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Illness Representation, Fatigue, and Depressive Symptoms in Patients with Stable

Coronary Disease

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THESIS

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LIST OF ABBREVIATIONS

ACS	Acute Coronary Syndrome
AMI	Acute Myocardial Infarction
CABG	Coronary Artery Bypass Graft Surgery
CHF	Congestive Heart Failure
CAD	Coronary Artery Disease
CCS	Canadian Cardiovascular Classification for Angina
HHU	Health History Update
HR	Hazard Ratio
IPQ	Illness Perception Questionnaire
IPQ-R	Illness Perception Questionnaire-Revised
PCI	Percutaneous Coronary Intervention
PHQ-9	Patient Health Questionnaire-9
POMS	Profile of Mood States
SF-36	Short Form- 36

SUMMARY

A study of secondary prevention behaviors and the influences of illness representation, fatigue, and depressive symptoms was carried out using a descriptive, correlation design. Leventhal's Self Regulation Model was the theoretical basis for this study. The purpose of this research was to examine the influence of illness representation, fatigue, and depressive symptoms for secondary prevention behaviors related to cardiac rehabilitation participation, smoking cessation, and medication use in patients with stable coronary artery disease (CAD). The specific medications of interest included lipid lowering agents, aspirin, and thienopyridines like clopidogrel and prasugrel. The Illness Perception Questionnaire-Revised, Profile of Mood States, Short Form-36, and Patient Health Questionnaire-9 were administered to patients (n=180) following treatment for stable coronary artery disease. Half of the patients (n=90) underwent percutaneous coronary intervention with optimal medical therapy (PCI/OMT) and the remaining patients (n=90) underwent coronary angiography with optimal medical therapy (OMT). Patients completed questionnaires during hospitalization and 30-days following hospital discharge. In addition, a medical record review was conducted to obtain past medical history, angiographic, medical treatment data.

At baseline, there were no differences in illness representation between those patients treated with PCI/OMT and OMT. However, by 30-days, differences in illness representation were observed with the OMT group classified as having a more chronic view of their illness. Additionally, those treated with OMT tended to view their illness as unpredictable with variation in symptoms from day-to-day. Compared to those treated with OMT, patients treated with PCI/OMT had a more acute illness model, suggesting that they viewed their disease process as an acute process rather than a chronic illness. Illness representation was found to be a significant

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SUMMARY (continued)

contributor for secondary prevention behaviors related to cardiac rehabilitation participation and medication use related to dual antiplatelet therapy.

Findings from this study also suggest that males and females differ in the experiences of fatigue associated with stable CAD. Higher fatigue scores were noted for females at baseline. By 30-days, fatigue scores were reversed, with females reporting lower fatigue scores compared to males. Fatigue was not found to be a significant contributor for secondary prevention behaviors. However, depressive symptoms were found to be a significant contributor for the regular use of thienopyridine agents.

Results from this study provide initial evidence for the influence of illness representation and secondary prevention in patients treated with stable coronary artery disease. Partial support was demonstrated for the use of Leventhal's Self Regulation model as a framework for secondary prevention behaviors in this population of patients. Results from this study suggest that a tailored educational approach may help to improve the adoption of secondary prevention behaviors after treatment for stable CAD.

I. INTRODUCTION

Cardiovascular disease is the leading cause of death in the United States. It is estimated that 1 in 3 deaths in the United States is associated with cardiovascular disease, and cardiovascular disease generates a cost of approximately \$503.2 billion per year (Lloyd-Jones et al., 2009). Stable coronary disease includes patients previously diagnosed with CAD that present with symptoms which have remained unchanged for the past 60 days and without recent myocardial damage. CAD is considered a chronic illness, requiring secondary prevention for long-term disease management. Secondary prevention programs, such as cardiac rehabilitation, are associated with a 45% reduction in mortality in patients with CAD (Goel, Lennon, Tilbury, Squires, & Thomas, 2010). However, only up to 20% of eligible patients participate in secondary prevention programs (Cundley & Frank, 1995; Goel et al., 2010). It has been suggested that illness representations, such as cognitive and emotional responses, appraisal, and coping processes (Cherrington, Moser, Lennie, & Kennedy, 2004), fatigue (Smolderen et al., 2009), and depressive symptoms (Grace et al., 2005a; Whooley et al., 2008) are associated with lower participation in secondary prevention programs and thus increase the risk of future cardiovascular events after diagnosis of CAD. With nearly 40% of patients presenting with stable CAD, it is important to understand the impact of various treatment modalities for this population, as well as the potential variations of illness representations, fatigue, and depressive symptoms towards secondary prevention behaviors (Lloyd-Jones et al., 2009).

A. Background

Patients are viewed as active decision makers in framing the long-term goals associated with chronic illness management, such as CAD. Patients form mental representations of the illness to promote self-regulation. Self-regulation is based primarily on the psychological factors that allow patients to go through the process of cognitive and emotional responses, appraisal, and coping processes. These processes take place all in an effort to understand what the illness represents. As a result, illness representations help to establish the patient's overall perception of the illness and his or her subsequent coping mechanisms after diagnosis.

Research has demonstrated that particular illness representations reduce participation in prevention programs and adherence to medications (Petrie & Weinmann, 1997). Additionally, the combined influence of illness representation and depressive symptoms are known factors for poor outcomes in patients with AMI (Cherrington, 2001). As a separate entity, depressive symptoms confer a relative risk between 1.5 and 2.5 for cardiovascular-related morbidity and mortality. Furthermore, fatigue is a commonly reported symptom during the recovery period after treatment for CAD (Barnason, Zimmerman, Brey, Catlin, & Nieveen, 2006) and is associated with a 42.6% rehospitalization rate within 1 year after treatment (Smolderen et al., 2009). The goal of the proposed study is to identify the association among illness representation, fatigue, and depressive symptoms so that secondary prevention programs for patients with stable CAD can be identified. Therefore, this study will serve as the preliminary investigation towards the development of a research program focused on improving secondary prevention behaviors in patients with CAD. As more is understood about factors which promote secondary prevention, healthcare providers may be in a better position to develop targeted interventions to improve outcomes in this population of patients.

B. <u>Selection of Study Variables</u>

1. <u>Illness Representation</u>

Prior research has shown illness representation to influence return to work and cardiac rehabilitation participation in patients treated after AMI (Cooper, Lloyd, Weinman, & Jackson, 1999; French, Cooper, & Weinman, 2006). These data limit the generalizability of findings because most patients were sampled following recovery for AMI, which is likely to result in differing perceptions of illness when compared to other cardiovascular diagnoses such as stable CAD. Furthermore, there is a paucity of data which examine illness representation in relation to specific patient-related outcomes (Cherrington, Moser, Lennie, & Kennedy, 2004). As a result, the effect of illness representation towards cardiac rehabilitation may also be extended to other secondary prevention behaviors such as medication–taking for cardiac specific therapies and smoking cessation. Therefore, illness representation may play an important role for secondary prevention in the stable CAD population and was selected as a key variable for use in this study.

2. <u>Fatigue</u>

Fatigue is commonly reported in acute and chronic illnesses such as acquired immune deficiency syndrome (Breitbart, McDonald, Rosenfeld, Monkman, & Passik, 1998), cancer (Reuter & HÄrter, 2004), congestive heart failure (Evangelista et al., 2008; Fink, Sullivan, Zerwic, & Piano, 2009), and AMI (Fennessy et al., 2010; McSweeney et al., 2003). Additionally, fatigue has prognostic implications for patients with heart failure and is reported to be a significant predictor (RR 1.09; 95% CI 1.02-1.18; p=.02) for further disease progression (Ekman et al., 2005). Despite the rate of fatigue experienced in cardiovascular patients, there is little data to indicate whether this symptom is experienced in patients with stable CAD. Additionally, it is unclear how much influence fatigue has towards patient-outcomes following treatment. In this study, multiple measures are used to examine the association of fatigue towards secondary prevention behaviors for patients with stable CAD.

3. Depressive Symptoms

Depression has long been known to influence secondary prevention outcomes in patients with cardiovascular disease (Simsek et al., 2009; Stafford, Jackson, & Berk, 2008; Zellweger, Osterwalder, Langewitz, & Pfisterer, 2004). In particular, since fatigue is also included as a study variable, it would be a methodological flaw to not include the measurement of depressive symptoms to assess symptom covariance within the sample (Fink et al., 2010). Given the overwhelming support for the role of depressive symptoms in this population, multiple measures for depressive symptoms are included in this study to compare with other cardiac samples. Furthermore, depressive symptoms are evaluated to assess the influence towards secondary prevention behaviors.

4. <u>Treatment Groups</u>

The clinical goals for managing CAD as a chronic illness is based on improvement in quality of life, by reducing or abolishing symptoms, and prevention of future myocardial infarction or death (Boden et al., 2007). Three modes of therapy currently exist for this population. First, medical therapy, which includes lifestyle changes, is a standard of care for this group of patients. Secondly, if clinically indicated, the patient may undergo percutaneous coronary intervention (PCI) with either balloon angioplasty or coronary stenting. Finally, in some cases, coronary disease may warrant CABG surgery. Prior research has demonstrated illness representation patterns in stable CAD patients undergoing CABG (Hermele, Olivo,

Namerow, & Oz, 2007). Other studies have used a combined AMI and stable CAD sample to evaluate perceptions in the causes of cardiovascular disease (Zerwic, King, & Wlasowicz, 1997). There are data which evaluate quality of life in patients receiving either: 1- PCI and optimal medical therapy (OMT) or 2- OMT alone (Boden et al., 2007; Weintraub et al., 2008). To date, no study has evaluated illness representation in a true stable CAD sample with comparisons between PCI/OMT and OMT groups. Therefore, treatment selection in this study is based on PCI/OMT and OMT classifications.

C. <u>Percutaneous Therapy for Stable CAD</u>

Coronary angiography remains the gold standard for diagnosing CAD. During coronary angiography, the coronary arteries are examined using radiologic images (x-rays) to view atherosclerotic lesions within the coronary vasculature. If a coronary lesion is found to be obstructing blood flow within the coronary artery, PCI is performed by placing balloon catheters and wires within the lumen of blocked arteries to reestablish blood flow to the myocardium. Balloon catheters are then used to displace atherosclerotic plaque, with the placement of drug-eluting stents for certain types of coronary lesions (Fennessy & Borden, 2006). Recent advancements in the treatment for coronary artery disease (CAD) have lead to the increased use of PCI, which now serves as a leading treatment for coronary revascularization over traditional surgical options (Lloyd-Jones et al., 2009).

It is important to note that not all patients with CAD will require PCI. Approximately 20-30% of patients who undergo coronary angiography are found to have non-obstructive CAD, which typically requires optimal medical therapy (OMT) without the use of PCI (Lloyd-Jones, Adams, Brown et al., 2009). Whether it is non-obstructive or obstructive CAD or whether it is

treated medically or with PCI, the long-term management of CAD is similar. However, it is likely that patients treated with PCI are likely to transition to an acute illness perception because of reduced or eliminated symptoms and overall improvement in functional status. For those patients treated with coronary angiography and OMT, symptoms may continue in this sample despite appropriate medication titration, resulting in subsequent changes in illness representation after treatment.

PCI is considered to be less invasive than surgical intervention and has resulted in shorter hospital length-of-stays, less discomfort during recovery, and an expedited return to physical functioning compared with surgical revascularization treatment (Charlson et al., 2008). These patients typically exhibit positive experiences as a result of the expedited treatment of CAD that PCI affords; however, the marked differences post-treatment compared with surgical treatment, such as coronary artery bypass surgery, may result in patients underestimating the long-term management of the disease process (Gulanick, Bliley, Perino, & Keough, 1997; Hermele et al., 2007). Furthermore, by undergoing PCI, patients are required to take dual antiplatelet therapy (aspirin and thienopyridines: clopidogrel or prasugrel) for a given period of time, typically for a period of up to 12 months if there is low risk for bleeding. It is estimated that 1 in 7 patients (13.6%) stop their antiplatelet medications and this is reported to be associated with late stent thrombosis, myocardial infarction, and death within 30 days after hospital discharge (Spertus et al., 2006). Spertus et al. demonstrated that patients who stopped thienopyridines as part of antiplatelet therapy by 30 days, had a higher risk of death within the following 11 months (7.5% versus 0.7%, p < 0.0001; adjusted hazard ratio=9.0; 95% CI=1.3 to 60.6) and subsequent rehospitalization (23% versus 14%, p=0.08; adjusted hazard ratio=1.5; 95% *CI*=0.78 to 3.0).

D. <u>Summary</u>

Despite the faster recovery times following PCI, patients still remain vulnerable to fatigue and depressive symptoms (Appels et al., 2005; Appels, Kop, Bar, Swart, & Mendes De Leon, 1995; Barnason et al., 2006; Odell, Grip, & Hallberg, 2006). These symptoms can extend to levels of emotional distress, which have been found to be predictive of mortality after PCI (Simsek et al., 2009). However, it is suggested that fatigue may also represent a somatic symptom of depressive symptoms in patients undergoing treatment for CAD (Irvine et al., 1999).

Understanding the association among the variables illness representations, fatigue, depressive symptoms and secondary prevention behaviors will assist in facilitating positive outcomes for those living with CAD. Although there is evidence to suggest that individually these variables are associated with secondary prevention behaviors after AMI (Grace, Shanmugasegaram, Gravely-Witte, Brual, & Suskin, 2009; Kronish et al., 2006; Petrie, Cameron, Ellis, Buick, & Weinman, 2002; Stafford, Berk, & Jackson, 2009), it is unknown as to whether these variables maintain similar effects for patients with CAD who are treated outside the context of AMI using less invasive therapies for coronary revascularization, such as PCI and OMT.

Investigators have examined illness representations for patients undergoing treatment for CAD; however, these studies incorporated diverse treatment methods and samples. An important limitation in previous research is that diverse treatment modalities and treatment settings used to treat CAD may represent a type of heterogeneity effect. For example, the cardiovascular community now uses the term acute coronary syndrome (ACS) to describe patients presenting with ST-elevation myocardial infarction, non-ST elevation myocardial

infarction, or unstable angina. While all three diagnoses are similar with regards to physiologic development and varying levels of ischemia, there are differences related to how these three diagnoses are treated and possibly perceived by the patient. For instance, the dramatic nature by which AMI is treated makes it difficult to generalize changes in illness representations for patients presenting with the unstable angina. Results from this study will provide valuable insight into how patients with CAD, outside the context of AMI, perceive their illness and cope with fatigue and depressive symptoms after treatment. Ultimately, this study will provide a focus for the improvement of secondary prevention behaviors in patients living with stable CAD.

E. Purpose and Aims

The purpose of this proposal is to examine the relationship between illness representations and secondary prevention behaviors in individuals with stable CAD. The specific aims which will guide the study are:

1) To compare group differences in illness representation (identity, cause, time-line, consequences, and cure/control) between patients with obstructive CAD receiving percutaneous coronary intervention/optimal medical therapy (PCI/OMT) and patients with nonobstructive CAD receiving optimal medical therapy (OMT).

It is hypothesized *[specific aim 1]* that group differences will be identified for illness representations (identity, cause, time-line, consequences, and cure/control) between patients receiving PCI/OMT therapy and OMT therapy.

2) To compare temporal changes in illness representation (identity, cause, time-line, consequences, and cure/control) from baseline (post-procedure) to 30-days after discharge for patients receiving PCI/OMT and OMT therapy.

It is hypothesized *[specific aim 2]* that illness representation (identity, cause, time-line, consequences, and cure/control) will change from baseline (measured post-procedure) to 30 days after discharge.

3) To determine if secondary prevention behaviors (cardiac rehabilitation participation, smoking cessation, and medication use related to lipid lowering and antiplatelet agents) are influenced by illness representation, fatigue, depressive symptoms, and demographics as measured at 30-days following treatment for CAD.

It is hypothesized [*specific aim 3*] that illness representation, fatigue, and depressive symptoms will influence the adoption of secondary prevention behaviors measured 30 days after discharge.

F. <u>Study Importance</u>

As rates of PCI therapies for stable CAD increase, it is imperative that researchers explore the association of psychological factors and secondary prevention in a sub-group of patients with CAD who are treated outside the context of acute myocardial infarction (AMI). The gap in the literature regarding the impact of psychological factors towards secondary prevention behaviors suggests that further investigation of illness representation is needed for patients treated for stable CAD. As more is known about these phenomena, it will be possible to build a program of intervention-based research to improve secondary prevention behaviors in the more than 40% of patients with CAD who are treated with PCI therapies outside the context of AMI.

G. <u>Study Overview</u>

Patients will be recruited from an outpatient clinical setting. A descriptive correlational design will be used to examine illness representations, fatigue, and depressive symptoms in patients treated with PCI and/or standard medical therapies for CAD. The primary goal of this study is to compare the associations among illness representation, fatigue, and depressive symptoms towards the adoption of secondary preventative behaviors 30 days after treatment for stable CAD.

The research problem introduced in this study will serve as groundwork for understanding the association among psychological factors that potentially impact the adoption of secondary prevention behaviors after diagnosis of CAD. This dissertation reflects the beginning stages towards establishing a program of research focused on secondary prevention behaviors in CAD. Research involving secondary prevention after treatment for CAD has gained increased attention by the American Heart Association and is one of the key initiatives outlined in the 2010 National Goals for improved cardiovascular health promotion and disease reduction by the year 2020 (Lloyd-Jones et al., 2010).

H. Definition of Key Terms

Acute Coronary Syndrome (ACS) — part of a spectrum used to describe patients who present with either acute myocardial infarction (ST elevation myocardial infarction-STEMI or Non-ST elevation myocardial infarction- NSTEMI) or unstable angina (Lloyd-Jones, Adams, Brown et al., 2009). Cardiac markers help to categorize myocardial infarction, which includes STEMI, NSTEMI, and unstable angina. This categorization is valuable because patients with ischemic discomfort may or may not have ST-segment elevations on their electrocardiogram. Those without ST elevations may ultimately be diagnosed with NSTEMI or with unstable angina based on the presence or absence of cardiac enzymes. Additionally, therapeutic decisions, such as administering an intravenous thrombolytic or performing primary percutaneous coronary intervention (PCI), are often made based on this categorization.

- Acute Myocardial Infarction (AMI)—cell death of cardiac myocytes caused by ischemia or decreased perfusion of the heart muscle. This can be categorized as acute, healing, or healed. In the setting of decreased perfusion, there is an imbalance between supply and demand. The most common cause of MI is narrowing of the epicardial blood vessels due to atheromatous plaques. Plaque rupture with subsequent exposure of the basement membrane results in platelet aggregation, thrombus formation, fibrin accumulation, and hemorrhage into the plaque with varying degrees of vasospasm (Lloyd-Jones et al., 2009). This can result in partial or complete occlusion of the vessel and subsequent myocardial ischemia. Total occlusion of the vessel for more than 4-6 hours results in irreversible myocardial necrosis, but reperfusion within this period can salvage the myocardium and reduce morbidity and mortality (Baim, 2006).
- Coronary Artery Disease (CAD)—a chronic disease resulting in the narrowing of coronary arteries and vessels that provide oxygen and essential nutrients to the myocardium (heart muscle). Atherosclerotic plaque in the form of fatty streaks lies along the lining of arteries. The accumulation of atherosclerotic plaque results in subsequent narrowing of the coronary arteries and reduced perfusion of the myocardium. Without sufficient perfusion, the heart muscle will become ischemic, thereby resulting in a myocardial infarction (MI) (Baim, 2006).

