:
T1: Pretest 1, initial assessment
T2: Pretest 2, within one week before surgery
T3: Posttest 1, after surgery before hospital discharge
T4: Posttest 2, 3-months after hospital discharge

Horizontal line at 26 on vertical axis:
Score for normal cognitive function

Horizontal line at 24 on vertical axis:
Score for impairment in population with cardiovascular disease

Mean Change for KT Performance Scores

Figure 2. KT Performance Score Change.

Horizontal Axis key:
T1: Pretest 1, initial assessment
T2: Pretest 2, within one week before surgery
T3: Posttest 1, after surgery before hospital discharge
T4: Posttest 2, 3-months after hospital discharge

PSMS. Lower scores on the PSMS indicate better functional performance. As noted in Figure 3, on the 61-point scale, mean performance scores showed no significant change between T1 (15.7) and T2 (14.7) but declined significantly (p = .05) from T1 (15.7) to the lowest performance point at T3 (23.9). Mean performance scores then improved significantly (p = .02) from T3 (23.9) to T4 (15.2), returning to a performance level that is not significantly different than the baseline mean score.

Mean Change for PSMS Performance Scores
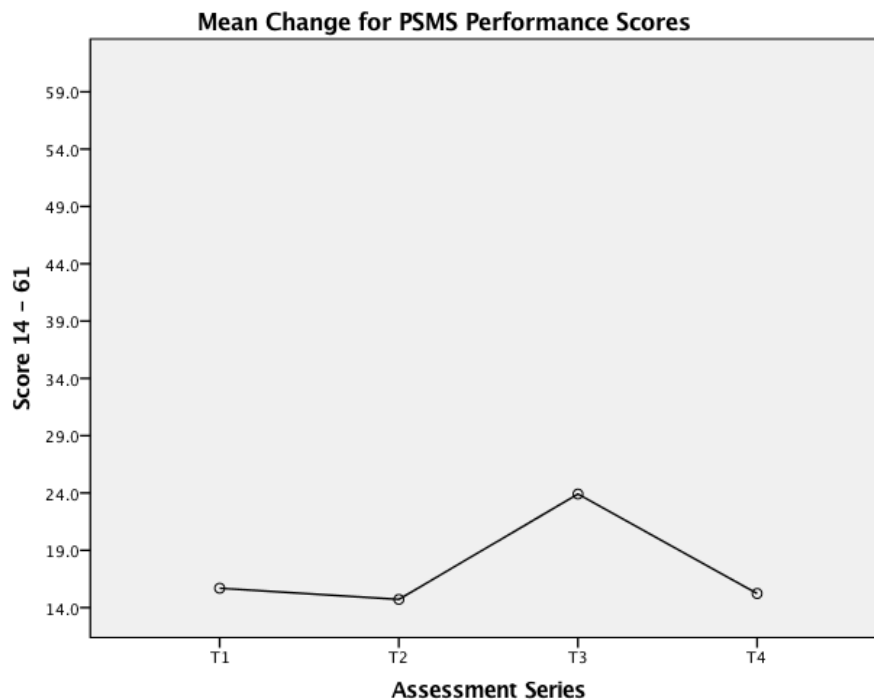
Figure 3. PSMS Performance Score Change.

Horizontal Axis key:
T1: Pretest 1, initial assessment
T2: Pretest 2, within one week before surgery
T3: Posttest 1, after surgery before hospital discharge
T4: Posttest 2, 3-months after hospital discharge

HADS. Lower scores on the HADS indicate better mood states of anxiety and depression, as noted in Figure 4 and Figure 5. Normative population data is available for the United Kingdom with mean scores of 6.14 (*SD* 3.76) for anxiety and 3.68 (*SD*

3.07) for depression (Crawford, Henry, Cromby, & Taylor, 2001), and for the South

American country of Colombia with 4.61 (*SD* 3.64) for anxiety and 4.30 (*SD* 3.91) for

depression (Hinz, Fink, Gomez, Daig, Gleasner, & Singer, 2014). In the current study,

the HADS Anxiety and Depression sub scales did not change significantly; mood stayed

stable throughout. Mean scores on both subscales were in the normal range (0 – 7) at

all time points.
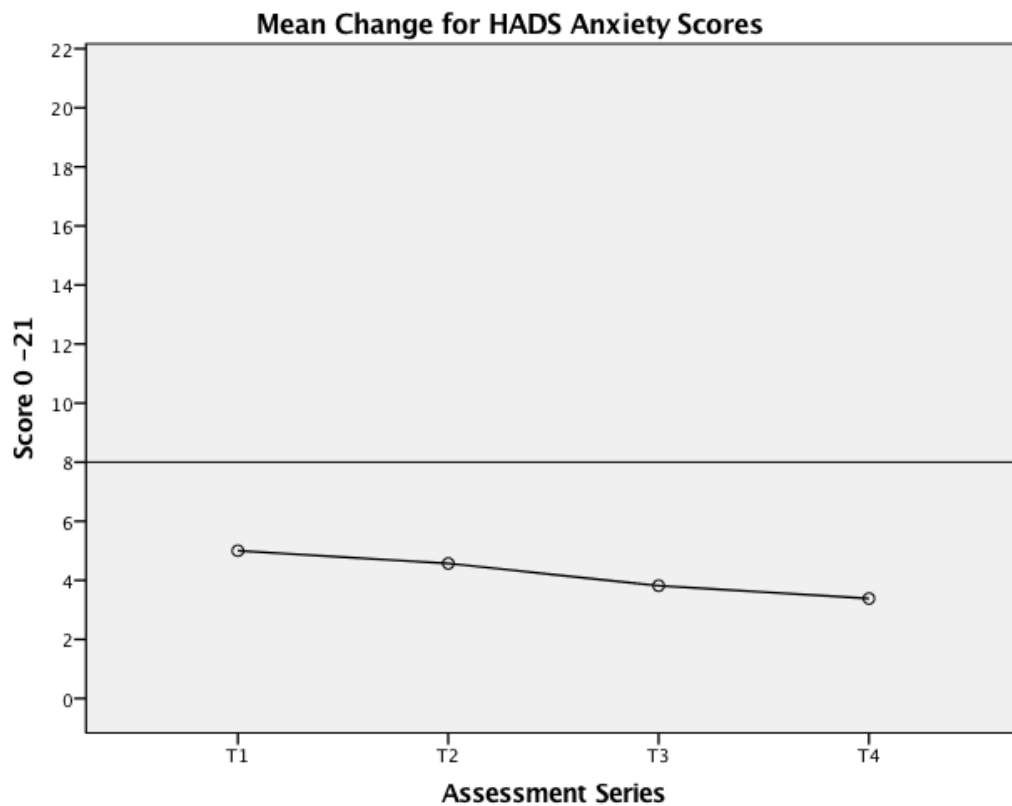
Figure 4. HADS Anxiety Performance Score Change.

Horizontal Axis key:
T1: Pretest 1, initial assessment
T2: Pretest 2, within one week before surgery
T3: Posttest 1, after surgery before hospital discharge
T4: Posttest 2, 3-months after hospital discharge

Vertical Axis key:
Score normal (0 – 7), abnormal (8 or above)