- Coronary Angiography— a study of the heart, which involves the percutaneous placement of a catheter via the femoral artery along the upper thigh, or brachial/ radial artery access along the upper extremities. Coronary angiography remains the gold standard procedure for determining the presence and severity of CAD. Using radiologic fluoroscopy, the catheter is guided to the heart and the tip is placed to engage the ostium of the left and right coronary arteries. Images are obtained while injecting contrast through the catheter (Baim, 2006).
- Depressive Symptoms— symptoms associated with depressed mood which include changes in appetite and sleeping patterns; feelings of worthlessness, hopelessness, and inappropriate guilt; loss of interest or pleasure in formerly important activities; fatigue; inability to concentrate; overwhelming sadness; disturbed thinking; physical symptoms such as headaches or stomachaches; and suicidal thoughts or behaviors (American Psychiatric Association, 1994).
- Dual antiplatelet therapy—Dual antiplatelet therapy with aspirin and a thienopyridine (clopidogrel [Plavix, Sanofi-Aventis] or prasugrel [Effient, Elli Lilly and Company]), has been shown to reduce cardiac events after coronary stenting. However, many patients prematurely discontinue dual antiplatelet therapy, which greatly increases the risk of stent thrombosis, myocardial infarction, and death.
- Fatigue—multidimensional concept associated with a state of decreased capacity for physical and/or mental activity due to an imbalance in the availability, utilization, and/or restoration of resources needed to perform activity (Aaronson et al., 1999).

- Illness Representations—an organized pattern of beliefs regarding a particular illness (Leventhal, Nerenz, & Steele, 1980).
- Ischemic Heart Disease—a condition closely related to acute myocardial infarction; however, the difference is based on the severity in terms of whether ischemia to the myocardium is severe enough to cause sufficient myocardial damage to release detectable quantities of biochemical markers (Anderson et al., 2007). Diagnosis is often made based on the patients presenting symptoms, clinical history, 12-lead electrocardiogram, biochemical markers, and/or imaging techniques (Thygesen et al., 2007).
- Percutaneous Coronary Intervention—family of percutaneous/catheter-based techniques, which includes standard balloon angioplasty (PTCA), intracoronary stenting, and atheroablative technologies (Anderson et al., 2007). Catheter-based approaches for revascularization involve imaging of the vascular branches within the coronary arteries to view the distribution and location of atherosclerotic plaque formation. Catheter-based devices are guided to the location of the atherosclerotic plaque(s), within the coronary arteries, to allow for the angiographic imaging of the culprit lesion(s) (Baim, 2006).
- Revascularization—treatment strategies, such as coronary artery bypass surgery or percutaneous coronary interventions, to restore blood flow to narrowed coronary arteries due to coronary artery disease (Anderson et al., 2007).
- Secondary Prevention—aggressive risk-reduction therapies targeted for patients with established coronary and other forms of atherosclerotic vascular disease. Risk reducing strategies include smoking cessation, blood pressure control, cholesterol management, physical activity, weight management, and medication adherence (Smith et al., 2006b).

- Stable CAD— a chronic illness found in adults previously diagnosed with coronary artery disease but without angina, or marked by the presence of symptoms which have remained stable for the past 60 days. There are no changes in the symptoms, duration, or cause of angina for the past 60 days, and there is no evidence of recent myocardial ischemia resulting in damage along the myocardial tissue. The goals for therapy include improvement in quality of life, improve understanding, education, long-term management of this chronic illness, and reduction of future cardiovascular events
- Symptoms—the subjective experience of illness which reflects changes in biophysical functioning, feelings, or cognition. In contrast, objective indictors of illness are referred to as signs. (Kozier, Erb, Berman, & Snyder, 2004).
- Unstable Angina—chest pain or discomfort that is accelerating in frequency or severity and may occur while at rest but does result in myocardial necrosis (Lloyd-Jones et al., 2009)

II. CONCEPTUAL FRAMEWORK AND RELATED LITERATURE

A. <u>Conceptual Framework</u>

Leventhal's self-regulation theory is used to guide this study (Leventhal, Nerenz, & Steele, 1984). This theory originated in research evaluating the role of fear-based messages in preventive health behaviors (Leventhal & Berkowitz, 1970). The self-regulation theory is described as a framework whereby individuals develop meanings of experiences to promote selfregulating behaviors. This theory views the patient as an active problem solver. A patient's response to illness is dynamic such that various coping responses will influence representations of illness. Therefore, response to illness is based on a mental representation of that illness. These representations may not be aligned with what is directed by the medical community; however, they are often times the foundation by which individual decisions are made (Ward, 1993). The response to illness involves (1) a cognitive representation of the health threat, (2) development of an action plan, and (3) an appraisal process to evaluate outcomes (Leventhal et al., 1984).

Published research in the field of illness representations use many different terms to describe similar theoretical constructs such as: illness representation, implicit models of beliefs, common-sense representation of illness, illness concept, and illness representations. Despite the various terms and methods, research in the field of illness representations typically includes five key components: (1) identity, (2) cause, (3) time-line, (4) consequences, and (5) cure/control (Leventhal et al., 1984). The first component, identity of illness, involves a process whereby individuals will attempt to match the symptoms with labels for a particular

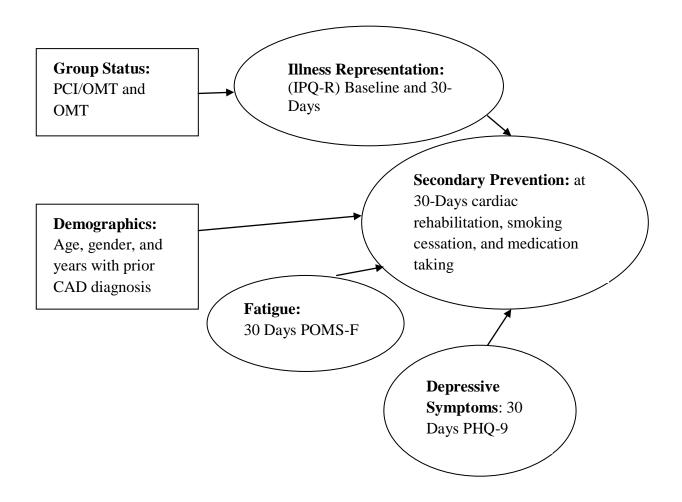
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disease or illness. The second component, cause, represents the individual's attempt to determine the causal component for a disease process. The time-line component refers to the individual's perception of the length of time (acute or chronic) for the disease to occur. The consequences component involves the individual's representations of the outcomes associated with the disease. Finally, cure/control refers to how an individual perceives his/her recovery from the disease or illness.

Several studies have used the self-regulation model to explain secondary prevention behaviors for patients with chronic illness (Brewer, Chapman, Brownlee, & Leventhal, 2002; Byrne, Walsh, & Murphy, 2005; Ross, Walker, & MacLeod, 2004). According to Leventhal's model, illness representation in the CAD population may be based on previous experiences with ischemic symptoms, prior diagnosis, and overall understanding regarding treatment for this chronic illness. Prior experiences with symptoms may help to facilitate appropriate labeling of the disease process and subsequent treatment and secondary prevention. In this study, Leventhal's Self-Regulation theory (see figure 1), is used as the conceptual guide, with a specific interest on illness representation portion of the theory. Therefore, this study was conducted for the purpose of understanding the role of illness representation, fatigue, and depressive symptoms towards the adoption of secondary prevention behaviors after treatment for stable CAD. The specific theoretical components of illness appraisal and coping, as described in Leventhals' theory, are not conceptualized in this study.

FIGURE I

PROPOSED STUDY MODEL BASED ON LEVENTHAL'S SELF REGULATION THEORY



Adapted from "Illness Representation and Coping with Health Threats, "by H. Leventhal, D. Nerenz, and D. Steele, 1984, *Handbook of Psychology and Health*.

B. <u>Percutaneous Coronary Intervention</u>

Catheter-based approaches for revascularization involve imaging of the vascular branches within the coronary arteries to view the distribution and location of atherosclerotic plaque formation. In CAD, atherosclerotic lesions can range in severity and result in decreased perfusion to the myocardium. Abnormalities in perfusion patterns to the myocardium require appropriate therapies to restore blood flow to the affected area. With percutaneous coronary intervention (PCI), catheter-based devices are guided to the location of the atherosclerotic plaque(s), within the coronary arteries, to allow for the angiographic imaging of the culprit lesion(s). Devices such as balloon catheters and stents are then used during the imaging process to aid in the restoration of coronary circulation (Baim, 2006). In contrast, traditional surgical treatment typically requires a sternotomy to access arteries and veins to bypass coronary arteries that are affected by atherosclerotic plaque.

C. <u>Medical Treatment for CAD</u>

Improvements in medical treatment options for CAD provide patients with a good longterm prognosis; however, these therapies require aggressive management by the healthcare team and improved adherence on the part of the patient (Smith et al., 2006b). Effective strategies for medical therapies include dual antiplatelet therapy, lipid lowering, beta blockers, and angiotensin converting enzyme inhibitors. According to current guidelines, the term medical therapy does not necessarily mean absence of PCI, but rather the use of evidence-based pharmacotherapy and lifestyle changes for improved outcomes in patients with CAD. Medical therapies are a proven option for this population and have been shown to improve moderate-to severe angina, with the use of PCI or CABG reserved for cases when symptoms persist (O'Roarke, 2008).

D. <u>Illness Representation</u>

There is an increasing interest in the role of psychological factors that may influence prognosis for patients living with CAD (Simsek et al., 2009; Smith, Pedersen, Van Domburg, & Denollet, 2008). Illness representation-based research is derived from the field of psychology (Leventhal, 1970; Leventhal et al., 1984) and is defined as an organized pattern of beliefs that patients have about a particular illness (Petrie, Jago, & Devcich, 2007; Petrie & Weinmann, 1997). Research in the area of illness representation has spanned chronic illnesses and populations (Petrie & Weinmann, 1997) with relationships found for secondary prevention outcomes such as medication taking (Horne & Weinman, 1999, 2002) and attendance in cardiac rehabilitation (Petrie, Cameron, Ellis, Buick, & Weinman, 2002).

E. <u>Illness Representation Associated with CAD</u>

There has been considerable focus on illness representation-based research within cardiology, specifically the AMI population (Cherrington, 2001; French, Cooper, & Weinman, 2006; Johnson & King, 1995; Petrie et al., 2002). Diagnosis of chronic illness, such as CAD, places individuals in a position that requires information to be processed for future physical and psychological adjustments (Petrie & Weinmann, 1997). Depending on the illness, this adjustment period may result in the loss of functioning over time or positively influencing the patient to adopt certain behaviors which prevents further damage and facilitates coping. A diagnosis of CAD serves as the impetus for the development of psychological effects and subsequent changes in behavior. Very little illness perception-based research has been conducted in the stable CAD population. Therefore, the background literature on illness representation associated with CAD is presented using data from the AMI population, with a follow-up summary of the initial research related to the stable CAD population. Illness perceptions have been shown to influence expectations of symptoms experienced during an AMI (Johnson & King, 1995) and are important during the recovery phase after the acute event (Petrie et al., 2002). The recovery period following AMI is often influenced by emotional factors. The onset of the AMI and emergent hospitalization produce psychological difficulties such as making sense out of symptoms, fear of further AMI, and concerns about being restored to baseline health status after diagnosis (Petrie & Weinmann, 1997).

The extent to which a patient views CAD as acute or chronic has been explored in the post-AMI population. There is data to suggest that the perception of AMI as an acute illness places patients at risk for inadequate lifestyle changes (Byrne et al., 2005; Petrie, Weinman, Sharpe, & Buckley, 1996). For example, Brink et al. (2006) reported that patients who viewed their condition as mild were more likely to perceive AMI as acute rather than chronic. In these scenarios, patients' representations are based on illness identity and the perceived length of convalescence. As a result, patients viewing a diagnosis as short lived were less likely to adopt secondary prevention behaviors.

Petrie et al. (1996) reported that patient beliefs in the consequences of AMI had the strongest relation to functional status outside of work. The greatest levels of disability were associated with patients who viewed their illness in light of extreme consequences. Furthermore, illness identity was found to account for 8% of the variance for sexual dysfunction during 6-months follow-up, suggesting a greater level of sexual difficulty for those patients who experienced multiple symptoms in follow-up (Petrie et al., 1996). Sleep patterns were not found to be associated with illness representations. A key finding reported by Petrie et al. suggests that illness representations before and after AMI are associated with recovery patterns and functional status after hospital discharge.

Two randomized trials have been conducted in the AMI population, which delivered tailored interventions to patients based on individual responses to items on an illness perception questionnaire (Broadbent, Ellis, Thomas, Gamble, & Petrie, 2009; Petrie et al., 2002). Results revealed positive changes for patients in the intervention groups. Patients who received the intervention were found to return to work faster when compared with patients in the control group. Those who received standard therapy were found to have a higher frequency of angina 3-months after hospital discharge. While both studies demonstrate the importance of illness representations on health outcomes after AMI, the ability to generalize these findings to other sub-groups of patients with CAD is limited. Furthermore, recovery after AMI often includes other symptoms beyond angina, such as fatigue and depressed mood. The measurement of additional symptoms and psychological factors were not considered, which further limits the generalizability, or external validity of these findings.

Hirani, Pugsley, and Newman (2006) compared illness representations in patients with CAD who were treated using medication-only, PCI, or Coronary Artery Bypass Grafting (CABG) treatments. A cross-sectional approach was used to measure the differences in representations across three types of therapy. Methods consisted of measuring illness representations after diagnosis of CAD but prior to receiving the therapy. Overall, significant differences were found for the perception of illness duration, with patients directed towards PCI therapy as viewing their illness as acute with possible resolution.

Results from Hirani et al. (2006) demonstrate illness representation differences according to the types of therapies used to treat CAD. While this study adds to the literature regarding illness representations associated with CAD, there are methodological limitations that need to be addressed. First, the sample was recruited from an outpatient setting after a decision was made for patients to undergo certain therapies. From a clinical standpoint, decisions to treat patients with medication therapy, PCI, or CABG typically require a review of the coronary anatomy through coronary angiograms to understand the severity of the disease process. Understanding the extent of disease within the coronary arteries provides clinicians with useful information to determine the clinical strategy that is best for the patient. It appears that patients from all groups underwent coronary angiograms and were then asked to follow-up in the outpatient clinic to review the options for treatment. Considering the length of time from when the angiogram was performed, until the time when decisions were made for treatment, the delays in treatment could represent a confounding effect in illness representation scores across all groups. Secondly, it is unknown how many of these patients were treated as a result of AMI. Finally, illness representation was measured at one time point, which limits the ability to understand potential temporal changes in illness representations before and after treatment.

Research related to illness representations for patients undergoing coronary angiography and/or PCI therapy demonstrates the presence of an emotional response immediately after treatment (Astin, Closs, McLenachan, Hunter, & Priestley, 2009; Astin & Jones, 2006; Devcich, Ellis, Gamble, & Petrie, 2008; Gulanick et al., 1997). Astin et al. (2004) conducted a mixed methods study to evaluate illness representations associated with PCI therapy. Patients who underwent PCI in the setting of AMI were found to experience a mismatch between their individual experiences and the reality of living with a chronic illness (Astin et al., 2004). The qualitative data suggest that patients tend to experience shock associated with the speed of care and the dramatic nature related to AMI diagnosis (Astin et al., 2004). Gender differences were exhibited in the study by Astin and Jones (2004) for CAD patients scheduled to undergo PCI. Males in this sample were found to attribute their disease to behavioral rather than biological causes, while females cited biological reasons for their illness (Astin & Jones, 2004).

Only one study has been found to report illness representations measured at two time points—before and after PCI (Astin & Jones, 2006). Illness representations were measured before and 6—8 months after treatment at a medical center located in Australia. Results demonstrated a shift in representations after illness, with scores after PCI indicating a chronic model of illness. Interestingly, patients had lower *cure/control* scores during the 6—8 month follow-up, indicating a weakened perception of control over the disease process (Astin & Jones, 2006). Scores related to the *consequences* of CAD also decreased during follow-up, which suggests that CAD was not viewed as having serious consequences over time (Astin & Jones, 2006).

Overall, results from this study suggest a shift in illness representations before and 6-8 months following PCI (Astin & Jones, 2006). However, 74% of the patients in this study attended cardiac rehabilitation, which is much higher than the average 10% reported in the United States (Cundley & Frank, 1995). There is a strong possibility that formal educational sessions through cardiac rehabilitation may have served as a potential confounder for these data. Furthermore, considering previous relationships reported between depressive symptoms and illness representations (Cherrington, 2001), the analysis by Astin et al. suggests that these associations were not taken into account before or after treatment.

F. <u>Fatigue</u>

Conceptually, the symptom of fatigue is complex and multidimensional, with characteristics involving biological, psychosocial, and behavioral processes (Aaronson et al.,

1999; Arnold, 2008; Evans & Lambert, 2007). Aaronson et al. defines fatigue as, "the awareness of a decreased capacity for physical and/or mental activity due to an imbalance in the availability, utilization, and/or restoration of resources needed to perform activity" (p. 46). Fatigue is a common symptom for individuals experiencing chronic illness, resulting in over \$300 million annually in health care and other costs (Evans & Wickstrom, 1999).

The multidimensional nature of fatigue and reliance on subjective reporting make it particularly difficult to assess clinical practice. For instance, the differential for fatigue spans across multiple systems, which can make it difficult to isolate the source of this symptom. It is suggested that symptoms of fatigue after AMI are associated with decreased participation in cardiac rehabilitation programs (Cundley & Frank, 1995). However, symptoms associated with fatigue are also common in depression (Irvine et al., 1999). Thus, there are concerns that symptoms of fatigue confound the assessment of depression in the AMI population.

G. Fatigue Associated with CAD

Fatigue has been shown to be associated with increased risk of fatal and non-fatal cardiac events in patients with and without cardiovascular disease (Williams et al., 2009). Fatigue is commonly reported in persons with cardiovascular disease. In the setting of AMI, the symptom of fatigue has been reported in up to 70% of patients after AMI (Chen, Woods, Wilkie, & Puntillo, 2005; DeVon, Ryan, Ochs, & Shapiro, 2008; Milner et al., 1999). Previous literature has cited "vital exhaustion" as a term used to describe extreme fatigue patterns in patients with CAD (Appels et al., 1995; Kop, Appels, Mendes De Leon, Swart, & Bar, 1994; von Känel, Bellingrath, & Kudielka, 2009; Wojciechowski, Strik, Falger, Lousberg, & Honig, 2000). In both healthy control and CAD patients, fatigue is a prognostic indicator for cardiovascular end points such as MI and death (Frasure-Smith, Lesperance, & Talajic, 1995). For example, the presence of vital exhaustion, a surrogate measure for fatigue, was found to be associated with a 2.28 relative risk for first time MI (Appels & Mulder, 1988) and patients with fatigue were three times as likely to have a recurrent cardiac event up to 9 years after MI diagnosis.