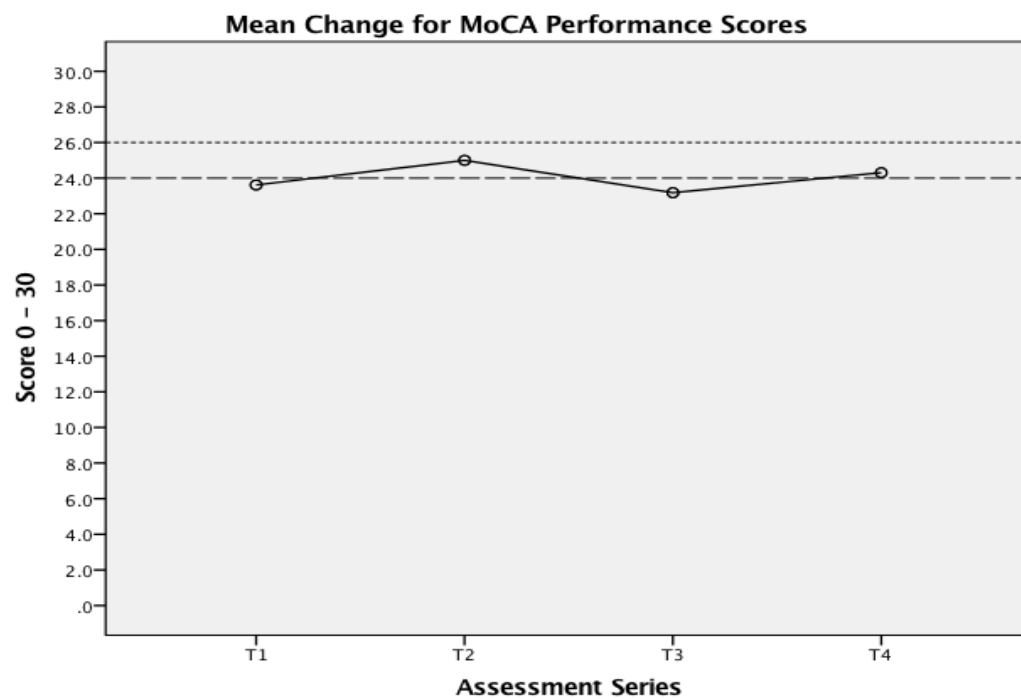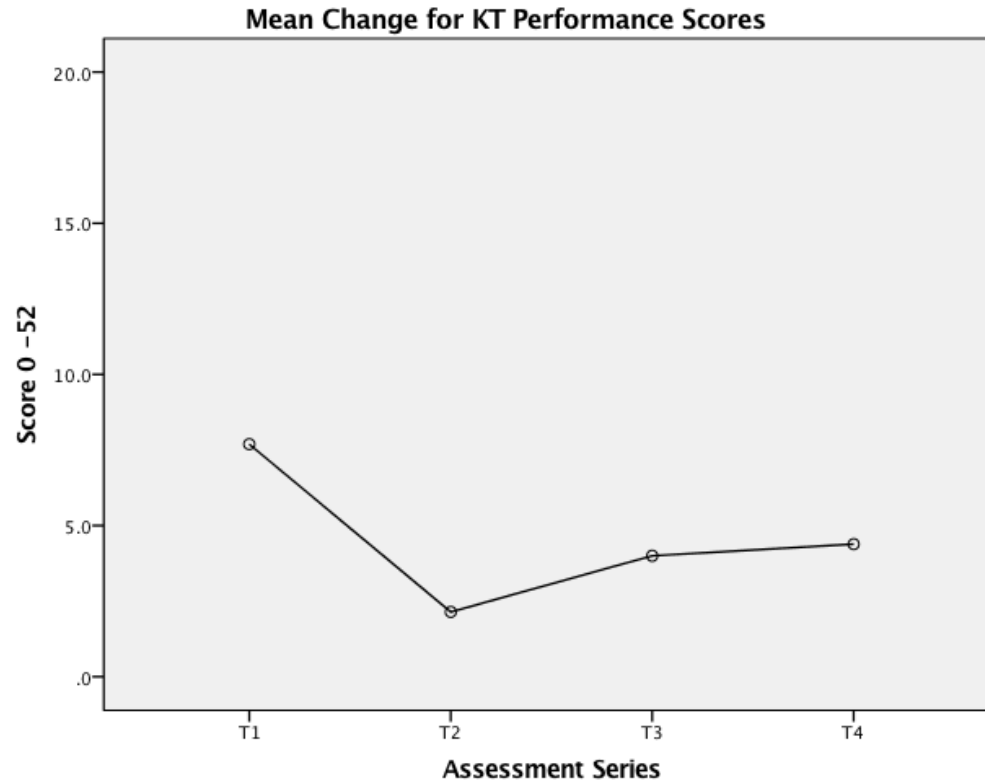**Mean Change for HADS Depression Scores**
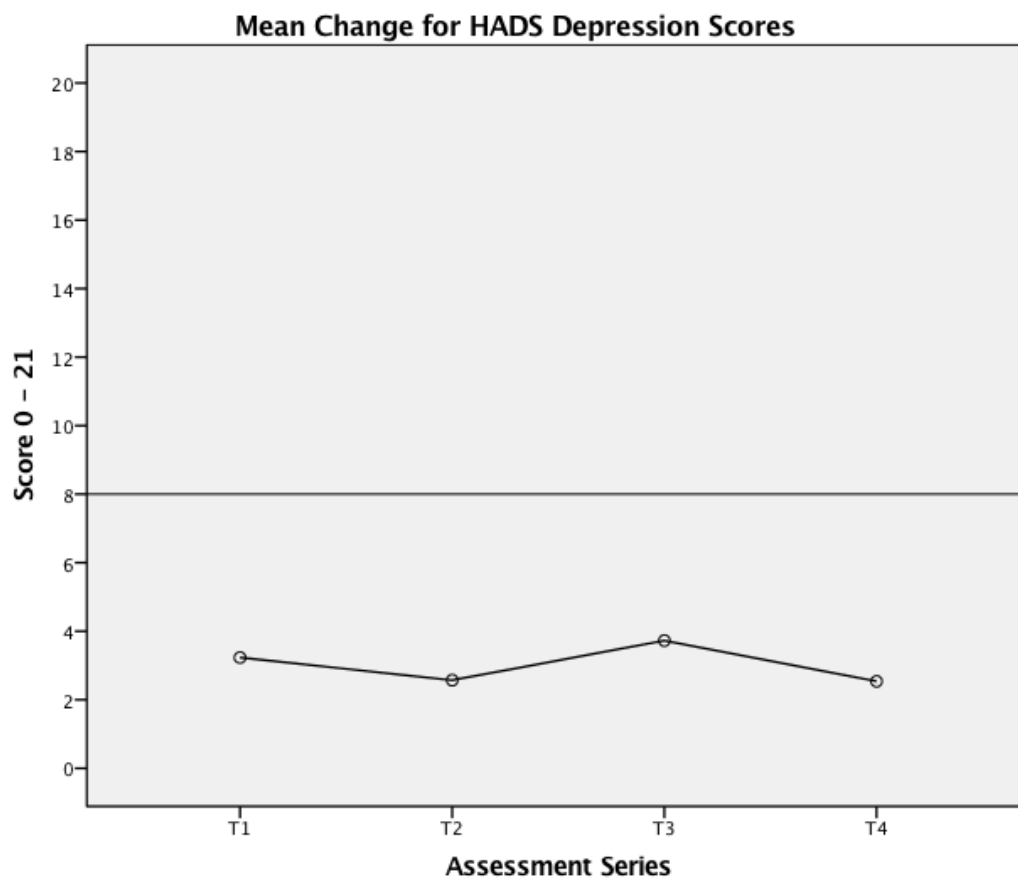
Figure 5. HADS Depression Performance Score Change.

Horizontal Axis key:
T1: Pretest 1, initial assessment
T2: Pretest 2, within one week before surgery
T3: Posttest 1, after surgery before hospital discharge
T4: Posttest 2, 3-months after hospital discharge

Vertical Axis key:
Score normal (0 – 7), abnormal (8 or above)

All mean raw scores were transformed to *t*-scores. The PSMS, KT, HADS

(anxiety and depression) raw scores were reversed to match the MoCA measure in

relation to high and low scores. Mean *t*-scores for all outcome measures over time are

shown in Figure 6. Higher scores on all measures indicate better global cognition, better

functional performance, better functional cognition, and better mood states.
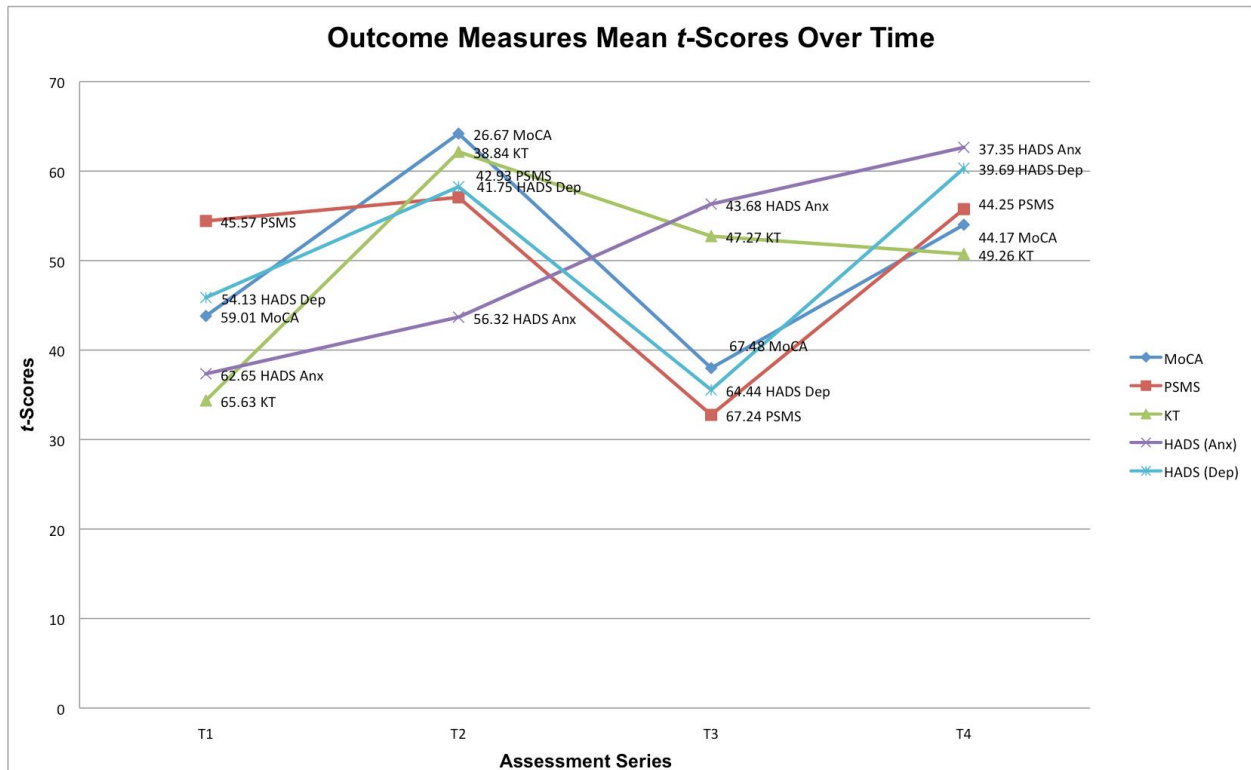
Figure 6. Outcome Measures Mean t-Scores Over Time All Measures.

Correlations

Correlations were run on mean scores for global cognition, functional cognition, and functional performance measurements to obtain Pearson correlation coefficients (See Table 5). It was necessary to convert the measures to t-scores, to standardize the different scales in order to make comparisons, and to adjust for the direction of high and low scores on the different measures. A relationship was shown between cognitive function (KT) and functional performance (PSMS) from T1 to T2 ($p = .05$; $r = .835$) and from T2 to T3 ($p = .05$; $r = .602$). There were no significant correlations found between global cognition as measured by the MoCA and functional cognition as measured by the KT. MoCA scores also did not significantly correlate with functional performance as measured by the PSMS.

In the weeks before surgery (T1 and T2), mean t-scores for functional performance (PSMS) showed a strong positive relationship with functional cognition (KT; $p = .05$; $r = .835$). This indicates that scores for functional performance and functional cognition both showed improvement in the weeks before surgery. Initially and after surgery (T1 and T3), meant t-scores for functional performance showed a weak negative relationship with functional cognition that was not significant. This indicates the while scores for functional performance decreased and functional cognition increased they were not associated just after surgery.

Just before and after surgery (T2 and T3), mean t-scores for functional performance (PSMS) showed a moderate positive correlation with functional cognition (KT; $p = .05$; $r = .602$). This indicates scores for functional performance and functional cognition both declined immediately after surgery.

After surgery, at three-months (T3 and T4), mean t-scores showed a weak positive correlation ($r = .436$) between functional performance and functional cognition that was not significant. This indicates that while scores for functional performance and functional cognition both increased they were not associated by three months after surgery.

On the measures taken immediately before and after surgery, functional cognition as measured by the KT correlated with functional performance as measured by the PSMS. It appears the KT, while not predictive of ADL/IADL performance, may help inform decisions about functional performance for this population. It is important to note that correlational analysis does not show cause and effect, only relationships that may or may not have the same cause. Interestingly, global cognition as measured by

the MoCA did not correlate with either functional cognition or functional performance as measured by the KT and PSMS. As discussed below, the small sample size did not achieve adequate power for the MoCA, so mean scores are not generalizable. Lack of correlation between the MoCA and KT cognitive measures may also be due to the different ways the two tests measure cognition. The MoCA measures isolated domains of cognition, while the KT measures the cueing required to successfully complete a kitchen task and the cognitive domains integrated within this task.

Table 5

Pearson Correlation Coefficients (r) for Mean t-score Outcome Measures

	MoCA (r)	KT (r)	PSMS
T1 – T2			
MoCA			
KT	-.279		
PSMS	-.513	**.835***	
T1 – T3			
MoCA			
KT	.063		
PSMS	.377	-.346	
T2 – T3			
MoCA			
KT	-.160		
PSMS	.117	**.602***	
T3 – T4			
MoCA			
KT	-.359		
PSMS	-.114	.436	

Note: * Correlation (r) is significant at the 0.05 level (2-tailed)

Effect Size Calculation and Power Analysis

Effect size was calculated to determine the magnitude of the relationship between time points in order to estimate the ecological validity of any change observed over time. When effects are strong, statistically significant levels can be detected with

small sample sizes. When relationships are modest larger sample sizes are needed to avoid Type II errors (accepting the null hypothesis when it is false, or concluding no relationship exists when it does; Polit & Beck, 2008). Polit and Beck (2008) suggest estimation of effect size in studies with no prior research as small ($\eta^2 = .20$), medium ($\eta^2 = .50$), and large ($\eta^2 = .80$).

As shown in Table 6, the effect size for global cognition (MoCA) suggests a small within subject effect $\eta^2 = .16$) and a large between subjects effect ($\eta^2 = .99$). Within subject effects measure how an individual in the sample changes over time. Between subject effects measure how individuals differ from one another on a particular variable over time. Functional cognition (KT) indicates a small within subject effect ($\eta^2 = .43$) and a medium between subjects effect ($\eta^2 = .76$). Functional performance (PSMS) indicates a small within subject effect ($\eta^2 = .49$) and a large between subjects effect ($\eta^2 = .98$). The effect size for mood states of anxiety and depression (HADS) indicates a small within subject effect ($\eta^2 = .05$ and .08) and a large between subjects effect ($\eta^2 = .72$ and .80).

Power can also be describe as $1 - \beta$ (where β *is the probability of a Type II* error [a false negative]) or the probability of failing to reject a false null hypothesis (Polit & Beck, 2008). When power is equal to .80, the risk of committing a Type II error is 20%, which allows for sample sizes large enough to obtain significant results (Polit & Beck, 2008). Power analyses were conducted on each repeated measure with NQuery Advisor ©, Version 7.0 (2007) to estimate sample sizes for subsequent study considerations at 80%, 90% and 95% power.

Table 6

Repeated Measures Analysis of Variance Results with Power Calculation

Measure	Type III Sum of Squares	*F (df)*	*p*	$\eta^2_{partial}$	Observed Power[a]
MoCA					
Within					
Greenhouse-Geisser	24.821	2.316 (1.743)	.129	.162	.391
Huynh-Feldt	24.821	2.316 (2.015)	.120	.162	.425
Lower-bound	24.821	2.316 (1.000)	.154	.162	.289
Between	30017.490	1447.398* (1)	.000	.992[c]	1.000
KT					
Within	207.976	9.107* (3)	.000	.431	.992
Between	1078.871	38.685* (1)	.000	.763[b]	1.000
PSMS					
Within					
Greenhouse-Geisser	743.631	11.397 (1.283)	.002	.487	.929
Huynh-Feldt	743.631	11.397 (1.370)	.002	.487	.941
Lower-bound	743.631	11.397 (1.000)	.002	.487	.872
Between	15719.305	588.631* (1)	.000	.980[c]	1.000
HADS Anxiety					
Within	12.710	.581 (3)	.632	.046	.158
Between	473.314	30.095* (1)	.000	.715[b]	.999
HADS Depression					
Within	20.650	.983 (3)	.412	.076	.245
Between	914.468	48.480* (1)	.000	.802[c]	1.000

Notes: *df* – degrees of freedom; HADS: Hospital Anxiety and Depression Scale; KT: Kettle Test; MoCA: Montreal Cognitive Assessment; PSMS: Physical Self Maintenance Scale. [a]Computed using alpha = .05, [b]Medium effect size, [c]Large effect size. *Significant at p < .05

A univariate single group repeated measures ANOVA using the Greenhouse-Geisser correction to nominal degrees of freedom with a sample size of 50, 64, and 77 and a 0.05 significance level will have 80%, 90% and 95% power to detect a difference in means across the four levels of the MoCA repeated measures factor characterized by an effect size of 0.0607 (e.g. a Variance of means, $V=S(m_i-m)^2/M$, of 0.477, and a within-group error term, of 2.80) assuming that the measure of "sphericity" of the

covariance matrix, epsilon, is 0.92, (its estimate, the Greenhouse-Geisser correction, has an expected bias of about $g_1/(n-1)$ where g_1 is -2.48; Muller & Barton, 1989). This analysis indicated that the current sample did not meet adequate power for the MoCA measure of global cognition.