H. <u>Fatigue and AMI</u>

Fatigue has been evaluated in patients before and after AMI (Fennessy et al., 2010), with research documenting prodromal symptoms prior to the acute event, particularly in females (Crane, 2005; Eckhardt et al., 2007; McSweeney, Cody, & Crane, 2001; McSweeney & Crane, 2000). Alsén, Brink and Persson (2008) used a qualitative approach to describe the extent to which AMI survivors managed fatigue during the recovery process. Survivors reported *living with incomprehensible fatigue* as a central theme four months after AMI (Alsén et al., 2008). Additionally, Alsén et al. (2010) demonstrated negative associations between the symptom of fatigue and health-related quality of life in a post-AMI sample (*n*=204). Despite the mounting evidence supporting the presence of fatigue during AMI, there is a paucity of data evaluating the symptom of fatigue for patients with stable CAD.

I. Fatigue and PCI

Barnason et al. (2006) reported on a pilot study which suggested the persistent presence of fatigue for patients (n=37) after PCI. Fatigue was found to be the most frequent symptom experienced 2, 4, and 6 weeks after PCI. This study is unique in that fatigue and physical functioning patterns were reported using a longitudinal design. These results suggest the presence of fatigue in the timeframe immediately after PCI; however, it is unclear if these symptoms were experienced prior to treatment. Furthermore, the measurement of fatigue was conducted using a presence/absence (occurrence) format with severity scales for each individual symptom, such as chest pain and shortness of breath. Therefore, fatigue was measured using a single-dimension approach, rather than accounting for the possible emotional and physical impact associated with this symptom. The small sample size and single-dimensional measurement of fatigue suggest that further research is needed to expand on this phenomenon before and after PCI.

J. Fatigue and Risk for Future Cardiovascular Events

Fatigue has been studied as a prognostic indictor for future cardiovascular events after PCI (Appels et al., 2005; Simsek et al., 2009). Simsek et al. (2009) evaluated fatigue (*n*=685) using a subscale from the Heart Patients Psychological Questionnaire from the Taxus drugeluting stent registry. Scores on the *Feelings of Being Disabled* questionnaire (example- "I quickly feel tired even if I don't do much") were found to be an independent predictor of mortality for patients four years after PCI, with most deaths occurring 1 year after the procedure (HR=2.4, 95% CI 1.3-4.4). These results suggest that examining fatigue may lead to improved risk stratification after PCI. Furthermore, the measurement of fatigue was reported 1 month and 4 years after PCI, suggesting the possibility that multiple confounders may have influenced fatigue levels during this time. Therefore, given the long follow-up used by Simsek et al., it is possible that fatigue may be the result of other clinical factors, rather than CAD.

Appels et al. (2005) used a randomized control design to determine if a behavioral intervention for exhaustion reduces cardiovascular events after PCI. While the intervention resulted in a reduction in the number of exhausted patients, there was no reduction in the number of new cardiovascular events. One important limitation is that patients were recruited with

multiple indications for PCI, such as post-MI angina, myocardial infarction, and unstable angina. More importantly, the results reported by Appels et al. suggest that by including multiple PCI indications in analyses, there is a risk of limiting the effect of an intervention due to the differences in co-morbidities for this heterogeneous group of patients. Therefore, future studies should use CAD samples with similar indications for PCI, in particular for the stable CAD population.

Smith et al. (2008) evaluated the symptoms of fatigue and depression for patients with varying levels of ischemic heart disease. From a methods standpoint, Smith et al. (2008) advanced what is known about fatigue and depression by including Type-D personality as a variable, which refers to the tendency for this population to experience negative emotions after diagnosis of CAD. This is the only study found to include patients with early stages of ischemic heart disease outside the setting of AMI who underwent PCI. Additionally, a comparison group of patients with ischemic congestive heart failure (CHF) was included to reference those patients with advanced heart disease. Smith et al. (2008) demonstrated that Type-D personality, rather than disease stage, was found to be associated with fatigue and depression [OR=2.96; 95% CI: 1.92-4.58, p<0.001].

In summary, fatigue is a symptom reported by patients after PCI. It remains unclear if this symptom is prodromal for stable CAD patients with ischemic symptoms who present outside the setting of AMI. Persistent fatigue was reported in patients after PCI; however, it is unknown how much influence was based on diagnosis of AMI and/or the simultaneous presence of depressive symptoms (Barnason et al., 2006). Only single measures of fatigue were used, so it remains a question as to whether various dimensions, such as physical and emotional symptom attributes, may be present for patients before and after PCI. Nevertheless, results from Smith et al. (2008) revealed promising opportunities for investigating psychologically-based interventions, such as illness representations, to target symptoms of fatigue in patients with CAD.

K. <u>Depressive Symptoms</u>

Depressive symptoms are best described as a constellation of symptoms associated with feeling blue, sad, down in the dumps, hopeless, and discouraged (Reuter & HÄrter, 2004; Zellweger et al, 2004; Ziegelstein, 2001). In some cases, anger, agitation, irritability, and frustration over minor matters may be reported along with traditional depressive symptoms, especially for males (Winkler, Pjrek, & Kasper, 2006). Somatic complaints such as body aches, sleep disturbances, and fatigue may also be reported (Jiang & Blumenthal, 2003). The everyday occurrence for some of these symptoms makes it particularly difficult to assess both in research and practice. The use of self-administered questionnaires with validated cut-points indicating low and high levels of depressive symptoms.

1. Depressive Symptoms in CAD

Depressive symptoms are present across all forms of CAD (Whooley et al., 2008). From a clinical standpoint, major depression is found in approximately 15—25% of the population living with CAD (Frasure-Smith et al., 1995), which is approximately threefold higher than what has been reported from community prevalence studies. It stands to reason that CAD patients with depressive symptoms, which are not necessarily indicative of major depression, are less likely to adopt secondary prevention behaviors after the acute event. As a result, previous research has explored secondary prevention a potential connection in explaining increased morbidity and mortality after AMI (Ziegelstein et al., 2000). Therefore, it is imperative that researchers include measures related to depressive symptoms when investigating psychologically-based phenomena within the CAD population.

Major depression is defined as a complex syndrome with diagnostic specific criteria, such as the presence of at least five related symptoms lasting at least two weeks in duration (American Psychiatric Association, 1994). Furthermore, the symptomatic overlap between depression and fatigue is often reported as a potential confounder in much of the medical-related literature (Irvine et al., 1999). The cancer-related literature has reported extensively on these issues, recommending that the assessment of depression focus on particular mood states and symptoms rather than on major depression as a whole (Reuter & HÄrter, 2004). Arnold et al. (2008) suggest that the association between fatigue and depression is not only an issue of covariance, but the association is also an issue of common etiologic factors. Therefore, for the purposes of clarity, depression in this proposal is conceptualized according to depressive symptoms.

Several studies have shown depressive symptoms to be associated with the development of CAD and increased mortality and subsequent cardiac events after diagnosis (Jiang & Blumenthal, 2003). Despite the prevalence of depressive symptoms in patients living with CAD, it is estimated that only 10% of patients with symptoms actually receive the appropriate treatment (Schleifer et al., 1989). The most common treatment options include the use of antidepressant medications and psychotherapy. The goal of both these treatment options is to reduce the level of depressive symptoms, improve functional status, and prevent suicide (Jiang & Blumenthal, 2003).

Psychotherapeutic approaches for treatment for depressive symptoms in CAD include behavioral, interpersonal, and cognitive-behavioral therapies (Jiang & Blumenthal, 2003).

Cognitive-behavioral therapies are designed to help alter a patient's cognitive view about self and the external world and are the basis for many interventions that have been designed to help reduce depressive symptoms in patients with CAD (Arnold, 2008). These intervention-based approaches provide researchers with an opportunity to investigate the modifiable determinants related to depressive symptoms that may accompany or manifest themselves in illness representation (Grace et al., 2005b; Stafford et al., 2009). Stafford et al. conducted a prospective study (*n*=193) to measure illness representations and depression at two time points: 3 and 9 months after hospital discharge. Illness representation contributed 9% of the explanatory variance, with negative illness beliefs regarding CAD predictive of higher levels of depressive symptoms at both time points (Stafford et al., 2009). These results suggest that interventions may be helpful to correct altered perceptions after diagnosis of CAD. However, the sample included various CAD presentations, which may have impacted illness belief scores at both time points.

Grace et al. (2005b) explored gender differences associated with illness representation and depressive symptoms. As part of their analysis, known correlates of depression were controlled for, such as: age, marital status, socioeconomic status, ethno-cultural background, physical activity, and functional status. For males (n=504), depressive symptoms and more negative illness representations were significantly associated (p<.001) with a belief in longer, more chronic time course for CAD, greater perceived consequences, and lower treatment control. Depressive symptomatology in females (n=157) were found to be significantly associated (p<.001) with younger age, lower activity status, and a more chronic time course. Grace et al. (2005b) were the first investigators to report gender differences associated with illness representations and depressive symptoms. However, the sample included a variety of patients with diagnoses such as unstable angina, MI, and congestive heart failure. Furthermore, patients included in this sample were treated with either PCI or CABG. Differences in convalescence between PCI and CABG imply that depressive symptoms and illness representations were influenced by varying post-procedure recovery patterns. Selection bias may have also played a role in the results since patients who were ineligible for cardiac rehabilitation were also excluded from participating in this study.

Previous investigators have demonstrated an association between illness representation and depressive symptoms, although the exact direction of this association has yet to have been fully explored (Grace et al., 2005b; Stafford et al., 2009). For example, it is possible that the negative representations of health may precipitate depressive symptoms in patients with CAD (Stafford et al., 2009). Conversely, it is quite possible for heightened depressive symptoms to impact illness representation. Either way, it appears as though the association between depressive symptoms and illness representations may be reciprocal in nature.

Depressive symptoms and fatigue co-vary in patients after AMI (Irvine et al., 1999; Wojciechowski et al., 2000). Fatigue is also reported as a depressive symptom. Results from Irvine et al. (1999) and Wojciechowski et al. (2000) suggest that depressive symptomatology and fatigue are not necessarily separate conceptual identities. However, both studies measured depressive symptoms and fatigue using only single measurements. Therefore, multi-dimensional measurement may be needed to fully understand the relationships between depressive symptoms and fatigue in patients with CAD. Future studies using multiple measures of depressive symptoms and fatigue may help to determine whether these associations are related to physical illness or simply another dimension of depressive symptoms (Fink et al., 2010).

L. Summary

Understanding the associations among illness representations, depressive symptoms, and fatigue is integral to facilitating the adoption of secondary prevention behaviors after treatment with coronary angiogram/PCI. Much of the research evaluating the role of illness representations in CAD has been done using samples of patients treated after AMI. In this study, illness representation is examined along with fatigue and depressive symptoms towards secondary prevention behaviors in patients with stable CAD after undergoing coronary angiography. Patients will be grouped according to two diagnoses: 1) obstructive or 2) non-nonobstructive disease. Modified conceptual models of the proposed study, based on Leventhal's' Self-Regulation Model are provided in Figure 1. Illness representation is the primary construct of interest for this study. Fatigue and depressive symptoms are also included to determine the influence towards secondary prevention at 30-days.

PCI is a rapidly growing treatment option for patients with CAD. Secondary prevention is necessary to control the progression of CAD after initial treatment. Investigators have demonstrated that in separate analyses, illness representations, depressive symptoms, and fatigue individually may impact the likelihood for adopting secondary prevention behaviors after diagnosis of CAD. Future research is needed to expand upon illness representation models to include additional factors such as depressive symptoms and fatigue, thereby providing some clarity as to how the patients formulate representations for secondary prevention behaviors after treatment for stable CAD.

III. METHODS

This section describes the methodology proposed for this study. Four sections are included: (A) design, setting, and sample, (B) data collection and recruitment procedures and inclusion/exclusion criteria, (C) methods for measurement, and (D) data analysis.

A. Design, Setting, and Sample

1. <u>Design</u>

A descriptive, two-group comparison design was utilized for this study. As depicted in Figure 2, eligible patients were identified after undergoing coronary angiography. Patients are typically referred for coronary angiography as a result of abnormal stress testing or the presence of symptoms. Since all patients were referred for evaluation of CAD, it is not known whether patients will have obstructive CAD requiring PCI therapy until after the procedure is completed. Therefore, the study included two different samples of patients who are referred for coronary angiography: (1) patients with non-obstructive CAD who are treated with *optimal medical therapy* (OMT group), and (2) patients with obstructive CAD, who required PCI or stent *implantation in addition to optimal medical therapy* (PCI/OMT group).

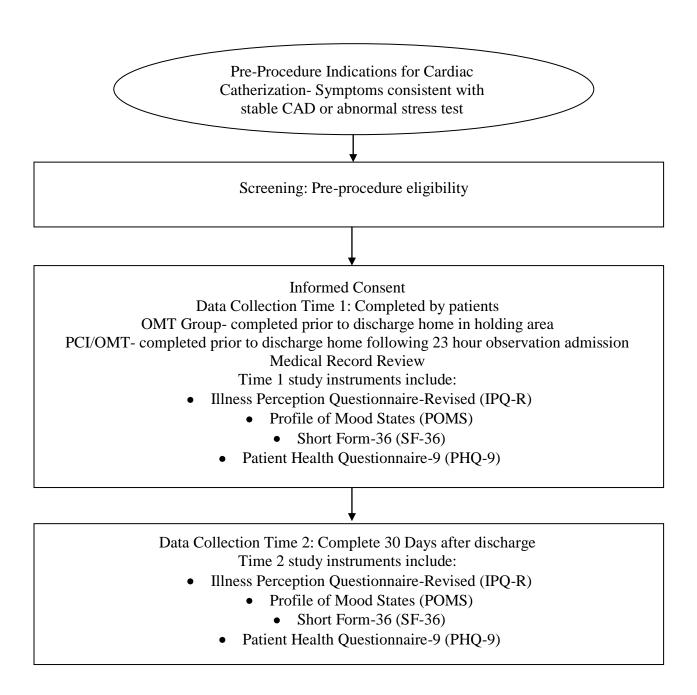
Of the patients referred for angiography, only patients in the PCI group were admitted to the interventional cardiology service for a 23-hour observation stay. In contrast, patients in the OMT group were sent home immediately after recovery in the cardiac catheterization holding area with instructions for future medical treatment of CAD. Patients are discharged home on the same day with baseline data collection completed prior to discharge from the cardiac catheterization holding area. For the PCI/OMT group, baseline data collection occurred after the patient was recovered and admitted to the observation area.

Data collection occurred at two time points; baseline and 30 days after discharge. Thirty days was selected as the second time point for data collection because this reflects the initial adjustment period after diagnosis of CAD. This time period was used to detect clinically relevant changes in illness representations following treatment for CAD. From a clinical standpoint, this 30 day timeframe allows for the examination of immediate adjustments in illness representation, while also excluding other confounding factors such as future medication changes and follow-up cardiovascular procedures (Sellier, 2007). For this population, it is expected that patients typically return for follow-up care within the first 30-days after treatment for CAD (Sellier, 2007). At baseline data collection, patients were guided through the consent process after undergoing either coronary angiography and OMT or PCI. Patients were asked to complete a set of questionnaires after recovery from the procedure. The questionnaires included the Illness Perception Questionnaire-Revised, Profile of Mood States, SF-36, and the Patient Health Questionnaire-9. A medical record review was conducted to collect additional demographic and co-morbidity data. At time two, 30 days after hospital discharge, patients were contacted via a mailed survey and asked to complete the following: Illness Perception Questionnaire-Revised, SF-36, Profile of Mood States, Patient Health Questionnaire-9, and the Health History Update. Telephone follow-up was offered for those patients who preferred to verbally report responses for 30-day data. Due to the mailed survey approach, it was not possible to ensure for a direct cut-off point for 30-days data collection. Therefore, it is possible that some data may have been collected after 30-days for the second time point.

Figure II. Flow chart of study sequence beginning from pre-procedure screening to data collection at baseline and 30-days. Instruments representing each construct of interested are listed for baseline and 30-day data collection.

FIGURE II

STUDY DESIGN AND SEQUENCE



2. <u>Setting</u>

Patients were recruited from Loyola University Medical Center in Maywood, IL. Loyola is a 575licensed-bed institution that includes the Loyola University Medical Center campus (Cardinal Bernardin Cancer Center, the Ronald McDonald[®] Children's Hospital of Loyola, Burn/Trauma Center, and Center for Heart & Vascular Medicine) and the 36-acre Gottlieb Hospital campus in Melrose Park. In addition to the Maywood and Melrose Park campus locations, Loyola features a network of specialty and primary care centers in Chicago's western and southwestern suburbs. Primary care facilities are located in Darien, Elmhurst, Hickory Hills, Homer Glen, LaGrange Park, Maywood, North Riverside, Oakbrook Terrace, Oak Park, Orland Park and Wheaton. Loyola University Medical Center (LUMC) has the largest cardiac catheterization facility within the Chicago area and performs approximately 200 percutaneous coronary interventions per month. LUMC is also the only hospital within the Chicago area to maintain a 24-hour in-house acute myocardial infarction team, which serves as a referral hub to care for patients in the western suburbs who present with cardiac symptoms during the off-hours. LUMC serves a diverse patient population throughout all of its facilities.

3. <u>Sample Size/Power</u>

Power analyses were performed for each aim using StatPower software version 2.0 (SPSS, Chicago, Illinois). Leventhal's self regulation model includes five key components: (1) identity, (2) cause, (3) time-line, (4) consequences, and (5) cure/control (Leventhal, Nerenz, & Steele, 1984). Summary scores are not calculated for either the IPQ or the IPQ-R. Since both the IPQ or IPQ-R tools have been used in research, the decision was made to calculate effect size

based on a subscale that is reported in both versions of these instruments and has an impact on the adoption of secondary prevention behaviors in patients with CAD.

Specific aim 1 compared differences in illness representation for patients receiving PCI therapy with those patients who received medical management for CAD. Calculations were done using an independent samples *t* test. Effect sizes for the differences for the group mean for Timeline scores ($d=[\mu_1-\mu_2]/\sigma$) were computed using the mean scores from Alsén et al. (2010) and Byrne et al. (2005). Effect sizes are classified as: small (d=.20), medium (d=.50), and large (d=.80) (Cohen, 1988). Based on previously reported mean Timeline subscale scores (22.5 versus 20.1), effect sizes calculations ranged from d=.47-.52, which supports a medium effect (Byrne et al., 2005b; Alsen et al. 2010). A sample size of 66 PCI and 66 non-PCI patients (total n=132) who underwent coronary angiography will have 80% power to detect a difference in timeline scores from time 1 to time 2 using an independent samples *t* test with a 0.05 two-sided level of significance.

Specific aim 2 compared changes in illness representation (identity, timeline, consequences, control, coherence, timeline, emotional, and causation) at baseline (post-procedure) and thirty days after discharge. To address power related to aim 2, calculations were based on a paired samples t test. The means for calculations were based on the Timeline subscale results (18.14 versus 20.01) from Alsén et al. (2010) resulting in an effect size of .36. Therefore, a paired samples t test with a 0.05 two-sided significance level had 80% power to detect the differences in IPQ scores for a sample size of 114 of patients (57 per group).

Specific aim 3 evaluated the influence of illness representations, fatigue, and depressive symptoms on secondary prevention behaviors. The power analysis for aim 3 was

calculated using a logistic regression model based on mean scores from the Timeline subscale from Alsén et al. (2010) and POMS-Fatigue subscale from Fennessy et al. (2010). Additional power analysis comparisons were done with mean scores from the PHQ-9 (Kroenke, Spitzer, & Williams, 2001). Power analyses using logistic regression with the timeline and POMS-fatigue subscales yielded the highest sample size requirement (n=180) compared to the analysis using the PHQ-9 and POMS-Fatigue subscales (n=143). Therefore, a logistic regression test using the highest sample size requirement (n=180) was selected to ensure 80% power to detect the group differences towards secondary preventions behaviors.

Attrition between data collection from baseline and time 2 was estimated within the cardiovascular community to approximate 25% in longitudinal studies (Bhaskar, Reitman, Sacks, Smith, & Chalmers, 1996). Therefore, attrition rate calculations for this proposal was based on a 25% rate, suggesting the possibility that 1/4 of the patients may not respond at time 2. Specific aim two focused on the repeated measurement of illness representation, with two measurement time points required to analyze these data. Therefore, to account for possible attrition, an additional 14 patients were recruited from the PCI and medically management groups. The total recruitment needed to address statistical power and attrition rates for specific aim 2 was 142 (57+14 PCI group; 57+14 Medical-management= 142 patients). However, a total 180 patients are required for logistic regression analysis for specific aim 3. Therefore, the 38 additional patients (180-142=38) required to account for attrition were divided between both groups: 38 remaining= 19 post-PCI group and 19 medical management group. *In summary, the total sample size needed to address the three specific aims in this proposal will be: post-PCI n=90 and medically managed group n=90 for total sample size n=180.*

B. Data Collection Procedures

1. <u>Recruitment and Procedures</u>

A convenience sample of 180 stable CAD patients was recruited. Patients were eligible for enrollment after undergoing coronary angiography and if treated medically for CAD (OMT group) or with PCI (PCI/OMT group). Patients were approached for enrollment after meeting clinical recovery goals. These goals included: (1) patients in the OMT group were recovered in the holding area and had stable hemodynamic patterns and the removal of bed rest from the activity status prior to discharge home on the same day and (2) patients in the PCI-group were admitted to the interventional service with stable hemodynamic patterns and the removal of bed rest status from the patient's activity level. This was done to ensure that the patient were recovered from sedation received during the procedure and had arterial/venous sheath devices removed.

After consultation with the interventional cardiologist (attending physician), the investigator approached patients to describe the study and invite them to participate. The study was thoroughly explained and the purpose, risks and benefits, and the voluntary nature of participation were emphasized. The subject was also provided a description of the questionnaires, the time needed to complete the questionnaires, and an overview of the data collection to occur 30 days after hospital discharge.

2. <u>Inclusion/Exclusion Criteria</u>

Inclusion criteria for the study were: (1) referred for coronary angiography due to ischemic symptoms or abnormal stress testing; (2) able to read and write English; (3) ages 35 years of age and older; (4) alert and oriented to person, place, and time and (5) and considered

clinically recovered from the procedure. Ages 35 and older was selected as the cut point to account for the lowest numbers of age in years typically treated for patients with stable CAD.

Patients were excluded if they: (1) were admitted for diagnosis of acute myocardial infarction as defined by Troponin T or I > 0.05 or ST segment elevation greater than 1 mm in two or more leads; (2) required CABG for treatment of CAD; or (3) were unable to render informed consent.

C. Measurement

1. Demographics

Demographic information was collected for the variables of age, gender, educational background, and marital status. Additional data were collected using a medical record review form for the variables: medications, co-morbidities, duration of illness, and angiographic data. Baseline data was collected through a medical record review that was completed by the investigator.

2. <u>Illness Perception Questionnaire-Revised</u>

The Illness Perception Questionnaire-Revised (IPQ-R) developed by Moss-Morris et al. (2002) was used to examine cognitive representations of CAD. The IPQ-R includes the five components of illness representations based on Leventhal's self-regulation model: (1) identity, (2) cause, (3) time-line, (4) consequences, and (5) cure/control (Leventhal, Meyer, & Nerenz, 1980; Leventhal et al., 1984). Additionally, the IPQ-R is a revised version of the original Illness Perception Questionnaire (IPQ) to include an expanded personal control/perceived control subscale and three additional subscales: (1) illness coherence, (2) timeline cycle, and (3)

emotional representation (see table 1). Items within the IPQ-R are measured using combined nominal (illness identity) and interval (views and causes of illness) scales. Versions of the IPQ-R for use in various illnesses and languages are available on the Illness Perception Questionnaire Website (Weinman, Petrie, Moss-Morris, Broadbent, & Siversten, 2010). For purposes of clarity, the IPQ-R are described in three sections: (1) illness identity, (2) views regarding illness, and (3) causes of illness.

TABLE I

ILLNESS PERCEPTION QUESTIONNAIRE-REVISED SCORING

Subscale	Scoring
1) Identity	Sum total of the yes responses for column 2
2) Timeline (acute and chronic)	Sum total for items IP1-IP5 + IP18
3) Consequences	Sum total for items IP6-IP11
4) Personal control	Sum total for IP12-IP17
5) Treatment control	Sum total for IP19-IP23
6) Illness Coherence	Sum total for IP24-IP28
7) Timeline cyclical	Sum total for IP29-IP32
8) Emotional Representation	Sum total for IP33-IP38
9) Causation ^a	Items C1-C18
Reverse Scoring	Items: IP1, IP4, IP8, IP15, IP17, IP18, IP19, IP23, IP24, IP25, IP26, IP27, IP36

Note. From "Scoring for the Illness Perception Questionnaire-Revised" by J. Weinman, K.J. Petrie, R. Moss-Morris, E. Broadbent, and B. Siversten, 2002, The Illness Perception Questionnaire Website, <u>http://www.uib.no/ipq/index.html</u>. ^aItems for causation are not used as an individual scale in its current form. These items require further analysis using advanced methodologies to assess the overall cause of a disease or illness.

a. <u>Illness Identity Scale</u>

The first IPQ-R section, *illness identity*, includes 14 symptoms of illness measured dichotomously. For each of the symptoms, patients are asked if he/she has experienced the symptom since his/her illness and if the symptom is related to his/her illness (Moss-Morris et al., 2002). These items create the general symptom experience subscale and the *illness identity* subscale. The *illness identity* subscale is the only item used for calculating a illness identity score. Therefore the "yes" responses for yes-rated symptoms in column 2 of the instrument which is labeled as, "*This symptom is related to my illness*" are totaled to establish the *illness identity* subscale, and the scores on the *illness identity* subscale range from 0-14.

The general symptom experience subscale (*I have experienced this symptom since my illness*) is not used for calculating any of the components related to illness representation; however, it may be used to assess for the validity of the *illness identity* subscale. In the analysis conducted by Moss-Morris et al. (2002), validity of the *illness identity* subscale was tested by conducting a paired t-test between the symptoms experienced and *illness identity* subscale. This analysis demonstrated a significant difference between the symptoms experienced compared to those associated with the illness (*t*=15.94, *p*<.001). The *illness identity* subscale consists of generalized symptoms and certain symptoms may not be associated with specific illnesses. Therefore, those symptoms that are not considered applicable for a particular illness are not relevant in determining internal consistency of the *illness identity* subscale. Researchers have reported internal consistency of the *illness identity* subscale (α =.75); however, this is more an indication of the high or low numbers of symptoms reported versus internal consistency of the subscale (Moss-Morris et al., 2002).

b. <u>Illness Representation Scale</u>

The second section, *Views about your illness*, assesses the components of illness representation related to timeline (acute/chronic), cyclical timeline, personal control, treatment control, consequences, illness coherence, and emotional representation. This section includes 38-items using a 5-point Likert scale, which ranges from "strongly disagree" to "strongly agree" (Moss-Morris et al., 2002). Of the total items in this section, 13-items are reversed scored (See table 1.) The ranges of scores and meanings of each subscale are listed in table 2. High scores on the identity, timeline, consequences, and cyclical dimensions represent strongly held beliefs about the number of symptoms attributed to the illness, the chronicity of the condition, the negative consequences of the illness, and the cyclical nature of the condition. High scores on the personal control, treatment control and coherence dimensions represent positive beliefs about the controllability of the illness and a personal understanding of the condition (Moss-Morris et al., 2002).

TABLE II

ILLNESS PERCEPTION QUESTIONNAIRE-REVISED:

DEFINITIONS AND SCORE RANGE

Defined	Score Range	Indication
Illness Identity: The number of symptoms reported as part of the illness	0-14	Higher scores represent greater number of symptoms associated with illness
Timeline (acute/chronic): How long the illness is perceived to last	6-30	Higher scores represent belief that illness will last a long time
Consequences: Expected effects and outcomes related to the illness	6-30	Higher scores on consequence scale indicate perception of serious consequences related to illness
Personal Control: Personal control over illness and self-efficacy beliefs	6-30	Higher scores indicate belief in personal control over illness
Treatment Control: Belief in the treatment or recommended advice	5-25	Higher scores indicate belief in level of treatment control over illness
Illness Coherence: Reflects overall understanding of the illness	4-20	Higher scores represent higher degree for understanding illness threat
Timeline Cyclical: Belief that illness is cyclical in nature	4-20	Higher scores represent belief that illness is cyclical in nature
Emotional Representation: Emotional representation related to illness	4-20	Higher scores represent higher degree of emotional response due to health threat.

c. <u>Causal Dimension Scale</u>

The final section reflects the *causal dimension* of the IPQ-R. Patients are asked to rate 18-items which may or may not be considered a cause of his/her illness. The directions for this section specifically ask for the participant's view of the cause, which should not reflect of suggestions made by their treating physician or family member. These items are answered using the same 5-point Likert scale used in the second section of the IPQ-R (ranging from strongly disagree to strongly agree). For scoring purposes, these items are not summed for a total. If an investigator is interested in examining the perceived causality of a disease or illness, advanced methods such as factor analysis may be used to compare these attributes (Weinman, Petrie, Sharpe, & Walker, 2000).

d. <u>IPQ-R Reliability</u>

The initial reporting of reliability statistics occurred after the revision of the IPQ and subsequent development of the IPQ-R in 2002. The sample used in the initial psychometric analysis included patients with various chronic illnesses such as asthma, diabetes, and multiple sclerosis. Patients diagnosed with MI (n=47) were also included in this analysis. Factor reliability was used to determine the internal reliability of the subscales corresponding to the subscales within the *Views about your illness*. All the subscales within the *Views about your illness* section demonstrated high reliability with the following ranges in Cronbach's alpha scores per subscale: Timeline Acute/Chronic (α =.89), Timeline Cyclical (α =.79), Consequences (α =.84), Personal Control (α =.81), Treatment Control (α =.80), Illness Coherence (α =80), and Emotional Representation (α =.88) subscales (Moss-Morris et al., 2002).

Byrne et al. (2005) used the IPQ-R to assess beliefs towards secondary prevention behaviors in patients (n=1084) living with CAD. The Cronbach's alphas were reported for the following subscales; timeline (α =.84), consequences (α =.82), personal control (α =.73), treatment control (α =.60), illness coherence (α =.86), timeline cyclical (α =.84), and emotional representation (α =.88) subscales (Byrne et al., 2005). In a study by Hermele et al. (2007), illness representation was measured in patients (n=138) undergoing CABG. Moderate to high reliability coefficients were reported for the illness representation subscales: timeline (.90), consequences (.78), personal control (.84), treatment control (.90), illness coherence (.90), and emotional representation (.85).

e. <u>IPQ-R Validity</u>

The IPQ-R was originally validated among patients from eight different chronic illness groups including asthma, diabetes, myocardial infarction, rheumatoid arthritis, acute/chronic pain, human immunodeficiency syndrome, and multiple sclerosis (Moss-Morris et al., 2002). Moss-Morris et al. (2002) conducted an analysis of construct validity by using techniques including: structural validity, discriminant validity, and predictive validity.

Construct validity is concerned with how many concepts a particular tool measures. This is usually obtained through advanced mathematical procedures such as factor analysis and structural equation modeling. Moss-Morris et al. (2002) evaluated construct validity by conducting two principal components analyses (PCA). These analyses accounted for 68% and 64% of the variance (Moss-Morris et al., 2002). The PCA results provided support for seven of the theoretical factors: timeline (acute/chronic), timeline cyclical, consequences, personal control, treatment control, illness coherence, and emotional representations (Moss-Morris et al., 2002).

2002). Overall, these results supported construct validity of the tool, in that most of the items loaded on only one factor. This indicated only a small amount of overlap of items and supported adequate separation of the theoretical concepts in the instrument.

Moss-Morris et al. (2002) provided support for discriminant validity by calculating correlations between the subscales of the IPQ-R and affective states as measured with the Positive and Negative Affect Schedule (PANAS). It was hypothesized that the IPQ-R dimensions can discriminate between positive and negative affective traits. Negative affective measures were found to be positively associated with the IPQ-R. Therefore, as increasing levels of negative affect increased (distress and discomfort) were associated with greater number of symptoms with the illness, viewed illness using a more chronic timeline, and had a greater degree of long-term consequences (r=.17 to r=.35; p<.05). Conversely, as the positive affect level increased, there was a negative relationship with illness coherence, identity, and chronic timeline (r=-.19 to r=-.26; p<.05). Patients with positive affect (enthusiasm and activity) were less likely to exhibit higher levels of illness representation typically measured in patients with a chronic illness. Therefore, the correlations demonstrated separation between the IPQ-R cognitive dimensions and positive and negative traits.

Predictive validity was assessed using a sample of patients (n=170) with multiple sclerosis (Moss-Morris et al., 2002). Comparisons were conducted to determine if the IPQ-R predicted adjustment to illness. The SIP was used to reflect sickness-related dysfunction as well as physical and mental fatigue. Separate linear regressions were used with illness severity entered in the first step and illness representation dimensions entered on the second step. Moss-Morris et al., (2002) demonstrated that the illness representation subscales accounted for 15% (F=3.75, p<.01) of the variance in the SIP scores. Illness severity was unrelated to fatigue scores; however, illness representation accounted for 27% (F=3.87, p<.001) of the variance in physical fatigue and 20% (F=2.48, p<.05) of the variance for mental fatigue. Finally, the consequences, timeline cyclical, and illness coherence were significant predictors for emotional concerns associated with multiple sclerosis (R^2 =.36, F=6.56). Personal control and treatment control were not found to be significant predictors for this population. The degenerative nature of multiple sclerosis may have resulted in the exclusion of both control (treatment and personal) and timeline (acute/chronic).

3. <u>Profile of Mood States</u>

The Profile of Mood States (POMS) is a 65-item self-report instrument to assess mood. The instrument includes 6 subscales: (1) tension-anxiety, (2) depression-dejection, (3) angerhostility, (4) fatigue-inertia, (5) vigor-activity, and (6) confusion-bewilderment (McNair, Lorr, & Droppleman, 1992). The POMS has been used to assess mood states in various cardiac populations, such as AMI (Fennessy et al., 2010; Rankin, 2002; Riegel & Gocka, 1995) and heart failure. (Evangelista et al., 2008; Fink et al., 2009; Stephen, 2008) Patients are given a list of words and asked to describe their mood state using a 5-point Likert scale from 0 = not at all to 4 = extremely (see Table 3). The POMS requires approximately a seventh grade reading level and typically takes about three to five minutes to complete (McNair, Lorr, & Droppleman, 1992). For the POMS, patients' are asked to reflect on the prior 7-day period for each of the measured time point in this study: hospital admission and 30 days after hospital discharge.

The POMS fatigue subscale (POMS-F) was used to measure the symptom of fatigue at baseline and 30 days after discharge. The POMS-F consists of seven items: (1) worn out, (2) listless, (3) fatigued, (4) exhausted, (5) sluggish, (6) weary, and (7) bushed. Scores range from

0-28, with higher scores reflecting higher levels of fatigue. Mean scores were 7.3 ± 5.7 for males and 8.7 ± 6.1 for females according to normative data using a healthy adult sample. (Nyenhuis, Yamamoto, Luchetta, Terrien, & Parmentier, 1999).

The vigor subscale (POMS-V) was used to measure vigor-activity at baseline and 30 days after discharge. The POMS-V subscale includes items related to energetic mood states and is considered a contrasting variable for the symptom of fatigue. Therefore, the POMS-V subscale was included in this analysis for the purpose of validity assessment. Items are endorsed on a 5-point scale ranging from "not at all" to "extremely". The score range is 0-32, with higher scores reflecting higher levels of vigor. Mean scores were 19.8 ± 6.8 for males and 18.9 ± 6.5 for females according to normative data using a healthy adult sample. (Nyenhuis et al., 1999)

The POMS Depression-Dejection Subscale (POMS-D) was included in this analysis for validity comparisons with other measures used to assess depressive symptoms (Patient Health Questionnaire-9). The POMS-D includes 15 items including: (1) unhappy, (2) sorry for things done, (3) sad, (4) blue, (5) hopeless, (6) unworthy, (7) discouraged, (8) lonely,(9) miserable, (10) gloomy, (11) desperate, (12) helpless, (13) worthless, (14) terrified, and(15) guilty. Higher scores reflect higher levels of depressed mood. Normative mean scores are 7.5 ± 9.2 for males and 8.5 ± 9.4 for females (Nyenhuis et al.,1999).

Scoring for each of the POMS subscales are derived by adding the numeric responses for each item within each of the 6 subscales. Items are scored from 0-4 and correspond to responses: (0) "not at all", (1) "a little", (2) "moderately", (3) quite a bit, and (4) "extremely". For this study, the POMS-Fatigue and POMS-Depression Dejection subscales were calculated for each subject. Normative means score were then compared with published means by other researchers as well as those published by the instrument developers (Nyenhuis et al., 1999).