A single-group repeated measures ANOVA with a sample size of 8, 10, and 12, and a 0.05 significance level will have 80%, 90% and 95% power respectively to detect a difference in means across the four levels of the KT repeated measures factor characterized by an effect size of 0.4310 (Dixon & Massey, 1983). This analysis indicated that the current sample met 95% power for the KT measure of functional cognition.

A univariate single group repeated measures ANOVA using the Greenhouse-Geisser correction to nominal degrees of freedom with a sample size of 9, 11, and 13 and a 0.05 significance level will have 80%, 90%, and 95% power to detect a difference in means across the four levels of the PSMS repeated measures factor characterized by an effect size of 0.6221 (e.g. a Variance of means, $V=S (m_i-m)^2 / M$, of 14.301, and a Within-group error term, of 4.79) assuming that the measure of "sphericity" of the covariance matrix, epsilon, is 0.57, (its estimate, the Greenhouse-Geisser correction, has an expected bias of about $g_1/(n-1)$ where g_1 is -0.12; Muller & Barton, 1989). This analysis indicated that the current sample had sufficient power of 95% for the PSMS functional performance measure.

A single-group repeated measures analysis of variance with a sample size of 38, 48, and 58, and a 0.050 significance level will have 80%, 90%, and 95% power respectively to detect a difference in means across the 4 levels of the HADS Anxiety

repeated measures factor characterized by an effect size of 0.0760 (Dixon & Massey, 1983). A single-group repeated measures analysis of variance with a sample size of 61, 75, and 95, and a 0.050 significance level will have 80%, 90%, and 95% power respectively to detect a difference in means across the 4 levels of the HADS Depression repeated measures factor characterized by an effect size of 0.0460 (Dixon & Massey, 1983). This analysis indicated that the current sample did not meet adequate power for the HADS measures of mood states.

The observed power to detect a significant mean change with power >= .80 was evident for KT and PSMS. Small sample sizes of 9, 11, and 13 for PSMS and KT would be adequate to sufficiently power subsequent studies at 80%, 90%, or 95% respectively. The current sample provided sufficient power at 95% to make trustworthy statements based on the PSMS and KT results. The current study sample was too small to adequately power the MoCA and HADS and a larger sample size is needed to trust results. Observed power was < .80 for MoCA and HADS Anxiety and Depression, which leaves interpretation of these results open to the risk of Type II errors. Large samples sizes of 50, 64, and 77 for the MoCA and 61, 75, and 95 for the HADS would be necessary to provide sufficient power for subsequent studies at 80%, 90%, or 95% respectively. The measures that were adequately powered showed significant change over time and strong positive correlation, whereas the inadequately powered measures did not change significantly over time or show strong correlation.

Summary

This chapter reported the results of the current study (n = 13) designed to compare mean changes in cognition and everyday function prior to and after open heart

surgery. ANOVA calculation revealed that functional cognition and functional performance changed significantly over time for the overall mean scores on both the KT and PSMS measures, which both were adequately powered for this study sample. Both scores declined immediately after surgery with a return near baseline within three months. No significant changes were noted on the MoCA cognition measure or the HADS mood measure. Results for effect size analyses from RM-ANOVA signified large between subject effects for MoCA, PSMS, and HADS, medium between subject effects for KT, and small within subject effects on all four measures (MoCA, KT, PSMS and HADS). Power analyses indicate small sample sizes will adequately power single group repeated measure ANOVA for the PSMS and KT, and that this current sample was adequately powered at 95%. Larger sample sizes than this study sample are necessary to adequately power the MoCA and HADS measures at 80%, 90%, and 95% at .050 significance levels. The next chapter will further discuss the meaning of these results as well as the limitations of the current research, implications of these results for clinicians, and recommendations for future research.

Chapter Five: Discussion

This chapter discusses the practical importance of the study results presented in Chapter Four. Possible explanations for findings and the relationship to the literature are considered first. Implications for occupational therapy practitioners and researchers are presented next. Study limitations and suggestions for future research are then presented.

Cognition, Performance, and Mood States

Global cognition. Global cognition as measured by the MoCA did not change significantly over time, nor did it significantly correlate with functional cognition (KT) or functional performance (PSMS) at any time points. Baseline and overall performance for participants in this study were below the threshold for normal cognitive function in relation to normative data across all time points for this measure and reached their highest level of performance at the 2nd pretest, just prior to surgery. This sample also scored below the norms across all time points in line with a previous report on subjects with cardiovascular disease that suggested a cutoff score of (< 24) for impairment on the MoCA (Rossetti, Lacritz, Cullum, & Weiner, 2011). Such a cutoff would place this sample in the normative range for the 2nd pretest just prior to surgery and by the three-month follow up. Normative data for the cardiovascular population may be lower than that for the general population, as suggested in other studies (Evered et al., 2016; Rankin et al., 2003; Rosengart et al., 2006; van Dijk et al., 2002).

Findings for the MoCA indicate a small within subject effect and a large between subjects effect. The large effect size supports further testing. Power analysis indicated a larger sample size would be necessary to adequately power findings for this measure. A sample size of 50 – 77 would provide the power (80 – 95%) to adequately reduce the possibility of Type II error.

Functional cognition. Prior research has utilized neuropsychological tests to measure cognition among open heart surgery patients, but there is no published evidence measuring functional cognition imbedded in a task. This study extends past research by describing where functional cognition declines in a kitchen task and the cueing necessary to complete this task successfully. Functional cognition, as measured by the KT, was above norms at baseline, significantly improved prior to surgery, fell off after surgery, but surpassed baseline at three months. This is consistent with other studies that demonstrate improved cognition three months after surgery (Anastasiadis et al., 2011; Baumgartner, 2007; Liimatainen et al. 2016); but diverges from others that report remaining deficits at four months (Zimpfer et al. (2004), and lasting as long as three to five years after surgery (Stroobant et al., 2002).

The KT, which requires preparation of two hot beverages, is intended to reveal valuable information about cognitive aspects of everyday functional performance and any cueing needed to successfully complete a multi-step task. Difficulties with visuospatial ability, executive function, and delayed recall skills were evident among study participants, presenting as problems in remembering how to operate the kettle and recalling when and how to tell that the water had reached boiling. These findings are consistent with the cognitive deficits found after surgery in prior studies (Efimova et

al., 2015; Gerriets et al., 2010; Keith et al., 2002; Kimodo et al., 2005; Newman, Grocott, et al., 2001; Slaughter et al., 2008; van Dijk et al., 2002). Several studies suggest that deficits in these cognitive skills may be preexisting in this population (Evered et al., 2016; Tully & Baker, 2013; Rankin et al., 2003; Rosengart et al., 2006; van Dijk et al., 2002). However, unlike the preceding studies this sample scored above norms before surgery on the KT.

This study was the first to use the KT and MoCA concurrently. These two cognition measures were expected to track similar arcs, but their results did not correlate with one another. The lack of correlation between the cognition measures may have been due to the inadequately powered MoCA measure, however a larger sample would be necessary to support or reject this assumption.

Functional performance. Everyday functional performance significantly changed over time as measured by mean scores on the PSMS self-report measure. Average scores dropped significantly immediately after surgery. Within three months, however, mean scores indicated a return to baseline independence for all functional activities. Surgery appears to temporarily impact functional performance. Participants reported an increased need for assistance with ADL/IADL directly after surgery. The effect of surgery on daily functioning appeared to dissipate as participants healed. At some point between surgery and the three-month follow up participants were able to resume daily activities without needing further assistance from others.