TABLE III

Subscale of Interest	Items within Subscale	
1. Fatigue/ Inertia	Worn-out	
	Listless	
	Fatigued	
	Exhausted	
	Sluggish	
	Weary	
	Bushed	
2. Depression/Dejection	Unhappy	
	Sorry for things done	
	Sad	
	Blue	
	Hopeless	
	Unworthy	
	Discouraged	
	Lonely	
	Miserable	
	Gloomy	
	Desperate	
	Helpless	
	Worthless	
	Terrified	
	Guilty	
3. Vigor	Lively	
	Active	
	Energetic	
	Cheerful	
	Alert	
	Full of pep	
	Carefree	
	Vigorous	

PROFILE OF MOOD STATES ITEMS AND SUBSCALES

Note. From "*Manual for Profile of Mood States*" by D. McNair, M. Lorr, & L. Droppleman, 1992, San Diego, CA.

a. <u>POMS Reliability</u>

Alpha coefficients have been published which support the level of internal reliability for the POMS (Norcross, Guadagnoli, & Prochaska, 1984). In a study by Norcross et al. (1984), alpha coefficients were .93 for the Fatigue subscale in outpatient psychiatric departments. Additionally, McNair et al. (1992) reported alpha coefficients of .93 (baseline) and .94 (6 weeks) for the Fatigue subscale in psychiatric patients. High internal consistency was also demonstrated in a previous pilot study examining fatigue in AMI patients (Fennessy et al., 2010) at two time points: hospitalization (POMS-Fatigue $\alpha = 0.89$; POMS-Vigor $\alpha = .86$; POMS-Depression/Dejection $\alpha = 0.90$) and 30 days after discharge (POMS-Fatigue $\alpha = 0.91$; POMS-Vigor $\alpha = .86$; POMS-Depression/Dejection $\alpha = 0.90$).

Test- retest is appropriate if the construct of interest is stable. For example, correlations reported for patients undergoing psychotherapy demonstrated r=.45—.66 for the fatigue subscale, which may suggest changes in fatigue level before and 6 weeks after therapy, rather than a direct reflection of the stability of the construct (McNair et al., 1992). Therefore, to capture the reliability of a construct that is expected to change across time, using internal consistency may be a more reliable assessment strategy than the test-retest strategy.

b. <u>POMS Validity</u>

Initial support for the validity of the POMS is based primarily on construct validity for adults treated in outpatient psychiatric facilities. Similar mood patterns were identified using factor analysis in healthy control and psychiatric patients, suggesting that the subscales within the POMS are valid measures of mood states (McNair et al., 1992). Construct validity was also assessed in a multi-trait/multi-method analysis (Nyenhuis et al. 1999). Nyenhuis et al. compared the POMS subscales to the Visual Analogue Mood Scale (VAMS), the Beck Depression Inventory (BDI), the State-Trait Anxiety Inventory (STAI), and the Geriatric Depression Scale (GDS). Convergent validity was demonstrated for the POMS-D subscale, with high correlations for responses associated with the VAMS sad item (r=.70, p<.001), BDI total scores (r=.69, p<.001), and GDS total scores (r=.78, p<.001). Nyenhuis et al. reported concurrent validity of the POMS-F and POMS-V subscales by comparing responses to the VAMS energetic subscale (POMS-F r=.44, p<.001; POMS-V r=.62, p<.001).

Discriminant validity of the POMS is reported by McNair et al. (1992) for adult psychiatric patients undergoing psychotherapy compared to healthy controls who did not exhibit changes in mood patterns. However, for patients receiving psychotherapy, there were significant improvements in scores (p<.01). Finally, in a psychometric analysis of the POMS-F subscale, Fink et al., (2010) demonstrated support for construct, convergent, and discriminant validity using an AMI sample. A key finding was in hypothesis testing for females compared to males, the POMS-F subscale was found to be related to the prodromal nature of fatigue before AMI (p<.003), which was not supported when measured using the Fatigue Severity Index (p=.09) (Fink et al., 2010).

4. <u>Short-Form-36</u>

The Short Form-36 (SF-36) is a quality of life, short-form health survey with 36 items yielding an 8-scale profile of functional health and well-being scores (see Table 4). It is often referred to as a generic measure since it does not target a specific age, disease, or treatment group. Items within the SF-36 are based on instruments used in the 1970s and 1980s, such as

the General Psychological Well-Being Inventory and the Health Perceptions Questionnaire (Ware, 2000). The subscales within the SF-36 are (1) physical functioning, (2) role physical, (3) role emotional, (4) bodily pain, (5) general health, (6) vitality, (7) social functioning, and (8) mental health (Ware, Kosinski, & Dewey, 2000). Summary measures of physical and mental health are also provided. Additionally, a health transition question is scored separately, but this is not considered a subscale (Ware et al., 2000).

Norm-based scoring is utilized to interpret the results of the SF-36 (Ware, 2000). Scores are calibrated so that each subscale is placed on a 100-point scale with a mean of 50 and standard deviation of 10. This norm-based score allows comparison with the values obtained in 1998 for the general population as well as previous research reporting results using the SF-36. Computation of each subscale is based on formulas published by Ware et al. (2000). According to these formulas, scores are transformed to compute a standardized z-score using means and standard deviations. Norm based z-scores are then computed to allow for standardization of scores. Finally, each subscale is given a weight to provide an overall mental and physical summary scale.

The complexity of the SF-36 subscales has led to the development of computerized programs to assist with calculations (Ware et al., 2000). In 2008, SPSS syntax code was created by doctoral students to assist with calculating the SF-36 subscales for the University of Illinois research practicum study entitled, *"Symptoms of fatigue associated with AMI*." This syntax code has been validated in two research studies (Fennessy et al., 2010; Fink et al., 2009) and was used to calculate the SF-36 subscales for this proposal. Furthermore, the primary subscale of interest for this proposal is the *Vitality* measure, which is included to represent a proxy measure for the

symptom of fatigue. The *General Health Perception* subscale was used for validation of the IPQ-R subscales that were used to measure illness representation.

a. <u>SF-36 Reliability</u>

The SF-36 is a widely used tool and has been used in over 4,000 studies in populations consisting of over 200 diseases and conditions (Ware, 2002). Cardiovascular disease is described as one of the more frequently used populations for this instrument. Within each population where the SF-36 has been used, internal consistency has been greater than 0.70, with only a slight decline in patients from disadvantaged backgrounds (Ware et al., 2000). The initial 15 studies published after the publication of the SF-36 reported an overall internal consistency of 0.80 for all of the subscales with the exception of social functioning (0.76) (Ware et al., 2000). For the SF-36, reliability was reported using the 1998 general US population sample (n=5,038) with the following alpha coefficients: physical functioning 0.57—0.84, role physical 0.87—0.91, bodily pain 0.76, general health 0.48—0.79, vitality 0.67—0.72, social functioning 0.78, role emotional 0.83—0.88, and mental health 0.62-0.74 (Ware et al., 2000).

b. <u>SF-36 Validity</u>

McHorney, Ware, Lu, and Sherbourne (1994) evaluated the overall scaling for all the subscales and found correlations between an item and its hypothesized scale to be higher than correlations between an individual item and any other random scale. Results from McHorney et al., (1994) demonstrate discriminant validity within the SF-36 subscales. For example, results suggest that the physical functioning, role-physical, and bodily pain scales have high correlations with each other, as measured within a general U.S. population. Similar relationships were noted within the constructs found to represent mental health subscales (Ware, 2000). Additionally,

convergent validity was noted in comparing the SF-36 with the Nottingham Health Profile, with negative correlations found between the energy subscale (Nottingham Health Profile) and the vitality subscale in the SF-36, with r= -.68 and r= -.87, respectively. In summary, results demonstrate that the SF-36 is a valid and reliable measure and will serve as a useful measure for validity comparisons of fatigue.

TABLE IV

SHORT FORM-36 ITEMS AND SUBSCALES

Scale	Items	Summary Measure
Physical Functioning	3a. Vigorous Activities 3b. Moderate activities 3c. Life and carry groceries 3d. Climb several flights 3e. Climb one flight 3f. Bend and kneel 3g. Walk- mile 3h.Walk- several blocks 3I. Walk- one block 3j. Bathe, dress	Physical Health
Role-Physical	4a. Cut down time 4b. Accomplished less 4c. Limited in kind 4d. Had difficulty	Physical Health
Bodily Pain	7. Pain magnitude 8. Pain interference	Physical health
General Health	 General health 11a. Sick easier 11b. As healthy 11c. Health to get worse 11d. Health excellent 	Physical Health
Vitality	9a. Pep/life 9e. Energy 9g. Worn out 9i. Tired	Mental Health
Social Functioning	5. Social extent 10. Social time	Mental Health
Role Emotional	5a. Cut down time 5b. Accomplished less 5c. Not careful	Mental Health
Mental Health	9b. Nervous 9c. Down in the dumps 9d. Peaceful 9f. Blue/sad 9h. Happy	Mental Health

Note. From "SF-36® Health Survey Update" by J. Ware 2002.

5. Patient Health Questionnaire-9

The nine-item Patient Health Questionnaire (PHQ-9) is a self-report, screening instrument used to measure the frequency of depressive symptoms as listed in the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* criteria for depression (American Psychiatric Association, 1994). The instrument measures depressive symptoms such as depressed mood, anhedonia, and changes in appetite, loss of energy, feelings of worthlessness, diminished concentration, and suicidal ideations (Cannon et al., 2007). Patients completing the PHQ indicate the frequency of experiencing each symptom during the previous two-week period. Items are scored zero for "*not at all*," 1 point for "*several days*," 2 points for "*more than half the days*" and 3 points for "*nearly every day*" (Kroenke et al., 2001). Scores range between 0—27 and can be analyzed as a continuous variable, categorically (specified according to increments), or dichotomously by using a standard cut point of 10, or higher for major depressive symptoms (Kroenke et al., 2001). Higher scores represent a greater frequency of depressive symptoms within the previous two-week period.

a. <u>PHQ-9 Reliability</u>

Initial reporting of reliability for the PHQ-9 was done as part of the Primary Care Evaluation of Mental Disorders study (PRIME-MD) (Spitzer, Kroenke, Williams, & Patient Health Questionnaire Primary Study Group, 1999). Internal consistency of the PHQ-9 was excellent, with a Cronbach's alpha of .89 in the PHQ-9 Primary Care Study and 0.86 in the PHQ Ob-Gyne Study (Kroenke et al., 2001). Test-retest reliability of the PHQ-9 was also excellent, with a correlation between the clinic-based PHQ-9 and telephone surveys completed within 48 hours of each administration (r=.84) (Kroenke et al., 2001) and r=.894, p<.001 in a one-month test-retest in a sample of Nigerian university students (n=512). Scores have been correlated across delivery methods, with nearly identical mean scores between the clinic-based PHQ-9 and telephone administered instruments (M=5.08 and M=5.03) (Kroenke et al., 2001).

b. <u>PHQ-9 Validity</u>

Initial support for validity of the PHQ-9 was established during the PRIME-MD study with the goal of determining criterion validity (Spitzer et al., 1999). In 803 patients with depressive symptoms as measured with the PHQ, 46% had not been previously identified as having any form of psychiatric diagnosis (Spitzer et al., 1999). These results demonstrate the ability of the PHQ to detect unrecognized cases of depression compared with the PRIME-MD instrument (criterion validity). Furthermore, results demonstrated concurrent validity with moderate associations (r=.27-.53) when compared with functional impairment, as measured using the Short Form 20 questionnaire. Finally, concurrent validity was reported between the PHQ-9 and the Beck Depression Index (r=.67, p<0.001) in a sample of Nigerian university students. The PHQ-9 has been used in cardiovascular populations and specifically in samples of outpatient with CAD (Whooley et al., 2008).

6. <u>Health History Update</u>

The health history update (HHU) is an 11-item self-report screening tool used to assess secondary prevention behaviors 30-days after hospital discharge. The HHU was used in the University of Illinois, College of Nursing research practicum study, "Symptom of Fatigue Before and After AMI" (Eckhardt et al., 2007; Fennessy et al., 2010; Fink et al., 2010) and is revised for this proposal to include additional screening questions to assess secondary prevention behaviors after treatment for stable CAD. These secondary prevention behaviors focus specifically on cardiac rehabilitation attendance, medication taking, i.e., antiplatelet and cholesterol lowering agents, and smoking cessation.

Medications related to antiplatelet and cholesterol lowering agents are the primary focus in the HHU. Since patients in this study have a prior CAD diagnosis, antiplatelet agents remain a key pharmacological agent. Additionally, lipid lowering agents are used in this population for improved cholesterol management after diagnosis of CAD. Cardiac rehabilitation attendance and smoking were assessed using a combination of yes/no and frequency-type items. In this study, parameters for the adoption of secondary prevention are based on established cut points for each of the behaviors. For example, medication taking with responses such as "all of the time" was defined as regular use of therapy and was dichotomously coded as "1". However, responses for "nearly all of the time", "most of the time", "half of the time", and "less than half of the time" were coded as "0" to indicate irregularity in medication-taking behavior. Cardiac rehabilitation and smoking cessation were assessed using yes/no responses. Responses for cardiac rehabilitation and smoking cessation are scored dichotomously, with "1" indicating cardiac rehabilitation attendance or continued smoking behavior and "0" as no attendance to cardiac rehabilitation and non-smoking status or recent cessation.

D. Data Analysis

Data analysis is based on the specific aims for this proposal. The first analysis focuses on evaluating differences in illness representations for the PCI/OMT and OMT patients *[specific aim 1]*. Secondly, differences in illness representations were also evaluated at baseline and thirty days for patients treated with PCI/OMT and OMT *[specific aim 2]*. Finally, these data analyses include simultaneous logistic regression analyses to evaluate the contribution of illness

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representation, fatigue, and depressive symptoms towards secondary prevention behaviors related to cardiac rehabilitation attendance, regular use of antiplatelet and lipid lowering medications, and current smoking status *[specific aim 3]*.

Analyses were conducted using PASW SPSS version 18.0 (Chicago, Illinois). The alpha level selected for statistical significance was p<.05. Descriptive statistics were used to summarize the baseline and thirty day characteristics of the study sample. A series of independent sample t tests and chi-square analyses were conducted to compare potential differences within baseline demographics and clinical characteristics between PCI/OMT versus OMT groups, as well gender. Independent sample t tests were used to evaluate for differences in illness representation in the PCI/OMT and OMT groups [*specific aim 1*]. A paired t test was used to detect differences in illness representation for the PCI/OMT and OMT groups at baseline and thirty days [*specific aim 2*]. Finally, simultaneous logistic regression models were used to evaluate the influence of illness representation, fatigue (POMS-Fatigue Subscale), and depressive symptoms (PHQ-9) towards secondary prevention behaviors for cardiac rehabilitation attendance, regular use of antiplatelet and lipid lowering medications, and current smoking status [*specific aim 3*].

For the logistic regression models, variables were entered simultaneously. Five separate logistic regression analyses were conducted for dichotomous outcome variables related to cardiac rehabilitation attendance, medication taking (thienopyridine, aspirin, and lipid lowering), and current smoking status. Subscales from the IPQ-R were correlated with secondary prevention behaviors and only those scales with significant correlations were included in the logistic regression models for each specific secondary prevention behavior. The following variables were entered simultaneously: age, gender (coded 0/1, 0=female, 1=male), number of

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years with prior CAD diagnosis, illness representation (IPQ-R), fatigue (POMS-fatigue), depressive symptoms (PHQ-9). The dependent variables were analyzed dichotomously (yes/no) for secondary prevention behaviors such as cardiac rehabilitation participation, medication taking, and smoking cessation.

Measures used in this study were evaluated for reliability and validity (see chapter 4). It was expected that fatigue, depressive symptoms, and illness representation were not stable constructs. Therefore, test-retest reliability was not assessed. Cronbach's alpha was used to assess internal consistency reliability. Validity of the instruments involved comparisons of similar subscales and measures used in this proposal. For example, validity of fatigue was assessed by comparing the POMS-Fatigue subscale with the SF-36 Vitality and the POMS-Vigor subscales using a standard correlation. Depressive symptoms measures were validated using a Pearson's correlation with the IPQ-R Emotional subscale and the POMS-Depression/Dejection subscale and the PHQ-9 score. Illness representation measures were assessed using Pearson's correlations between the IPQ-R subscales and the SF-36 General Health subscale. Furthermore, the results of fatigue, depressive symptoms, and illness representation obtained in this study were compared with similar populations from the literature.

E. Human Subjects Research

The data collected as part of this dissertation proposal involved data from human subjects via interviews, medical record reviews, and questionnaires solely for the purposes of research. Approval was obtained from the institutional review board at Loyola University Medical Center and the University of Illinois at Chicago before initiating data collection.

IV. RESULTS

A. <u>Data Quality</u>

These data were entered into the database with secondary auditing and data cleaning to ensure complete and accurate data entry. Variables in the study were evaluated for basic assumptions prior to analysis using univariate and normality testing. Pearson product moment and Spearman Rank correlations were calculated and compared to evaluate relationships between other variables used in this study. Outliers were examined using descriptive statistics and did not require any corrections.

1. <u>Missing Data</u>

A missing value analysis was conducted to evaluate responses for items on the POMS, SF-36, PHQ-9, and IPQ-R. For the POMS, PHQ-9, and IPQ-R, a missing data rule was created to prevent calculations of subscales if there were greater than 10% missing items for the particular subscale. The SF-36 incorporates the use of mean substitution when more than 50% of the items for the subscale are answered (Ware, Kosinski, & Dewey, 2000). These data were then evaluated to ensure that items were missing completely at random (Nunnally & Bernstein, 1994). A regression imputation from items in the same subscale was used when less than 10% of data. Therefore, statistical analyses for this study were conducted using only those patients who responded to items that were sufficient to meet the missing data guidelines for this study. Missing data resulted in missing responses (n=13) for the IPQ-R treatment control subscale at baseline and each of the IPQ-R subscales (n=1) at 30-days.

Prior to addressing the study aims, descriptive and correlational statistics were used to identify general demographic and clinical characteristics. Normality of the distribution of subscale scores were verified. Univariate analyses were conducted to evaluate for differences in demographic and clinical characteristics based on treatment group (PCI/OMT and OMT) and gender. Guidelines for interpreting correlationals were based on effect sizes by Cohen (1988): correlations in the range of .10 to .29 were considered small, .30-.49 medium, and values between .50 and 1.0 were classified as large. Significance was set at the 95% level (p<0.05).

B. <u>Reliability and Validity</u>

1. Reliability Assessment

Internal consistency reliability was computed for the IPQ-R, POMS, SF-36, and PHQ-9 subscales (see Table I). Borderline reliability was demonstrated at both time points for the IPQ-R subscales measured at baseline. For the POMS subscales, unacceptable to high reliability (α =.515-.941) was noted at both time points. Low to high reliability scores were reported for the SF-36 subscales at baseline and 30-days (α =.684-.905). Acceptable to high reliability was noted for the PHQ-9 subscales at both time points (α =.732-.924).

Reliability assessment for the IPQ-R was defined as borderline based on lower reliability scores reported at baseline and 30-daya ranging between .515 and .960. Low reliability scores may have been due to respondent fatigue. For this study, packets of questionnaires were distributed to patients; however, the IPQ-R questionnaire was placed last in the series of questionnaires, thereby suggesting the influence of respondent fatigue in answering these items. Additionally, improvements in reliability scores were reported for the IPQ-R timeline cyclical scores from .545 to .960. Since a Cronbach's alpha is measuring how well items in a particular

scale measure the same concept, items in the timeline cyclical subscale may not have been as clearly understood by patients at baseline compared to 30-days. However, this does not preclude the possibility that additional items or improvements in measurement may be needed for the IPQ-R questionnaire. Similar reliability scores were reported with the SF-36; however, these scores were found to be slightly improved from the IPQ-R. The reverse scored items may have been confusing to the patients, which again reflects either respondent fatigue or simple guessing for these responses.

TABLE V

Study Subscales	Baseline Cronbach's α	30-Day Cronbach's α
POMS-Fatigue	.874	.840
POMS-Vigor	.776	.515
POMS-Depression Dejection	.941	.840
SF-36 Vitality	.824	.667
SF-36 Physical Functioning	.905	.898
SF-36 General Health	.684	.684
IPQ-R Timeline (acute/chronic)	.585	.525
IPQ-R Timeline (cyclical)	.545	.960
IPQ-R Consequences	.625	.595
IPQ-R Personal Control	.515	.528
IPQ-R Treatment Control	.560	.564
IPQ-R Illness Coherence	.820	.790
IPQ-R Emotional Representation	.643	.518
PHQ-9 Summary	.924	.732

INTERNAL CONSISTENCY OF MAJOR STUDY SUBSCALES

Abbreviations: POMS, Profile of Mood States; IPQ-R, Illness Perception Questionnaire Revised; PHQ-9, Patient Health Questionnaire-9.

2. <u>Validity</u>

Pearson Correlations were used to determine the amount of shared variance between variables known to measure similar or different constructs related to illness representation, fatigue, and depressive symptoms. Pearson's correlations for baseline and 30-day subscale scores are reported in TII and III. Discriminant validity was partially supported. Moderate to strong correlations were found (r=.30-.50) among the baseline POMS-Fatigue, POMS-Vigor, and SF-36 Vitality subscales. It was hypothesized that higher scores on the POMS-Fatigue subscale would be inversely correlated with the POMS-Vigor (baseline r=-.43, p=.01; 30-days r=-.51, p=.01).

Validity assessment of the IPQ-R subscales was determined by using an IPQ-R summary score, which was calculated as the overall mean score of the IPQ-R subscales combined. Construct validity of the IPQ-R subscales was examined by comparing correlations between the IPQ-Summary score and SF-36 General Health subscales at baseline (r=-.36, p=.01) and 30-days (r=-.19, p=.670). At 30-days, comparisons between the IPQ-R summary score and SF-36 General Health score remained inverse; however, this was not significant, possibly due to low response rate (n=94) compared to baseline comparisons (n=180). Therefore, as illness representation scores increased, to reflect a more negative perception of illness, general health scores were decreased. Construct validity assessment of depression Dejection and PHQ-9 subscales at baseline and 30-days. Moderate, positive correlations between the POMS-Depression Dejection and PHQ-9 subscales were demonstrated at baseline (r=.37, p<.001) and 30-days (r=.43, p<.001).

TABLE VI

	1	2	3	4	5	6	7	8
1. POMS-Fatigue	-							
2. POMS-Vigor	43**	-						
3. POMS-Depression	.40**	31**	-					
4. SF-36 Vitality	36**	36 **	24**					
5. SF-36 Physical Functioning	29**	09	07	.12	_			
6. SF-36 General Health	11	12	08	.10	.49**			
7. IPQ-R Summary	.14	05	.35**	08	06**	36**		
8. PHQ-9 Summary	.42**	29 **	.37**	17*	15*	.10	- 10	-

BASELINE SUBSCALE CORRELATIONS (n=180)

*<.05, **=.01

TABLE VII

	1	2	3	4	5	6	7	8
1. POMS-Fatigue, <i>n</i> =95	-							
2. POMS-Vigor, <i>n</i> =95	07	-						
3. POMS-Depression, <i>n</i> =95	.11	09	-					
4. SF-36 Vitality, <i>n</i> =95	51**	.11	09					
5. SF-36 Physical Functioning, <i>n</i> =95	55**	.08	06	.42**	_			
6. SF-36 General Health, n=95	42**	.03	29**	.28**	.56**	_		
7. IPQ-R Summary, <i>n</i> =94	.51**	.13	.14	54**	19	05		
8. PHQ-9 Summary, <i>n</i> =94	.17**	08	.43**	28*	22	.10	- .10	-

30-DAY SUBSCALE CORRELATIONS

* < .05, **= .01

C. <u>Sampling Information and Demographics</u>

1. <u>Sampling Information</u>

Data collection for this study began on August 31, 2010 and ended on February 28, 2011. All data were collected by the student investigator using a survey design at baseline and mailed survey at 30-days following hospital discharge. Recruitment took place within the Heart Vascular Center at Loyola University Medical Center. All the questionnaires were designed for self-administration with the option of completing data collection via telephone follow-up (n=2) at 30-days. The response rate was 100% at baseline, which was collected during hospitalization. The response rate at 30-days was 52.8% (n=95) for completed questionnaires. The total number of study refusals were n=3.

2. <u>Demographic Data</u>

Descriptive statistics were used to analyze baseline demographic data. The following measures were calculated: 1) mean, 2) standard deviation, and 3) percentage of occurrence within subgroup. At baseline data collection the sample of 180 patients consisted of 129 males (71.7%) and 51 females (28.3%). The age range for patients was 42 to 85 years of age. Demographic characteristics by treatment group and gender are shown in tables IV and V.

This sample of patients with stable CAD were predominantly white (n=141, 78.3%), married (66.7%, n=120), retired (56.7%, n=102) and had a college level of education or less (88.9%, n=160). The proportion of Hispanics were significantly greater in the PCI/OMT group (13.3%, n=12) compared with OMT (6.7%, n=6, p=.006). Females were found to be significantly older than males (p=.009), with the age range for males 43 years to 87 years

(M=64.7, SD= 8.0) and for females 54-80 years (M=67.3, SD= 5.8). Males in this sample had higher levels of education, with over 64% (n=78) classified as college educated or higher, when compared to females (37%, n=19, p<.01). Additionally, males were more likely to be employed on a full or part-time basis (n=57, 41.1%) compared to females (n=4, 7.8%, p<.01).

3. <u>Clinical Characteristics</u>

Patients treated with insulin therapy for diabetes were more likely to undergo PCI/OMT therapy (p=0.006). There was a greater incidence of stable angina (66.7%, n=60) and Canadian Cardiovascular Score (CCS) 3-4 anginal classification (37.8%, n=34) for those treated with PCI/OMT compared to the OMT group (stable angina 61.1%, n=55, χ^2 =.717, p=.02; CCS 3-4 25.6%, n=23, χ^2 =11.39, p=.02). A CCS score of 3-4 denotes greater limitations in physical functioning due to symptoms experienced with everyday (class 3) or any activity (class 4). Stress testing was conducted in 71% (n=125) patients, with a higher incidence of positive results (77.6%, n=69) in the PCI/OMT group compared to the OMT group (55.2%, n=48, χ^2 =12.16, p=.007). Patients treated with PCI/OMT had a longer length-of-stay (M=21.7 hours, SD=4.6) compared to the OMT group (M=10.8 hours, SD=4.9, t=-15.34, p<.01).

Overall, patients in this study were living with a prior CAD diagnosis for 8 years (*SD* 5.1), with males having a longer history of CAD (8.3 years, *SD* 4.6) when compared to females (7.2 years, *SD* 6.2); however, these differences were not significant (χ^2 =1.29, *p*=.25). Females were more likely to have a prior history of smoking (45.1%, *n*=23; males 10.1%, *n*=13, χ^2 =28.01, p<.01), and heart failure (54.9%, *n*=28; males 20.2%, *n*=26, χ^2 =21.01, *p*<.01). For males, there was a greater incidence of hypertension (86%, *n*=111, χ^2 =5.83, *p*=.01; females 70.6%, *n*=36), and diabetes (62%, *n*=80, χ^2 =4.27, *p*=.03; females 45.1%, *n*=23). In general, males in this sample were classified as NYHA or CCS 3-4 (66%, *n*=85) compared to females (51%, *n*=6,

 χ^2 =37.58, *p*<.01). Of those patients within the PCI/OMT group, 97.8% (*n*=88) had a drugeluting stent(s) placed as part of their treatment.

TABLE VIII

Demographics	Total	PCI/OMT	OMT	Test	P value
	<i>n</i> =180	<i>n</i> =90	<i>n</i> =90	Statistic	
Age (SD), years	65.1 (8.3)	64.7 (8.0)	65.5 (8.7)	<i>t</i> =.594	.553
Gender , <i>n</i> (%)					
Male	129 (71.7)	70 (77.8)	59 (65.6)	$\chi^2 = 3.31$.069
Female	51 (28.3)	20 (22.2)	31 (34.4)		
Education, n (%)					
Middle School	6 (3.3)	3 (3.3)	3 (3.3)	$\chi^2 = 2.42$.787
High School	56 (31.1)	31(27.8)	25 (34.5)		
Vocational	6 (3.3)	4 (2.2)	2 (4.4)		
Associate	15 (8.4)	8 (7.8)	7 (8.9)		
College	77 (42.8)	34 (47.8)	43 (37.8)		
Graduate School	20 (11.1)	10 (11.1)	10 (11.1)		
Race , <i>n</i> (%)					
African American	12 (6.7)	8 (8.9)	4 (4.4)	$\chi^2 = 12.34$.006
Hispanic	18 (10.0)	12 (13.3)	6 (6.7)		
White	141 (78.3)	70 (77.8)	71 (78.9)		
Other	9 (5.0)	0	9 (10.0)		
Marital Status, n (%)					
Married	120 (66.7)	62 (68.9)	58 (64.4)	$\chi^2 = 6.25$.10
Divorced	20 (11.1)	10 (11.1)	10 (11.1)		
Widowed	34 (18.9)	18 (20.0)	16 (17.8)		
Single	6 (3.3)	0	6 (6.7)		
Employment Status , <i>n</i>					
(%)					
Full-time	45 (25.0)	25 (27.8)	20 (22.2)	$\chi^2 = 3.92$.560
Part-time	12 (6.7)	5 (5.6)	7 (7.8)		
Retired	102 (56.7)	50 (55.6)	52 (57.8)		
Homemaker	10 (5.6)	3 (3.2)	7 (7.8)		
Disabled	10 (0.6)	6 (6.7)	4 (4.4)		
Unemployed	1 (0.6)	1 (1.1)	0		

DEMOGRAPHIC CHARACTERISTICS

Abbreviations: PCI, Percutaneous Coronary Intervention, OMT, Optimal Medical Therapy

TABLE IX

Demographics Female Test Total Male **P** value n(%) *n*=180 *n*=129 (71.7) *n*=51 (28.3) Statistic Age (SD), years 65.1 (8.3) 64.7 (8.0) 67.3 (5.8) *t*=-2.63 .009 $\chi^2 = 3.31$ **PCI/OMT vs. OMT**, *n*(%) .069 90 (50.0) 70 (77.8) 59 (65.6) PCI/OMT 20 (22.2) OMT 90 (50.0) 31 (34.4) $\chi^2 = 24.00$ Education, *n* (%) <.01 Middle School 6 (4.7) 0 6 (3.3) High School 56 (31.1) 28(21.7)28 (54.9) Vocational 6 (3.3) 6 (4.7) 0 11 (8.5) Associate 15 (8.4) 4 (7.8) 77 (42.8) 59 (45.7) 18 (35.3) College Graduate School 20 (11.1) 19 (14.7) 1 (2.0) **Race**, *n* (%) $\chi^2 = 6.33$.096 African American 12 (6.7) 6 (4.7) 6 (11.8) Hispanic 18 (10.0) 13 (10.1) 5 (9.8) White 141 (78.3) 101 (78.3) 40 (78.4) Other 0 9 (5.0) 9 (7.0) Marital Status, n (%) $\chi^2 = 34.18$ 120 (66.7) <.01 Married 98 (76.0) 22 (43.1) Divorced 20 (11.1) 14 (10.9) 6 (11.8) Widowed 34 (18.9) 11 (8.5) 23 (45.1) Single 6 (3.3) 6 (4.6) 0 $\chi^2 = 44.89$ **Employment Status**, n <.01 (%) 45 (34.9) 4 (7.8) Full-time 45 (25.0) Part-time 12 (6.7) 8 (6.2) 0 Retired 102 (56.7) 68 (52.7) 34 (66.7) Homemaker 10 (5.6) 0 10 (19.6) Disabled 10 (0.6) 7 (5.4) 3 (5.9) Unemployed 1(0.6)1(0.8)0

DEMOGRAPHIC CHARACTERISTICS BY GENDER

Abbreviations: PCI, Percutaneous Coronary Intervention, OMT, Optimal Medical Therapy

TABLE X

Clinical Characteristics	Total	PCI/OMT	OMT	Test	P value
	<i>n</i> =180	<i>n</i> =90	<i>n</i> =90	Statistic	
		(50.0)	(50.0)		
Years with Prior CAD	8.0 (5.1)	9.4 (4.6)	6.7 (5.3)	<i>t</i> =-3.61	< 0.05
Diagnosis, n (SD)		,()			
Prior History , <i>n</i> (%)					
Smoking (within past 1 year)	36 (20.0)	14 (15.6)	22 (24.4)	$\chi^2 = 2.22$.136
Hypertension	147 (81.7)	69 (76.7)	78 (86.7)	$\chi^2 = 3.00$.083
Dyslipidemia	167 (92.8)	84 (93.3)	83 (92.2)	$\chi^2 = .083$.773
Family History of CAD	80 (44.4)	39 (43.3)	41 (45.6)	$\chi^2 = .090$.764
Myocardial Infarction	104 (57.8)	47 (52.2)	57 (63.3)	$\chi^{2}_{2} = .131$.131
Heart Failure	54 (30.0)	32 (35.6)	22 (24.4)	$\chi^2 = .104$.104
PCI	128 (71.1)	62 (68.9)	66 (73.8)	$\chi^2 = .511$.511
CABG	69 (38.3)	31 (34.4)	38 (42.2)	$\chi^2 = .283$.283
PAD	62 (34.4)	25 (27.8)	37 (41.4)	$\chi^2 = 3.54$.060
Chronic Lung Disease	25 (13.9)	20 (22.2)	22 (24.4)	$\chi^2 = .124$.724
Diabetes	103 (57.2)	53 (58.9)	50 (55.6)	$\chi^2 = .204$.651
Dialysis	15 (8.3)	1 (1.1)	14 (15.6)	$\chi^2 = 12.29$	< 0.01
Diabetes Treatment:				<i>,</i> ,	
Oral Agent(s)	34 (33.0)	11 (20.8)	23 (46.0)	$\chi^2 = 7.41$.006
Insulin	69 (67.0)	42 (79.2)	27 (54.0)	<i>,</i> ,	
Presentation Type (%):			× ,		
No Symptoms, No Angina	35 (19.4)	11 (12.2)	24 (26.7)	$\chi^2 = 7.17$.028
Symptoms Unlikely Ischemic	30 (16.7)	19 (21.1)	11 (12.2)	<i>,</i> ,	
Stable angina	115 (63.9)	60 (66.7)	55 (61.1)		
Anginal Classification within	~ /		× ,		
Past 2 Weeks (%):					
No symptoms	38 (21.1)	24 (26.7)	14 (15.6)	$\chi^2 = 11.39$.022
CCS 1	23 (12.8)	8 (8.9)	15 (16.7)	<i>,</i> ,	
CCS 2	62 (34.4)	24 (26.6)	38 (42.1)		
CCS 3	55 (30.6)	32 (35.6)	23 (25.6)		
CCS 4	2 (1.1)	2 (2.2)	0		
Stress Testing Result (%),			-		
<i>n</i> =176:					
Negative	4 (2.3)	0	4 (4.6)	$\chi^2 = 12.16$.007
Positive	117 (66.5)	69 (77.6)	48 (55.2)		
Indeterminate	4 (2.2)	2 (2.2)	2 (2.3)		
No Stress Test	51 (29.0)	18 (20.2)	33 (37.9)		
Duration of Hospitalization (hours):	16.3 (7.2)	21.7 (4.6)	10.8 (4.9)	<i>t</i> =-15.34	< 0.01

CLINICAL CHARACTERISTICS BY TREATMENT

Clinical Characteristics	Total <i>n</i> =180	PCI/OMT <i>n</i> =90 (50.0)	OMT <i>n</i> =90 (50.0)	Test Statistic	P value
PCI type (%):					
Drug-Eluting	-	88 (97.8)	-		
Bare Metal	-	1 (1.1)	-		
Rotoblator	-	1 (1.1)	-		

Abbreviations: CAD, Coronary Artery Disease, PCI, Percutaneous Coronary Intervention, CABG, Coronary Artery Bypass Graft Surgery, CVA, Cerebrovascular Accident, PAD, Peripheral Arterial Disease, CCS, Canadian Cardiovascular Society Functional Classification

TABLE XI

Clinical Characteristics	Total n=180	Male n=129 (71.7)	Female <i>n</i> =51 (28.3)	Test Statistic	P value
Years with Prior CAD Diagnosis, n (SD)	8.0 (5.1)	8.3 (4.69)	7.2 (6.2)	<i>t</i> =1.29	.253
Prior History , <i>n</i> (%)					
Smoking (within past 1 year)	36 (20.0)	13 (10.1)	23 (45.1)	$\chi^2 = 28.01$	< 0.01
Hypertension	147 (81.7)	111 (86.0)	36 (70.6)	$\chi^2 = 5.83$.016
Dyslipidemia	167 (92.8)	124 (96.1)	43 (84.3)	$\chi^2 = 7.60$.06
Family History of CAD	80 (44.4)	58 (45.0)	22 (43.1)	$\chi^2_2 = .049$.764
Myocardial Infarction	104 (57.8)	75 (58.1)	29 (56.9)	$\chi^2_2 = .876$.876
Heart Failure	54 (30.0)	26 (20.2)	28 (54.9)	$\chi^2_2 = 21.01$	< 0.01
PCI	128 (71.1)	91 (70.5)	37 (72.5)	$\chi^2_2 = .072$.789
CABG	69 (38.3)	53 (41.1)	16 (31.4)	$\chi^2 = 1.45$.227
PAD	62 (34.4)	39 (30.2)	23 (45.1)	$\chi^2 = 3.57$.059
Chronic Lung Disease	25 (13.9)	27 (20.9)	15 (29.4)	$\chi^2 = 1.47$.225
Diabetes Dialysis	103 (57.2) 15 (8.3)	80 (62.0) 12 (9.3)	23 (45.1) 3 (5.9)	$\chi^2 = 4.27$ $\chi^2 = .560$.039 .454
Diabetes Treatment, <i>n</i> =103:					
Oral Agent(s)	34 (33.0)	27 (33.8)	7 (30.4)	$\chi^2 = .089$.766
Insulin	69 (67.0)	53 (66.3)	16 (69.6)	70	
Presentation Type (%):					
No Symptoms, No Angina	35 (19.4)	32 (24.8)	3 (5.9)	$\chi^2 = 9.12$.010
Symptoms Unlikely Ischemic	30 (16.7)	22 (17.1)	8 (15.7)		
Stable angina	115 (63.9)	75 (58.1)	40 (78.4)		
Anginal Classification within Past 2 weeks (%):					
No symptoms	38 (21.1)	35 (27.1)	3 (15.9)	$\chi^2 = 37.58$	< 0.01
CCS 1	23 (12.8)	9 (7.0)	14 (27.5)		
CCS 2	62 (34.4)	54 (41.9)	8 (15.7)		
CCS 3	55 (30.6)	29 (22.5)	6 (51.0)		
CCS 4	2 (1.1)	2 (1.6)	-		

CLINICAL CHARACTERISTICS BY GENDER

Clinical Charac	eteristics	Total n=180	Male n=129 (71.7)	Female <i>n</i> =51 (28.3)	Test Statistic	<i>P</i> value
Stress Testing F	Result (%),		-	-	-	-
<i>n</i> =176:						
	Negative	4 (2.3)	2 (1.6)	2 (4.0)	$\chi^2 = 3.32$.344*
	Positive	117 (66.5)	86 (68.3)	31 (62.0)		
	Indeterminate	4 (2.2)	4 (3.2)	0		
	No Stress Test	51 (29.0)	34 (27.0)	17 (34.0)		
Duration of Ho (hours):	spitalization	16.3 (7.2)	16.5 (7.2)	15.7 (7.3)	<i>t</i> =.718	.860
PCI type (%):						
	Drug-Eluting	-	88 (97.8)	-		
	Bare Metal	-	1 (1.1)	-		
	Rotoblator	-	1 (1.1)	-		

Abbreviations: CAD, Coronary Artery Disease, PCI, Percutaneous Coronary Intervention, CABG, Coronary Artery Bypass Graft Surgery, CVA, Cerebrovascular Accident, PAD, Peripheral Arterial Disease, CCS, Canadian Cardiovascular Society Functional Classification

4. <u>Post-Procedure Characteristics</u>

There were no significant differences in post-procedure complications following treatment (see table VIII); although, patients in the OMT group, had an increased rate of hematomas, although this was not found to be statistically significant between the PCI (3.3%, n=3) and PCI/OMT groups (56.7%, n=6, $\chi^2=1.05$, p=.30). There were no significant differences in prescribed medications for the management of CAD. Overall, 71.1% (n=128) of patients were discharged home on a thienopyridine agent (clopidogrel or prasugrel), with 100% (n=90) of those within the PCI/OMT group. Patients in the OMT group had an increased rate of emergency department visits (13.3% OMT versus 7.8% PCI/OMT, p=.24) within 30-days after treatment.