Functional cognition and functional performance. This study found that both the KT and PSMS were adequately powered and showed significant change over time. It appears that surgery had a temporary impact on both functional cognition, as

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measured by the KT, and functional performance, as measured by the PSMS. The results of this comparison suggest, but do not show a causal connection for, a possible cognitive element in the functional change noted by participants in the study. It is possible, however, that cognition did not have an impact on functional performance, especially given the lack of correlation of the MoCA and KT. Perhaps functional change was simply a matter of physical recovery from the trauma of surgery itself.

Anxiety and depression. An analysis of mean scores showed no change on the study's mood questionnaire and scores were above norms across all time points. Overall mean scores for all four of the assessment points indicated participants self reported their mood within normal levels of anxiety and depression, which imply that mood stayed the same throughout the study. This sample had a mean age of 60.15 and was predominantly men 60 years or older (61.6%). This reflects literature that measured anxiety and depression at multiple time points and found younger patients (age 36-60) are more anxious before surgery and anxiety declines after surgery, whereas older adults (age 60-78) are less anxious and show hardly any change over time (Krannich et al., 2007). It is difficult to determine why this sample seemed relatively stable and above norms for mood states. It is possible a selection bias contributed or that participants with more distressed mood states may have self selected to opt out or were not considered appropriate candidates by personnel that screened for recruitment. It is possible that cardiac surgery does not have a negative impact on anxiety and depression. Inferences about the usefulness of this measure on this population require further study using an adequately powered sample.

Piloted Procedures and Measures

        Procedures. One study objective was to pilot procedures and the potential efficacy of a larger scaled study. Participant recruitment and retention is essential to the success of a study of this nature. Over the 18-month data collection period, conducted entirely on the outpatient ambulatory care cardiac floor of a single large hospital, the study did not meet its goal of 36 participants. A number of factors may have contributed to this shortcoming.

        As a pilot study, one researcher completed consent and the assessments at all time points. The researcher was only available on one day per week to recruit participants at the study location due to schedule parameters. Possible subjects may have been lost due to no researcher presence on ancillary days, and unavailability to recruit additional participants while engaged in assessment and consent with other participants.

        Future studies should consider additional staff to consent and carry out assessments to allow for multiple possible candidates available at the same time. Closer collaboration with the LVAD coordinator to identify potential participants and arrange earlier access and scheduling opportunities with this population may increase recruitment rates and accommodate the intensive education required at their preoperative testing and training visit. The addition of multi-site points at another clinic at this facility or another hospital may improve access to potential participants. Providing flyers to referring heart clinics, and expanding recruitment of CABG and HVR participants to the inpatient side at the facility might improve recruitment efforts.

The study demonstrated acceptable retention rates overall and the final sample achieved the power needed for two of the assessments after the surgical procedure groups were combined into one open heart surgery group. Although two participants were lost to follow up, this was not related to study procedures or processes. Both participants indicated a desire to complete the study but one was unable due to transportation issues and the other due to a secondary condition discovered after surgery that required additional medical attention. Subsequent researchers are advised to plan for up to a 13.3% attrition rate based on the retention and attrition rate of this pilot study.

Initially, compensation for participants was limited to a lottery at the end of the study that would have awarded a $50 gift card to one participant. In an effort to increase recruitment, funds were made available for all participants to be offered a $25 gift card in appreciation for completion of the study, in addition to the previously planned lottery. Recruitment improved when compensation was made available. Some potential participants were lost due to transportation issues and several volunteers reported they were hungry and would like to eat and come back before participating. Adjustments were made to accommodate these requests to return after eating.

This researcher was able to track participants who opted in or out of the study only after they were consented for surgery, prescreened for participation and then agreed to hear about the study, but it was sometimes difficult to know who was eligible and often unclear about how many patients heard about the study but declined. While the researcher was present to huddle with cardiac unit staff once each week to prepare for volunteers, frequent turnover of nursing and orientation of new staff may have

impacted recruitment. Sometimes staff reported they forgot to ask patients if they were interested, did not have time, were confused about inclusion/exclusion criteria, or were unable to prioritize recruitment among necessary job related tasks. In an effort to improve this a notation labeled "study?" was placed on the printed schedule next to potential volunteers appointment time slots in order to remind staff that the researcher was present.

Future researchers may wish to consider a better tracking method for documenting missed potential participants. This might include a checklist for staff to document whether a patient was consented for surgery or not, which procedure was planned, whether or not they met inclusion criteria, whether or not they agreed to hear about the study, and whether or not they were given the chance to opt in or out. Current literature that looks at the challenges in recruitment of patients with heart disease in two clinics provides a clear design to follow which may improve the process of successfully tracking and documenting the steps of recruitment and the reasons for refusal in this patient population (Pressler et al., 2008).

Suitability of measures. The outcome measures appeared acceptable to study participants and had clear instructions for administration and scoring. Overall the measures were completed in a reasonable timeframe and each measure was individually completed in a timely manner. Subsequent studies may consider electronic questionnaires or virtual chat/observation options with computer or smart phones for off-site study assessment to optimize participant wait time and improve efficiency. This may further reduce the time needed for study personnel during administration and scoring of assessments. Of note, during the time following the KT some participants chose to

consume the beverage they prepared and this created an unanticipated opportunity and social environment for conversation. During this time participants disclosed values and important life priorities that were prevalent during this time in their lives. Future researchers may want to incorporate a qualitative component to capture this meaningful information to better address the needs of this population.

Clinical Relevance

The study findings are clinically relevant to the assessment of cognition and functional performance after CABG, HVR, and LVAD placement surgeries. Results from other studies have demonstrated a decline in cognition after surgery and differing rates of return to pretest cognitive function over time. This is one of the first studies to explore the impact of open heart surgery on both cognition and functional performance of daily tasks, and to include multiple pretests. One recent study reported significant declines in functional performance directly after CABG surgery with a slow recovery that did not, however, return to baseline by six months (Niemeyer-Guimarães et al., 2016). This is one of the first studies to report findings that open heart surgery impacts both functional cognition and everyday functional performance and that both demonstrate a gradual return to baseline by three months. It is clear that the relationship between change in functional cognition and functional performance deserves further study. The nature of this relationship may or may not explain why functional performance changes when cognitive function changes. Functional changes may have had nothing to do with cognition, but to some other factors not measured in this study that later researchers may wish to tease out.

Participants reported they required increased assistance with ADL/IADL directly after surgery, and this need for functional support returned to baseline within three-months. Occupational therapists in hospitals may wish to prioritize assessment and treatment of ADL/IADL directly after surgery before discharge home. Acute care practitioners may wish to prioritize patient and family training in ADL/IADL and address areas that require assistance as needed. Practitioners may want to determine if patients have access to caregiver assistance and make sure patients and caregivers receive training in compensatory or adaptive techniques. Practitioners may wish to consider transitions in care by facilitating follow up in home health or outpatient settings to progress occupation and track independence with IADL if patients desire to resume these tasks independently. Home health and outpatient OTs may wish to focus assessment and treatment on ADL/IADL performance up to three months after surgery.

This study was the first to use the KT on a cardiovascular population. Based on these findings, practitioners may wish to consider a cognitive assessment such as the KT for both pre-surgical and post-surgical testing, since the KT demonstrated the need for specific and general cues to successfully carry out steps of ADL tasks. The KT is useful to occupational therapy practitioners in assessment of cognitive function performance given that it identifies where steps of a task breakdown and what types of self initiated techniques or external cueing may help participants get back on track. The KT provides useful information about what types of cueing may be necessary to successfully complete a multi-step task. Occupational therapists should plan to provide general or specific cues, or allow their patients time to complete tasks slowly and to employ trial and error techniques, as this may help patients to succeed. Practitioners

may want to consider interventions that support attention, working memory, and executive function in the home environment, at least during the first three months after surgery. This is especially important to make sure clients remember to take their medications, pay their bills, get to appointments, prepare meals safely, and observe precautions once they return home. Because of the potential biases that affect self-report measures of function, OTs may wish to incorporate functional performance assessments that include observation of ADL/IADL rather than just self-report questionnaires. Since the MoCA mean scores were below norms across all time points it may be beneficial to refer individual clients that fall in this range for further neuropsychological testing.

Assessment considerations. It is important to determine the best outcome measures when considering assessment of cognition and function after open heart surgery. Self-report questionnaires such as the PSMS and HADS reflect certain self-report biases with potential for exaggerated responses, different interpretation of response choices, or inaccurate responses due to lack of interest. However, the significant changes in ADL/IADL that participants reported in this study can guide practitioners in selection of observational assessments to use in the future. The PSMS does not address all areas of occupation in the OTPF (AOTA, 2014) and practitioners may wish to use a more comprehensive assessment that explores participation in more occupations. Use of the KT allowed for observation of functional cognitive performance, which enhanced ecological validity, providing insight into steps of the task that were challenging and the types of skills participants employed and the cueing that aided task completion.

When practitioners or researchers choose outcome measures and plan study procedures it is important to consider the time and energy commitments of elective open heart surgery patients. These individuals face multiple pre-operative testing, lab and education requirements, and may be dealing with decreased levels of energy and endurance. This study appears to support use of the KT and PSMS as screening tools that require little time or energy for users. Any adjustments to schedules or use of downtime or participation waiting time may expedite study processes and procedures and increase recruitment and retention. Participants could complete the PSMS during wait times and complete the KT under observation later. The LVAD group may need earlier recruitment and enrollment contact points to offer options to come back another day to balance out the extensive preoperative training requirements along with study assessments.

Limitations

Sampling limitations. Participants were selected from volunteers as a consecutive convenience sample from one location, an outpatient preoperative cardiac clinic at one university hospital system. Selection bias could influence the sample since it was not randomized or controlled. The participants were all male (only one female consented, but did not complete the study), and mostly White (76.92%), only 23.08% identifying as Black/African American, with no other races represented. The sample size was small (n = 13) and reflected 46.15% HVR, 38.46% CABG, and 15.39% LVAD. The results of the pooled sample did not allow for group comparisons as was originally planned. Nevertheless, the sample was adequately powered for the KT and PSMS. The study sample does not reflect the general population and generalization of these results

is limited to white males. This study sample over represented White males at 76.9%, under represented Black males at 23.1%, and represented neither females nor Hispanics. Future studies may consider stratified random sampling to capture more females, participants in the 30 – 49 age range, participants of other races, or nonprobability quota sampling to increase representativeness of the sample (Polit & Beck, 2008), however this would increase the risk of selection bias.

The research design excluded participants with a clinical diagnosis of dementia, stroke or brain injury with residual cognitive deficits, intellectual disability, visual impairment that may have impeded safe preparation of hot beverages for the KT, inability to use at least one hand for writing and preparation of hot beverages, and living residence not within close proximity to the institution. The participants in the study were screened to reduce the impact of multiple comorbidities and impairments. Expanding inclusion criterion to include participants with varying cognitive, sensory, and physical abilities may reflect a more accurate representation of the population of interest at large and enhance generalization of results. However, the tradeoff of widening the inclusion criteria adds the possibility of confounding variables. Of note for future study considerations, there is now an electronic MoCA test for use on tablets, and also a version of the MoCA available for individuals with vision impairments.

The researcher and screening personnel were not blinded to surgical group, which could have influenced recruitment and assessment procedures. These sampling restrictions limit generalizing of results to other geographic regions, other races/ethnicities, other genders, or to patients undergoing open heart surgery with any of the excluded comorbid impairments. Future researchers may wish to use a blinded

randomized control model with a more inclusive and larger sample to better generalize results.

Instrument limitations. The two assessments that measure functional performance change and anxiety and depression (PSMS and HADS) relied on self-report, which additionally relies on the participants' full understanding of the questions and veracity in responses. Participants were aware that the researcher was conducting the study in partial completion of a doctoral degree, and therefore, due to the Hawthorne effect, participants may have inflated or adjusted their responses because they knew they were being observed due to a social desirability response. This effect may also partially explain the higher than normative levels on the HADS score for this sample. This study implemented the KT and MoCA as objective measures to help minimize self-report bias.

Suggestions for Further Research

This study may provide a foundation for future research on the effects of open heart surgery on cognition and functional performance of ADL/IADL. Several studies have indicated the presence of cognitive decline and suggested research to further evaluate and treat these deficits. This study expands research in open heart surgery to include measures of global cognition, functional cognition, functional performance of ADL/IADL, and mood. Inclusion of these variables of interest in the literature may lead to improved outcomes for individuals after surgery to successfully participate in meaningful daily activities.

This pilot study may provide future researchers with the appropriate outcome measures, effect sizes, and sample size estimates necessary to adequately power

subsequent studies. Some decline may be expected in self-reported function due to post-operative precautions, general fatigue, or pain that may contribute to decreased participation in daily tasks. Future researchers may want to determine the degree to which each of these factors contributes to the change in functional performance and if access to IADL support is available. Finally, the addition of more qualitative measures that explore self-reported functional performance ratings, and satisfaction with cognitive function and functional performance may enrich our understanding of factors that contribute to successful participation in daily activities.

To the best knowledge of this researcher, this study is the first to explore the impact of open heart surgery on both functional cognition and functional performance of ADL/IADL at the same time. The KT may prove useful to researchers given the significant results, the small sample size needed for adequate power, and because it taps into cognitive abilities that may track with everyday functional changes as measured by the PSMS. Future investigators may choose to continue exploration of this relationship more fully to improve cognitive and functional assessment and treatment options for this population. Future researchers may wish to consider these self-reported areas of functional performance decline in specific ADL/IADL tasks when choosing ecologically valid ADL/IADL instruments for observational study measures. Future studies might attempt to explore the specific tasks that decline in ADL/IADL after surgery and identify the most difficulty or challenging ones during the timeframe after surgery up to three months after surgery. Additionally, research ought to focus on the link between cognition imbedded in function rather than continue to generate studies that separate these variables.

Researchers may wish to explore the use of qualitative measures that clarify the meaning and choice behind these self-reported declines. This may reveal differences in functional changes that reflect adherence to post operative precautions or are related to some other reason not measured by the PSMS. Future researchers may choose to examine the specific areas of self-reported decline in ADL/IADL and choose measures that assess participants through observation during actual performance of these tasks. Researchers may also consider assessments that measure patient satisfaction with performance levels of ADL/IADL as the PSMS measure only reports perception of the highest level of performance on any current day. Additionally, an objective observational assessment of ADL/IADL would be more accurate than a self-report questionnaire.

Conclusion

This study found that open heart surgery impacts both functional cognition and everyday functional performance, indicating that patients may require assistance to perform key ADL/IADL for at least three months post-surgery. The KT and PSMS instruments, used in an acute care setting immediately before and after surgery may help inform practitioners about the cognitive and functional impact for these patients. Although these results appear promising, more research is necessary to determine the degree to which these factors impact patient outcomes. More research is also necessary to identify other factors that may contribute to cognitive and/or functional difficulties and recovery after open heart surgery. As a pilot study, recommendations to improve recruitment, processes, procedures, and the insights and findings from this study may help inform future researchers. Practitioners can use the findings of this study to better prioritize and guide assessment and treatment options.

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Appendix A

IRB Initial and Continuation Approval
and Informed Consent

IRB HM20003749 The Cognitive and Functional Impact of Open Heart Surgery: A Pilot Study
On 7/31/2015, the referenced research study was ***approved*** by expedited review according to 45 CFR 46.110, category 7, by VCU IRB Panel B.

- The information found in the electronic version of this study's smart form and uploaded documents now represents the currently approved study, documents, informed consent process, and HIPAA pathway (if applicable). You may access this information by clicking the Study Number above.

This approval expires on 6/30/2016. Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review notices will be sent to you prior to the scheduled review.

If you have any questions, please contact the Office of Research Subjects Protection (ORSP) or the IRB reviewer(s) assigned to this study.

The reviewer(s) assigned to your study will be listed in the History tab and on the study workspace. Click on their name to see their contact information.