In evaluating for gender differences (see table IX), males were found to have an increased rate of return to the emergency department (6.15%, n=11) compared to females (5.5%, n=10, p=.002). Discharge medication therapy differed for Angiotensin Receptor Blockers between males (5.4%, n=7) and females (15.7%, n=8; $X^2=2.145$, df=1, p=.02). For antiplatelet therapy, all females (100%, n=51) were prescribed aspirin, but this was not significantly different when compared to males (93.8%, n=121, p=.06).

TABLE XII

Post-Procedure Recovery, <i>n</i> (%),	Total n=180	PCI/OMT <i>n</i> =90	OMT <i>n</i> =90	Test Statistic	P value
Complications:					
Bleeding within 72 Hours	1 (0.6)	0	1(1.1)	$\chi^2 = 1.00$.316
Hematoma	9 (5.0)	3 (3.3)	6 (6.7)	$\chi^2 = 1.05$.305
Post-procedure GI bleed	1 (0.6)	0	6 (6.7) 1 (1.1)	$\chi^2 = 1.00$.316
Return to ED within 30 days after discharge	19 (21.0)	7 (7.8)	12 (13.3)	$\chi^2 = .833$.326
Prescribed Discharge Medications:					
Ace-Inhibitors	120 (66.7)	55 (61.1)	65 (72.2)	$\chi^2 = 1.62$.202
Angiotensin Receptor Blockers	17 (9.5)	7 (7.8)	10 (11.1)	$\chi^{2} = 1.81$.178
Beta-Blockers	132 (73.3)	63 (70.0)	69 (76.7)	$\chi^2 = 1.02$.312
Lipid Lowering Agent	170 (94.4)	86 (95.1)	84 (93.3)	$\chi^2 = .871$.351
Prescribed Antiplatelet Therapy:					
Aspirin	154 (85.6)	84 (93.3)	88 (97.8)	$\chi^2 = 2.09$.148
Thienopyridine	128 (71.1)	90 (100)		$\chi^2 = 12.85$	< 0.01

POST PROCEDURE BY TREATMENT

Abbreviations: GI, Gastrointestinal, ED, Emergency Department

TABLE XIII

Post-Procedure Recovery, n (%),	Total <i>n</i> =180	Male n=129 (71.7)	Female <i>n</i> =51 (28.3)	Test Statistic	P value
Complications:					
Bleeding within 72 Hours	1 (0.6)	0	1(2.0)	$\chi^2 = 2.54$.111
Hematoma	9 (5.0)	8 (6.2)	1 (2.0)	$\chi^2 = 1.38$.239
Post-procedure GI bleed	1 (0.6)	1 (0.8)	0	$\chi^2 = .398$.528
Return to ED within 30 days after discharge	21 (22.6)	11 (8.5)	10 (19.6)	$\chi^2 = 2.54$ $\chi^2 = 1.38$ $\chi^2 = .398$ $\chi^2 = 9.72$.002
Discharge Medications:					
Ace-Inhibitors	120 (66.7)	82 (63.6)	40 (78.4)	$\gamma^2 = 3.69$.054
Angiotensin Receptor Blockers	17 (9.5)	7 (5.4)	8 (15.7)	· · · ·	.025
Beta-Blockers	. ,	93 (72.1)	39 (76.5)		.550
Lipid Lowering Agent	170 (94.4)	129 (100)	51 (100)	λ	
Antiplatelet Therapy:					
aspirin	154 (85.6)	121 (93.8)	51 (100)	$\chi^2 = 3.31$.069
thienopyridine	128 (71.1)	122 (94.6)	46 (90.2)	$\chi^2 = 3.31$ $\chi^2 = 1.12$.289

POST PROCEDURE BY GENDER

Abbreviations: GI, Gastrointestinal, ED, Emergency Department

5. <u>30-Day Secondary Prevention</u>

A health history update was used to gather self-reported secondary prevention behaviors during the 30-day follow-up (see tables X and XI). Cardiac rehabilitation referrals were offered to all patients prior to their discharge home. Patients who underwent PCI/OMT met with a cardiovascular nurse practitioner to review secondary prevention following PCI and the benefits for attending cardiac rehabilitation services. Participation in a cardiac rehabilitation program was reported in 28.7% of the patients (n=94) at 30-days. Significant differences were noted between treatment groups (PCI/OMT vs. OMT) for cardiac rehabilitation participation (PCI/OMT 17.0%, n=8; OMT 40.4%, n=19, p=.02). No differences were noted for current smoking/tobacco abuse (PCI/OMT 14.9%, n=7; OMT 17.8%, n=8, p=.708). Patients in the PCI/OMT group reported greater level of missed doses in the use of thienopyridines (17%, n=11) compared to the OMT group (15.1%, n=5, p=.055).

Gender differences for 30-day secondary prevention behaviors were reported for cardiac rehabilitation attendance (males 21.9%, n=16; females 11.7%, n=11, $\chi^2=8.65$, p=.003). Additionally, males reported greater level of missed doses in the use of lipid lowering (9.1%, n=8) compared to females (6.8%, n=6, p=.06). There were no significant differences in the overall use of thienopyridine medications (t=.313, p=.209) based on gender; however, males were more likely to report greater missed doses for taking on it on a regular basis (males 12.5%, n=10; females 6.2%, n=5).

TABLE XIV

Secondary Prevention at 30- days:	Total	PCI/OMT	OMT	Test Statistic	P value
Cardiac Rehabilitation Attendance	<i>n</i> =94	<i>n</i> =47	<i>n</i> =47	$\chi^2 = 5.36$.021
Yes	27 (28.7)	8 (17.0)	19 (40.4)		
No	67 (71.3)	39 (83.0)	28 (59.6)		
Physical Activity at 30-days	<i>n</i> =92	<i>n</i> =47	<i>n</i> =45	$\chi^2 = 13.80$.008
Not at all	1 (1.1)		1 (2.2)		
A little active (1-2 times/month)	6 (6.5)	2 (4.3)	4 (8.9)		
Fairly active (3-4 times/month)	48 (52.2)	19 (40.4)	29 (64.4)		
Very active (3-4 times/week)	30 (32.6)	19 (40.4)	11 (24.4)		
Extremely active (>5 times/week)	7 (7.6)	7 (14.9)			
Smoking Within Past 30-days	<i>n</i> =92	<i>n</i> =47	<i>n</i> =45	$\chi^2 = .213$.708
Yes	15 (16.3)	7(14.9)	8 (17.8)		
No	77 (83.7)	40 (85.1)	37 (82.2)		
Lipid Lowering Medication Use in Past 30-days	<i>n</i> =87	<i>n</i> =42	<i>n</i> =45		
All of the time	73 (83.9)	33 (78.6)	40 (88.9)	$\chi^2 = 2.35$.308
Nearly all of the time	5 (5.7)	4 (9.5)	1 (2.2)		
Most of the time	9 (10.3)	5 (11.9)	4 (8.9)		
Half of the time	-	-	-		
Less than half of the time	-	-	-		
Aspirin use in past 30-days	<i>n</i> =92	<i>n</i> =47	<i>n</i> =45		
All of the time	76 (82.6)	37 (78.7)	39 (86.7)	$\chi^2 = 1.91$.383
Nearly all of the time	8 (8.7)	6 (12.8)	2 (4.4)		
Most of the time	8 (8.7)	4 (8.5)	4 (8.9)		
Half of the time	-	-	-		
Less than half of the time	-	-	-		

30-DAY SECONDARY PREVENTION BY TREATMENT

Secondary Prevention at 30- days:	Total	PCI/OMT	OMT	Test Statistic	P value
Thienopyridine use in past 30- days	<i>n</i> =80	<i>n</i> =47	<i>n</i> =33	X ² =5.73	0.055
All of the time Nearly all of the time	· /	36 (76.6) 9 (19.1)	28 (84.8) 1 (3.0)		
Most of the time	, ,	2 (4.3)	4 (12.1)		
Half of the time	· /	-	-		
Less than half of the time		-	-		

Abbreviations: GI, Gastrointestinal, ED, Emergency Department.

TABLE XV

Secondary Prevention at 30-days:	Total	Male	Female	Test Statistic	P value
Cardiac Rehabilitation Attendance	<i>n</i> =94	<i>n</i> =73	<i>n</i> =21	$\chi^2 = 8.65$	0.003
Yes	27 (28.7)	16 (21.9)	11 (52.4)		
No	67 (71.3)	57 (78.1)	10 (47.6)		
Physical Activity at 30-days	<i>n</i> =92	<i>n</i> =72	<i>n</i> =20	χ ² =7.72	0.102
Not at all	1 (1.1)		1 (5.0)		
A little active (1-2 times/month)	6 (6.5)	3 (4.2)	3 (15.0)		
Fairly active (3-4 times/month)	48 (52.2)	40 (55.6)	8 (40.0)		
Very active (3-4 times/week)	30 (32.6)	22 (30.6)	8 (40.0)		
Extremely active (>5 times/week)	7 (7.6)	7 (9.7)			
Smoking Within Past 30-Days	<i>n</i> =92	<i>n</i> =72	<i>n</i> =20	χ ² =.193	0.661
Yes	15 (16.3)	11 (15.3)	4 (20.0)		
No	77 (83.7)	61 (84.7)	16 (80.0)		
Lipid Lowering Medication Use in Past 30-days	<i>n</i> =87	<i>n</i> =67	<i>n</i> =20	χ ² =5.54	0.063
All of the time	73 (83.9)	59 (79.7)	14 (66.7)		
Nearly all of the time	5 (5.7)	4 (5.4)	1 (4.8)		
Most of the time	9 (10.3)	4 (5.4)	5 (23.8)		
Half of the time	-	-	-		
Less than half of the time	-	-	-		
Aspirin Use in Past 30-Days	<i>n</i> =92	<i>n</i> =72	<i>n</i> =20	$\chi^2 = 1.49$	0.474
All of the time	76 (82.6)	60 (83.3)	16 (80.0)		
Nearly all of the time	8 (8.7)	7 (9.7)	1 (5.0)		
Most of the time	8 (8.7)	5 (6.9)	3 (15.0)		
Half of the time	-	-	-		
Less than half of the time	-	-	-		

30-DAY SECONDARY PREVENTION BY GENDER

Secondary Prevention at 30- days:	Total	Male	Female	Test Statistic	<i>P</i> value
Thienopyridine Use in Past 30- days	<i>n</i> =80	<i>n</i> =60	<i>n</i> =20	3.13	0.209
•	64 (80.0)	35 (77.8)	28 (84.8)		*
Nearly all of the time	10 (12.5)	8 (17.8)	1 (3.0)		
Most of the time	6 (7.5)	2 (4.4)	4 (12.1)		
Half of the time	-	-	-		
Less than half of the time	-	-	-		

Abbreviations: GI, Gastrointestinal, ED, Emergency Department.

D. <u>Subscale Descriptions</u>

1. <u>Illness Representation</u>

Patients were asked to complete the IPQ-R at baseline and 30-days. IPQ-R subscales include: timeline (acute/chronic), timeline cyclical, consequences, control (personal/treatment), illness coherence, and emotional representation. The score range and description of each IPQ-R subscale are listed in Table 2 within Chapter 3, page 50. IPQ-R subscale scores based on responses for this study are provided by treatment (see tables XII and XIII) and gender (see tables XV and XVI).

At baseline, there were no significant differences in the IPQ-R subscales when comparing treatment groups (see table XII). At 30-days, patients treated with PCI/OMT had a more acute timeline (M=16.4, SD=5.5) compared to OMT (M=18.8, SD 4.9, t=2.14, p=.035). Patients treated with OMT had significantly higher timeline (cyclical) scores (M=10.2, SD=4.5) compared to the PCI/OMT group (M=7.1, SD=3.3, t=3.69, p<.01). Patients who were treated with PCI scored higher on the illness coherence subscale (M=12.0, SD=2.8) compared to the OMT group (M=17.4, SD=5.2), although this did not reach statistical significance (t=-1.50, p=.135).

At baseline (see table XV), females had timeline acute/chronic scores, which suggests a chronic illness model (M=18.8, SD=4.2) when compared to males (M=16.3, SD=4.7, t=-3.28, p=.001). Additionally, females had a greater perception of treatment control (females M=16.9, SD=1.7; males M=14.8, SD=3.3, t=-3.62, p=<.01) and overall understanding of CAD (M=14.1, SD=3.7) compared to males (M=12.3, SD=4.1, t=-2.75, p=.006). Females also had a greater

emotional response to CAD (M=14.1, SD=3.7) compared to males (M=12.3, SD=4.1, t=-2.75, p=.006).

At 30-days (see table XVI), gender differences remained for illness coherence (males M=19.1, SD=5.4; females M=17.4, SD=5.2, t=-6.68, p<.01), and emotional representation (males M=12.2, SD=3.0; females M=10.6, SD=1.8, t=2.83, p=.006). Additional gender differences were noted for the timeline (cyclical) subscales (males M=9.1, SD=4.3; females M=6.9, SD=3.2, t=2.15, p=.034) and consequences subscales (males M=14.7, SD=4.9; female M=12.7, SD=2.1, t=2.71, p=.008). Overall, the stable CAD sample in this study had lower IPQ-R subscale score when compared to published means (Alsen et al.,2010) for samples such as AMI and chronic kidney disease (see table XVIII), which demonstrates a more acute illness representation when compared to other disease processes.

2. <u>Profile of Mood States</u>

Patients completed the POMS at baseline and 30-days. The POMS was used to assess the symptom of fatigue (POMS-Fatigue and POMS-Vigor), and depressive mood (POMS-Depression Dejection) in patients with stable CAD. No significant differences were noted in the baseline POMS-Depression Dejection scores for those who did not return 30-day data (M=8.9, SD=11.0; response: M= 6.7, SD=7.5; t=1.56, p=.119). In general, there were no differences between treatment groups at baseline and 30-days for the POMS-Fatigue, POMS-Vigor, and POMS-Depression Dejection subscales (see tables XII and XIII). Patients treated with either PCI/OMT or OMT demonstrated significant changes in POMS-Fatigue scores (see table XIV), with higher POMS-Fatigue reported at baseline (PCI/OMT: M=12.5, SD= 6.2, t=7.00, p<.001; OMT M=13.0, SD=5.7) compared to 30-days (PCI/OMT: M=5.0, SD= 4.2, t=7.00, p<.001; OMT M=5.5, SD=4.3). Additionally, patients treated with PCI/OMT and OMT demonstrated a

significant improvement in POMS-Vigor scores from baseline (PCI/OMT: *M*=13.9 *SD*=4.4, *t*=-2.88, *p*=.006; OMT: *M*=14.2, *SD*=4.6, *t*=-3.57, *p*=.001) to 30-days (PCI/OMT: *M*=17.0, *SD*=4.7; OMT *M*=17.9, *SD*=3.3) after treatment for CAD.

At baseline (see table XV), gender differences were demonstrated with females reporting higher POMS-Fatigue scores (M=14.8, SD=6.3) compared to males (M=12.1, SD=6.4, t=-2.52, p=.012). Additional gender differences were noted, with females reporting lower POMS-Vigor scores (female M=10.3, SD=4.7) and lower POMS-Depression Dejection scores (M=5.9, SD=5.4) compared to males (Vigor M=13.5, SD=5.2, t=-2.52, p=.012; Depression Dejection M=8.4, SD=10.5, t=2.13, p=.034). The higher POMS-Depression Dejection scores for males at baseline suggest higher levels of depressed mood when compared to females. At 30-days (see table XVI), gender differences were maintained for the POMS-Depression Dejection subscale, with females reporting lower scores (M=2.1, SD= 1.0) compared to males (M=4.7, SD=4.5, t=4.60, p=0.01). Again, males reported higher POMS-Depression at 30-days, which suggests higher levels of depressed mood at 30-days following treatment.