Attachment – Conditions of Approval

_____

_____

Conditions of Approval:

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must (as applicable):

1. Conduct the research as described in and required by the Protocol.
2. Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).
3. Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent is specifically approved).
4. Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translated version.
5. Obtain prior approval from VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research participants (e.g., permanent/temporary change of PI, addition of performance/collaborative sites, request to include newly incarcerated participants or participants that are wards of the state, addition/deletion of participant groups, etc.). Any departure from these approved documents must be reported to the VCU IRB immediately as an Unanticipated Problem (see #7).
6. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.
7. Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in VCU IRB WPP VIII-7:
8. Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of research participants.
9. Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.
10. All protocols that administer acute medical treatment to human research participants must have an emergency preparedness plan. Please refer to VCU guidance on http:/www.research.vcu.edu/irb/guidance.htm.
11. The VCU IRBs operate under the regulatory authorities as described within:
a. U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.
b. U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.
c. Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: THE COGNITIVE AND FUNCTIONAL IMPACT OF OPEN HEART SURGERY: A PILOT STUDY COMPARING THREE COMMON PROCEDURES (CORONARY ARTERY BYPASS GRAFT SURGERY, HEART VALVE REPLACEMENT, AND LEFT VENTRICULAR ASSIST DEVICE)

VCU IRB NO.: HM20003749

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY
The purpose of this research study is to find out about cognitive and functional abilities in adults after coronary artery bypass graft surgery, heart valve replacement, and left ventricular assist device placement.

You are being asked to participate in this study because you are 18 years or older and are having either coronary artery bypass graft surgery, heart valve replacement, or left ventricular assist device placement.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT
If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

If you decide to participate in this study you will be asked to complete 4 sessions that will last approximately 60 minutes each:
Before surgery
      1st session at the outpatient clinic
      2nd session either in the outpatient clinic or your home
After surgery
      3rd session in the hospital right before discharge, and
      4th session 3-months after surgery in the outpatient clinic
At each session you will be asked to fill out 2 brief questionnaires and complete 2 brief assessments. One questionnaire has 14 questions about your feelings over the last week, and the other has 14 questions about your level of abilities to perform daily tasks. Next the study investigator will ask you to complete a brief task of 13 items including pen and paper tasks and following verbal instructions. Finally, you will be asked to complete a brief kitchen task, specifically making a hot beverage. The study investigator will manually write down your responses on the assessment forms during the sessions. Total enrollment will be 42 volunteers (14 having coronary artery bypass graft surgery,

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14 having heart valve replacement, and 14 having left ventricular assist device placement).

Significant new findings developed during the course of the research, which may relate to your willingness to continue participation will be provided to you.

RISKS AND DISCOMFORTS

The risks associated with this study impose no more than typical with daily life. The risk involved is minimal and involves the possibility of spilling a hot beverage on ones self during preparation of this beverage. However, study staff will stand within reaching distance and physically assist to stop any unsafe activity related to preparation and pouring of hot liquids. All assessments and questionnaires will be completed in a private setting.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information
The following people and/or groups may request my Protected Health Information:
- Principal Investigator and Research Staff
- Clinic Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Institutional Review Boards
- Government/Health Agencies

Authority to Release Protected Health Information
The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:
- Health Care Providers at the VCUHS
- Principal Investigator and Research Staff
- Clinic Collaborators
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released
The following types of information may be used for the conduct of this research:

☐ Complete health record　☐ Diagnosis & treatment codes　☒ Discharge summary

☒ History and physical exam　　　　　　　　　　　　　☒ Progress notes
☐ Laboratory test results　☐ X-ray reports　☐ X-ray films / images
☐ Photographs, videotapes　☐ Complete billing record　☐ Itemized bill
☐ Information about drug or alcohol abuse　☐ Information about Hepatitis B or C tests
☐ Information about psychiatric care　☐ Information about sexually transmitted diseases
☐ Other (specify): Data collected will be deidentified

Right to Revoke Authorization and Re-disclosure
You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. Because data collected will be deidentified, there is no way to trace back to you. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

BENEFITS TO YOU AND OTHERS
You may not get any direct benefit from this study, but, the information we learn from people in this study may help us design better ways to identify and provide treatment to people after open heart surgeries. You will obtain immediate information about your cognitive abilities and ADL/IADL performance after surgery compared to before. The study will contribute to the knowledge of cognitive changes patients experience after undergoing open heart surgery, the potential differences in surgical groups, and the effect on performance of ADL/IADL. The long-term outcome would be improved assessment tools used to identify cognitive deficits in this population and determine patients in need of full neuropsychological evaluation and treatment for ADL/IADL.

COSTS
There are no costs for participating in this study other than the time you will spend in each of the four meetings (filling out the two questionnaires and completing the two assessments).

PAYMENT FOR PARTICIPATION

Participants that complete the study will be entered into a raffle after completion of the 4th assessment. Their participant number will be entered into a drawing for a $50.00 gift card. The drawing will take place after all participants complete the study. The gift card will be presented to one participant. The raffle will be drawn once all study participants have completed their 3-month follow up assessments.

ALTERNATIVES
The only alternative is to not participate in the study.

CONFIDENTIALITY

Potentially identifiable information about you will consist of your address, email, telephone number, self-report surveys, assessments, observation notes, and data abstracted from the medical record. Data is being collected only for research purposes.

Your data will be identified by ID numbers, not names, and stored separately from research data in a locked research area. All personal identifying information will be kept in password-protected files and these files will be deleted within 5 years of the close of

the study. Other records of surveys, assessments, and observation notes will be kept in a locked file cabinet for 5 years after the close of the study. As required by law, five years after the study ends all data will be destroyed at that time. Access to all data will be limited to study personnel. Data and safety monitoring plans are established.
We will not tell anyone the answers you give us; however, information from the study and information from your medical record and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services or other federal regulatory bodies.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study. Your decision to withdraw will involve no penalty or loss of care, service or benefits to which you are otherwise entitled from this agency or service provider.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent. The reasons might include:
- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Robert Fix, MS OTR/L

24 hr phone 804-928-4298

and/or

Tony Gentry, PhD

804-828-2219

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

> *Office of Research*
>
> *Virginia Commonwealth University*
>
> *800 East Leigh Street, Suite 3000*
>
> *P.O. Box 980568*
>
> *Richmond, VA 23298*
>
> *Telephone: (804) 827-2157*

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

_____

Participant name printed

_____   _____
Participant signature   Date

_____   _____
Printed name of Person Conducting Informed consent   Date

_____   _____
Signature of Person Conducting Informed Consent   Date

_____   _____
Principal Investigator Signature (if different from above)   Date

_____   _____
Witness Signature   Date

IRB HM20003749_CR2 The Cognitive and Functional Impact of Open Heart Surgery: A Pilot Study
On 5/22/2017, this research study was ***approved for continuation*** by expedited review according to 45 CFR 46.108(b) and 45 CFR 46.109(e) and 45 CFR 46.110 by VCU IRB Panel A. This study is approved under Expedited category 7.

- The information found in the electronic version of this study's smart form and uploaded documents now represents the currently approved study, documents, informed consent process, and HIPAA pathway (if applicable). Please see instruction box below for details on viewing the approved study.

This approval expires on 4/30/2018. Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review notices will be sent to you prior to the scheduled review.
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7. Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in VCU IRB WPP VII-6):
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c) Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).
Conditions of Approval (version 010507)

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VCU IRB NO.: HM20003749

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- Clinic Collaborators
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☐ Other (specify): Data collected will be deidentified

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COSTS
There are no costs for participating in this study other than the time you will spend in each of the four meetings (filling out the two questionnaires and completing the two assessments).

PAYMENT FOR PARTICIPATION

Participants that complete the study will receive a $25.00 gift card in appreciation for their time. The gift card will be presented to each participant at the completion of the 3-month follow up assessments. Additionally, all participants that complete the study will be entered into a raffle after completion of the 4th assessment. Their participant number will be entered into a drawing for a $50.00 gift card. The drawing will take place after all participants complete the study. The gift card will be presented to one participant. The raffle will be drawn once all study participants have completed their 3-month follow up assessments.

ALTERNATIVES
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the study. Other records of surveys, assessments, and observation notes will be kept in a locked file cabinet for 5 years after the close of the study. As required by law, five years after the study ends all data will be destroyed at that time. Access to all data will be limited to study personnel. Data and safety monitoring plans are established.

We will not tell anyone the answers you give us; however, information from the study and information from your medical record and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services or other federal regulatory bodies.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

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- you have not followed study instructions.

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Robert Fix, MS OTR/L

24 hr phone 804-928-4298

and/or

Tony Gentry, PhD

804-828-2219

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

> Office of Research
>
> Virginia Commonwealth University
>
> 800 East Leigh Street, Suite 3000
>
> P.O. Box 980568
>
> Richmond, VA 23298
>
> Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

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_____

Participant name printed

_____   _____

Participant signature   Date

_____   _____

Printed name of Person Conducting Informed consent   Date

_____   _____

Signature of Person Conducting Informed Consent   Date

_____   _____

Principal Investigator Signature (if different from above)   Date

_____   _____

Witness Signature   Date

Appendix B

Recruitment Flyer

Participants are now being accepted to take part in a research study conducted at Virginia Commonwealth University Medical Center.

Adults aged 18 years or older that are having surgery for either coronary artery bypass graft surgery, heart valve replacement, or left ventricular assist device placement are welcome to participate.

Study participants will be asked to complete 2 short questionnaires, 1 paper and pen task, and 1 brief kitchen task on 4 separate occasions. The sessions will be completed:
Before surgery
    1st session at the outpatient clinic
    2nd session either in the outpatient clinic or your home
After surgery
    3rd session in the hospital right before discharge, and
    4th session 3-months after surgery in the outpatient clinic

To learn more about this opportunity, please contact:

Robert Fix, Occupational Therapist, MS OTR/L

Virginia Commonwealth University

804-928-4298

This study is being conducted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, Health Related Sciences at Virginia Commonwealth University, through the Department of Occupational Therapy.
VCU IRB#: HM20003749

Appendix C

Demographics Form

Demographics Form

Participant Identification Code (PIC):

Gender: __ Male   __ Female

Date of Birth: ___ / ___ / _____
                        MM   DD   YYYY

Education Level: __ Number of years

Race ("X" ONLY one with which you MOST CLOSELY identify):
___ American Indian of Alaska Native
___ Asian
___ Black or African-American
___ Hispanic or Latino
___ Native Hawaiian or Other Pacific Islander
___ White
___ More than one race
___ Unknown or not reported

Community Dwelling:
___ Yes ___ No

Medical History of:
___ Dementia
___ Stroke with ongoing cognitive or motor deficits

Surgical Group:
___ CABG ___ HVR ___ LVAD

Date Informed Consent Signed: ___ / ___ / _____
                                                         MM   DD   YYYY

Investigator Signature: _____   ___ / ___ / _____
                                                         MM   DD   YYYY

Appendix D

Original Study Design and Analysis

The following section presents the originally proposed and approved study design and data analysis.

Original Study Design

The quasi-experimental study was to compare three levels of open heart surgical groups (CABG, HVR, and LVAD) with a double pre-test and double post-test model. The addition of a second pre-test prior to the first can reduce threats from maturation by describing pre-treatment differences; reveal threats from regression if any group is atypically lower or higher between pre-tests; and more precisely estimates correlations between observations due to a clearer estimate of the correlation between non-treatment points in time (Shadish, Cook, & Campbell, 2002). This study design was to incorporate the use of repeated measures, due to the desire to assess the change in cognition and functional abilities over time. The use of this design was to afford comparison of changes on assessments before surgery (1st pre-test to 2nd pre-test), with surgery (2nd pre-test to 1st post-test), and after surgery (1st post-test to 2nd post-test). Since the role of the pilot was to assess the feasibility of subsequent study this pilot design was to set the stage for any future study (Moore, Carter, Nietert, & Stewart, 2011; Jairath, Hogerney, & Parsons, 2000).

Original Statistical Analysis

The MoCA, KT and PSMS assessment tools used in this study were to provide scores for comparisons at each time point. The HADS assessment score at each corresponding time point and age were to be used as control variables. All data was to be screened for normality and if skewed, transformations were to be applied. Data from

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the assessment tools were to be entered into the statistical software SPSS v. 24 (2016) to conduct the following statistical analyses:

Descriptive statistics were to be run to examine and present the demographic data. The results were to reveal basic similarities and differences in the population.

MoCA and KT: Individual scores from each participant in each surgical group were to be run for each of the four administrations of the tests. Repeated measures ANCOVA were to be used to compare change on this assessment across administrations for each individual in each surgical group, with a significance of $p < .05$. A full model was to be utilized to examine between subjects in surgical groups with time interaction and within subjects by time interaction, with a covariate. The model was to use a continuous multilevel dependent variable (MoCA and KT), a discrete IV (surgical groups), and covariates (HADS and age). A Bonferroni adjustment was to be applied to account for multiple significance tests on the 2 measures for the 3 surgical groups, with a new significance level of $p < .025$ (Tabachnick & Fidell, 2007). This analysis was to address:

H1 – Controlling for age and anxiety/depression, cognition will decrease within surgical groups over time.

MoCA, KT and PSMS: Individual scores from each participant in each surgical group were to be compared across each of the four administrations of the tests. A mixed model repeated measure MANCOVA was to be used to examine each participant at 4 observations, with a significance of $p < .05$. It was assumed that data would be missing at random; therefore auto correlation was to be used to assure that subjects with missing data would not be thrown out of the model. The model was to use

continuous multilevel dependent variables, DV_1 (MoCA and KT) and DV_2 (PSMS),

multiple discrete independent variables (CABG, HVR, and LVAD), and covariates

(HADS and age). A Bonferroni adjustment was to be applied to account for multiple

significance tests on the 3 measures for the 3 surgical groups, with a new significance

level of $p < .0167$ (Tabachnick & Fidell, 2007). Planned post hoc analyses were to

include Tukey's test which would allow for all pairwise comparisons of means and

Scheffe's test which would allow for an unlimited number and complexity of

comparisons (Tabachnick & Fidell, 2007). This analysis was to address:

H2 – Controlling for age and anxiety/depression, cognition and functional abilities

will be significantly different between the 3 surgical groups.

Additionally, the individual scores from each participant in each surgical group

were to be analyzed through a linear regression technique using multilevel linear

modeling in repeated measures setting. This technique was considered to be

advantageous because it did not require complete data over occasions, equal number

of cases, or equal intervals of measurements for each case; and when random slopes

and intercepts are specified each case would be assigned a regression equation,

therefore evaluation of individual differences in means or patterns of means would be

capable of being identified in repeated measurements (Tabachnick & Fidell, 2007). The

model was to use one continuous dependent variable (PSMS) and two continuous

independent variables (MoCA and KT), and covariates (HADS and age). This was to

address:

H3 – Controlling for age and anxiety/depression, there will be a direct correlation between cognition and the functional ability to perform ADL/IADL over time as measured by changes in scores on the MoCA, KT, and PSMS

HADS: This assessment was to produce two scores, one for anxiety and one for depression. This moderating variable was to be dichotomized as 0 = "no" for presence of anxiety or depression with scores of 0 – 7, and 1 = "yes" for presence of anxiety or depression with scores of 8 or above. This moderating variable was to be a control variable and entered as such in all analyses as anxiety (0 = no, 1 = yes) and depression (0 = no, 1 = yes).

Age: Age was to be determined by age at time of consent and was not to be adjusted or changed in the event of a birthday during the time of the study. This moderating variable was to be entered in all models as a control variable and defined by number of years.

Effect size: Effect size was to be estimated to calculate power analysis and generate an appropriate sample size necessary for subsequent study of the population and variables of interest.

Data analyses were to be piloted and to use the resulting means to conduct sample size estimates. The software Nquery was to be used to determine the appropriate formula to estimate effect size of a 3-group one-way ANOVA. Next, this formula was to be used to determine the time and group effect sizes for each measure. Then, power analysis was to be completed to determine the sample size necessary for an appropriately powered subsequent study.

Vita

Robert Charles Fix was born on September 24, 1967, in Glen Ridge, New Jersey. He graduated from Blue Ridge High School, New Milford, Pennsylvania in 1985. He received his Bachelor of Fine Art in Theatre from Clarion University of Pennsylvania in 1989. He performed in professional musical theatre productions regionally until returning to graduate school in 2002. Robert received a Masters of Science in Occupational Therapy from Virginia Commonwealth University (VCU) in 2004. Upon graduation he began working in an acute care hospital setting at Virginia Commonwealth University Health where he continues to work to this day. Over the years he completed a Certificate in Aging Studies from VCU in 2008, and completed and maintains a Certified Stroke and Rehabilitation Specialist (CSRS) certification since 2015. Robert joined the part time interdisciplinary plenary faculty of the Virginia Geriatric Education Center at VCU's Virginia Center on Aging in 2011. He is a guest lecturer and clinical faculty member for the Occupational Therapy Department at VCU.