Significant change scores (see table VXII) were demonstrated for POMS-Fatigue from baseline (male: M=12.9, SD=6.0, t=9.13, p<.001; female: M=12.1, SD=5.5, t=5.43, p<.001) to 30-days (male: M=5.1, SD=3.8; female: M=5.8, SD=5.7) for both males and females in this study. Additionally, significant improvements in POMS-Vigor scores were reported for males and females from baseline (male: M=14.6, SD=4.4, t=1.86, p=.066; female: M=12.3, SD=4.5, t=-3.19, p=.005) to 30-days (males: M=17.0, SD=4.3; female: M=16.8, SD=3.4). Females demonstrated significant reductions in POMS-Depression/Dejection scores from baseline (M=6.0, SD=4.4; males: M=6.9, SD=8.2) to 30-days (M=2.1, SD=1.0, t=4.21, p<.001; males: M=4.7, SD=4.5, t=1.86, p=.066).

3. Short Form-36

Patients completed the SF-36 at baseline and 30-days following hospital discharge. The SF-36 was used to measure Vitality, a proxy measure for fatigue, as well as the Physical Functioning and General Health subscales. At baseline (see table XII), significant differences in Vitality were demonstrated between the PCI/OMT (M=43.1, SD 9.5) and OMT (M=46.0, SD=8.9, X^2 =2.10, p=.03). At 30-days (see table XVI), significant differences were noted, with males reporting higher scores vitality scores (M=52.2, SD=7.5; females M=46.7, SD= 6.9, t=3.00, p=.003) and lower physical functioning scores (M=41.7, SD=10.2, t=1.67, p=.09) compared to females.

Males demonstrated a significant improvement (see table XVII) in Vitality scores from baseline (male: M=44.9, SD=10.3, t=-4.83, p<.001; female: M=45.4, SD=6.3, t=.856, p=.40) to 30-days (male: M=52.2, SD=7.5; female: M=46.7, SD=6.9). Females had significant improvements in General Health scores from baseline (male: M=43.0, SD=9.3, t=-.64, p=.52; female: M=43.2, SD=4.5, t=-2.38, p=.02) to 30-days (male: M=43.6, SD=7.7; female: M=45.8, SD 4.5) after treatment for CAD. Both males and females reported significant improvements in Physical Functioning scores from baseline (male: M=39.2, SD=9.7, t=-3.08, p=.003; female M=41.9, SD=11.7, t=-4.18, p<.001) to 30-days (male: M=42.7, SD 10.5; female: M=48.1, SD9.4) after treatment.

Comparisons of the Vitality, Physical Functioning, and General Health subscales were made with published means from similar cardiovascular samples (see table XX). Overall, there were no significant differences between the SF-36 subscales reported in this study and scores from a prior AMI sample (Fennessy et al., 2010). However, lower Physical Functioning (M=40.9, SD=11.0, t=8.36, p=<.01) and General Health (M=43.2, SD=8.8, t=9.09, p<.01) scores were demonstrated in this study compared to published means provided by the COURAGE trial, which used a similar stable CAD sample; however, inclusion criteria from COURAGE limited patients with extensive comorbidities (Weintraub et al., 2008).

4. <u>Patient Health Questionnaire-9</u>

The PHQ-9 was administered at both time points to assess for depressive symptoms. There were no treatment or gender group differences for the PHQ-9 scores at baseline or 30-days (see tables XII and XIII). Scores of 5, 10, 15, and 20 are established cut points for mild, moderate, moderately severe, and severe depression classifications (Kroenke & Spitzer, 2002). Overall, patients in this sample were classified with mild depressive symptoms at baseline (score range 0-22, M=6.1, SD 6.2) and no depressive symptoms at 30-days (score range 0-10, M=2.7, SD=2.2). Patients treated with OMT demonstrated a significant reduction in depressive symptoms, as measured by the PHQ-9, from baseline (OMT: M=3.9, SD=4.3, t=2.21, p=.03; PCI/OMT: M=4.7, SD=5.9, t=1.92, p=.06) to 30-days (OMT: M=2.5, SD=1.9; PCI/OMT: M=2.8, SD=2.5).

Patients (n=41, 22.7%) scoring greater than 10 (moderate depressive symptoms or higher) on the PHQ-9 at baseline were predominately male (61%, n=25), with a mean age of 68 (SD=5.2) years, non-Hispanic white (90.2%, n=37) and had less than high school education (36.6%, n=15). Significant differences were noted in the response rate for 30-day data collection based on the baseline PHQ-9 score (non-response: M=8.1, SD=6.7; response: M= 4.4, SD=5.2; t=4.21, p<.05), with higher baseline PHQ-9 scores for non-responders at 30-days.

TABLE XVI

Subscale Comparisons:	PCI/OMT (SD)	OMT (SD)	Test Statistic	<i>P</i> Value
POMS Baseline	<i>n</i> =90	<i>n</i> =90		
Fatigue	12.7 (6.2)	13.0 (6.7)	<i>t</i> =.366	.715
Vigor	12.5 (5.3)	12.8 (5.3)	<i>t</i> =.547	.585
Depression Dejection	7.9 (9.5)	7.6 (9.2)	<i>t</i> =198	.844
SF-36 Baseline	<i>n</i> =90	<i>n</i> =90		
Vitality	43.1 (9.5)	46.0 (8.9)	<i>t</i> =2.10	.037
Physical Functioning	40.3(10.5)	41.5 (10.6)	<i>t</i> =.797	.427
General Health	44.3 (9.3)	42.0 (8.1)	<i>t</i> =-1.70	.090
IPQ-R Baseline	<i>n</i> =90	<i>n</i> =90		
Timeline (acute/chronic)	17.2 (4.9)	16.8 (4.4)	<i>t</i> =-5.28	.598
Timeline (cyclical)	6.9 (2.6)	7.1 (2.8)	<i>t</i> =.465	.643
Consequences	14.5 (3.7)	14.1 (3.5)	<i>t</i> =814	.417
Personal Control	18.3 (4.7)	17.2 (4.2)	<i>t</i> =-1.59	.113
Treatment Control, <i>n</i> =167	15.1 (3.4)	15.5 (2.9)	<i>t</i> =.754	.452
Illness Coherence	15.6 (7.2)	15.4 (7.9)	<i>t</i> =173	.863
Emotional Representation	12.8 (4.0)	12.9 (4.1)	<i>t</i> =.200	.842
PHQ-9 Baseline, n=180	5.9 (6.6)	6.3 (5.8)	<i>t</i> =.415	.679

BASELINE SUBSCALE COMPARISONS BY TREATMENT

Abbreviations: PCI/OMT, Percutaneous Intervention with Optimal Medical Therapy; OMT, Optimal Medical Therapy; POMS, Profile of Mood States; Short-Form-36; IPQ-R, Illness Perception Questionnaire-Revised; PHQ-9, Patient Health Questionnaire Revised.

TABLE XVII

Subscale Comparisons:	e Comparisons: PCI/OMT (SD)		Test Statistic	<i>P</i> Value	
POMS 30-DAYS	<i>n</i> =48	<i>n</i> =47			
Fatigue	4.9 (4.2)	5.5 (4.3)	<i>t</i> =.549	.584	
Vigor	17.0 (4.6)	17.9 (3.3)	<i>t</i> =1.13	.259	
Depression Dejection	4.7 (5.3)	3.6 (2.3)	<i>t</i> =1.37	.175	
SF-36 30-Days	<i>n</i> =48	<i>n</i> =47			
Vitality	52.1 (7.2)	49.8 (7.9)	<i>t</i> =-1.45	.149	
Physical Functioning	47.0 (9.0)	40.7 (10.9)	<i>t</i> =-3.06	.003	
General Health	45.0 (8.5)	43.1 (5.3)	<i>t</i> =-1.31	.191	
IPQ-R 30-Days	<i>n</i> =48	<i>n</i> =46			
Timeline (acute/chronic)	16.4 (5.5)	18.8 (4.9)	<i>t</i> =2.14	.035	
Timeline (cyclical)	7.1 (3.3)	10.2 (4.5)	<i>t</i> =3.69	< 0.01	
Consequences	14.9 (4.8)	13.6 (4.0)	<i>t</i> =-1.43	.155	
Personal Control	18.1 (3.8)	17.3 (3.6)	<i>t</i> =-1.04	.297	
Treatment Control	15.2 (2.7)	15.2 (2.2)	<i>t</i> =.059	.953	
Illness Coherence	19.1 (5.4)	17.4 (5.2)	<i>t</i> =-1.50	.135	
Emotional Representation	12.0 (2.8)	11.6 (3.0)	<i>t</i> =640	.524	
PHQ-9 30-Days	<i>n</i> =48	<i>n</i> =46			
PHQ-9	2.8 (2.5)	2.5 (2.5)	<i>t</i> =787	.433	

30-DAY SUBSCALE COMPARISONS BY TREATMENT

Abbreviations: PCI/OMT, Percutaneous Intervention with Optimal Medical Therapy; OMT, Optimal Medical Therapy; POMS, Profile of Mood States; Short-Form-36; IPQ-R, Illness Perception Questionnaire-Revised; PHQ-9, Patient Health Questionnaire Revised.

TABLE XVIII

SUBSCALE COMPARISONS BASELINE AND 30-DAYS: TREATMENT SUB-GROUP ANALYSIS

Subscale	PCI/	PCI/	Mean	t	PCI/	OMT	OMT	Mean	t	OMT*
Comparisons:	OMT	OMT	Diff.	Value	OMT [*]	(SD)	(SD)	Diff.	Value	р
	(SD)	(SD)			р	Baseline	30-Days			Value
	Baseline	30-Days			Value	<i>n</i> =46	<i>n</i> =46			
	<i>n</i> =48	<i>n</i> =48								
POMS										
Fatigue	12.5 (6.2)	5.0 (4.2)	7.50	<i>t</i> =7.00	<.001	13.0 (5.7)	5.5 (4.3)	7.49	<i>t</i> =7.84	<.001
Vigor	13.9 (4.4)	17.0 (4.7)	-3.06	t = -2.88	.006	14.2 (4.6)	17.9 (3.3)	-3.71	<i>t</i> =-3.57	.001
Depression/Dejection	7.7 (8.6)	4.7 (5.3)	3.00	<i>t</i> =1.99	.052	5.6 (6.1)	3.6 (2.3)	2.04	<i>t</i> =1.92	.061
SF-36										
Vitality	42.4 (10.1)	52.1 (7.2)	-9.74	<i>t</i> =-5.3	<.001	47.8 (8.2)	49.8 (8.0)	-2.04	<i>t</i> =-1.36	.178
Physical Functioning	40.2 (11.0)	46.6 (8.0)	-6.40	<i>t</i> =3.65	.001	39.3 (9.3)	40.7(10.9)	-1.32	<i>t</i> =945	.349
General Health	44.9 (10.1)	45.0 (8.5)	.04	<i>t</i> =042	.967	41.1 (5.7)	43.1 (5.3)	-1.98	<i>t</i> =-2.54	.014
IPQ-R										
Timeline	16.7 (5.0)	16.4 (5.5)	.29	<i>t</i> =.370	.713	17.3 (3.2)	18.8 (4.9)	-1.50	<i>t</i> =-1.69	.098
(acute/chronic)										
Timeline(cyclical)	6.5 (2.7)	7.1 (3.3)	61	<i>t</i> =1.59	.117	7.1 (2.4)	10.2 (4.5)	-3.10	<i>t</i> =-4.57	<.001
Consequences	14.6 (3.5)	14.9 (4.8)	34	<i>t</i> =346	.731	13.4 (3.6)	13.6 (4.0)	134	<i>t</i> =155	.878
Personal Control	19.0 (4.2)	18.1 (3.8)	.82	<i>t</i> =1.07	.289	16.4 (4.7)	17.3 (3.6)	873	<i>t</i> =-2.00	.051
Treatment Control	15.8 (2.6)	15.2 (2.7)	.64	<i>t</i> =1.40	.168	16.1 (1.9)	15.2 (2.2)	.956	<i>t</i> =3.26	.002
Illness Coherence	14.7 (7.2)	19.1 (5.4)	-4.40	<i>t</i> =-4.43	<.001	14.1 (8.0)	17.4 (5.2)	-3.32	<i>t</i> =-3.74	.001
Emotional	12.5 (3.3)	12.0 (2.8)	.52	<i>t</i> =.986	.329	11.8 (3.7)	11.6 (3.0)	.152	<i>t</i> =.239	.812
Representation										
PHQ-9										
PHQ Summary	4.7 (5.9)	2.8 (2.5)	1.85	t=1.92	.060	3.9 (4.3)	2.5 (1.9)	1.41	<i>t</i> =2.21	.032

Abbreviations: PCI/OMT, Percutaneous Intervention with Optimal Medical Therapy; OMT, Optimal Medical Therapy; POMS, Profile of Mood States; Short-Form-36; IPQ-R, Illness Perception Questionnaire-Revised; PHQ-9, Patient Health Questionnaire Revised, ^{*}paired samples t test

TABLE XIX

Subscale Comparisons:	Male (SD)	Female (SD)	Test Statistic	P Value
POMS Baseline	<i>n</i> =129	<i>n</i> =51		
Fatigue	12.1 (6.4)	14.8 (6.3)	<i>t</i> =-2.52	.012
Vigor	13.5 (5.2)	10.3 (4.7)	<i>t</i> =.289	< 0.01
Depression Dejection	8.4 (10.5)	5.9 (5.4)	<i>t</i> =2.13	.034
SF-36 Baseline	<i>n</i> =74	<i>n</i> =21		
Vitality	44.0 (10.0)	44.0 (7.0)	<i>t</i> =.537	.592
Physical Functioning	41.7 (10.2)	38.8 (11.1)	<i>t</i> =1.67	.096
General Health	43.7 (9.3)	41.8 (7.3)	<i>t</i> =1.47	.145
IPQ-R Baseline	<i>n</i> =129	<i>n</i> =51		
Timeline (acute/chronic)	16.3(4.7)	18.8 (4.2)	<i>t</i> =-3.28	.001
Timeline (cyclical)	7.2 (2.6)	7.0 (3.0)	<i>t</i> =.221	.825
Consequences	14.3 (3.7)	14.2 (3.2)	<i>t</i> =.217	.828
Personal Control	17.7 (4.6)	18.0 (4.0)	<i>t</i> =.375	.708
Treatment Control, <i>n</i> =167	14.8 (3.3)	16.9 (1.7)	<i>t</i> =-3.62	< 0.01
Female, <i>n</i> =38				
Illness Coherence	14.2 (7.7)	18.8 (6.1)	<i>t</i> =-3.75	< 0.01
Emotional Representation PHQ-9 Baseline	12.3 (4.1)	14.1 (3.7)	<i>t</i> =-2.75	.006
PHQ-9	5.8 (6.5)	6.9 (5.5)	<i>t</i> =966	.335

BASELINE SUBSCALE COMPARISONS BY GENDER

TABLE XX

Subscale Comparisons:	Male (SD)	Female (SD)	Test Statistic	P Value
POMS 30-DAYS	<i>n</i> =74	<i>n</i> =21		
Fatigue	5.1 (3.8)	5.8 (5.7)	<i>t</i> =514	.612
Vigor	17.7 (4.2)	16.8 (3.4)	<i>t</i> =.881	.381
Depression Dejection	4.7 (4.5)	2.1 (1.0)	<i>t</i> =4.60	< 0.01
SF-36 30-Days	<i>n</i> =74	<i>n</i> =21		
Vitality	52.2 (7.5)	46.7 (6.9)	<i>t</i> =3.00	.003
Physical Functioning	42.7 (10.5)	48.1 (9.4)	<i>t</i> =-2.12	.037
General Health	43.6 (7.7)	45.8 (4.5)	<i>t</i> =-1.24	.217
IPQ-R 30-Days	<i>n</i> =73	<i>n</i> =21		
Timeline (acute/chronic)	17.4 (5.8)	18.2 (3.2)	<i>t</i> =878	.384
Timeline (cyclical)	9.1 (4.3)	6.9 (3.2)	<i>t</i> =2.15	.034
Consequences	14.7 (4.9)	12.7 (2.1)	<i>t</i> =2.71	.008
Personal Control	17.6 (3.8)	18.1 (3.6)	<i>t</i> =487	.628
Treatment Control	17.2 (5.7)	21.9 (.83)	<i>t</i> =-3.55	.001
Illness Coherence	19.1 (5.4)	17.4 (5.2)	<i>t</i> =-6.68	< 0.01
Emotional Representation	12.2 (3.0)	10.6 (1.8)	<i>t</i> =2.83	.006
PHQ-9 30-Days				
PHQ-9	2.7 (2.5)	2.5 (1.3)	<i>t</i> =.435	.665

30-DAYS SUBSCALE COMPARISONS BY GENDER

Table XVII. Subscale comparisons based on PCI and PCI/OMT group status for calculated subscales. Abbreviations: PCI/OMT, Percutaneous Intervention with Optimal Medical Therapy; OMT, Optimal Medical Therapy; POMS, Profile of Mood States; SF-36, Short-Form-36; IPQ-R, Illness Perception Questionnaire-Revised; PHQ-9, Patient Health Questionnaire, *paired samples *t* test.

TABLE XXI

SUBSCALE COMPARISONS BASELINE AND 30-DAYS BY GENDER

Subscale	Male	Male	Mean	t	Male ^a	Female	Female	Mean	t Value	Female ^a
Comparisons:	(SD) Baseline n=74	(SD) 30-Days <i>n</i> =74	Diff.	Value	<i>p</i> Value	(SD) Baseline n=21	(SD) 30-Days <i>n</i> =21	Diff.		<i>p</i> Value
POMS	11-1-	11-14				<i>n–</i> 21	11-21			
Fatigue	12.9 (6.0)	5.1 (3.8)	7.81	<i>t</i> =9.13	<.001	12.1 (5.5)	5.8 (5.7)	6.38	<i>t</i> =5.43	<.001
Vigor	14.6 (4.4)	17.0 (4.3)	-3.08	$t=-3.56^{*}$.001	12.3 (4.5)	16.8 (3.4)	-4.47	t=-3.19	.005
Depression/Dejection	6.9 (8.2)	4.7 (4.5)	2.15	<i>t</i> =1.86	.066	6.0 (4.4)	2.1 (1.0)	3.85	<i>t</i> =4.21	<.001
SF-36										
Vitality	44.9 (10.3)	52.2 (7.5)	-7.24	<i>t</i> =-4.83	<.001	45.4 (6.3)	46.7 (6.9)	-1.30	<i>t</i> =.856	.402
Physical Functioning	39.2 (9.7)	42.7 (10.5)	-3.48	<i>t</i> =-3.08	.003	41.9 (11.7)	48.1(9.4)	-6.21	<i>t</i> =-4.18	<.001
General Health	43.0 (9.3)	43.6 (7.7)	55	<i>t</i> =64	.521	43.2 (4.5)	45.8 (4.5)	-2.58	<i>t</i> =-2.38	.027
IPQ-R										
Timeline	16.2 (4.3)	17.4 (5.8)	-1.13	<i>t</i> =-1.61 [*]	.111	19.6 (2.8)	18.2 (3.2)	1.33	<i>t</i> =-1.35	.189
(acute/chronic)										
Timeline(cyclical)	6.9 (2.7)	9.1 (4.3)	-2.16	$t = -4.34^{*}$	<.001	6.2 (1.8)	6.9 (3.2)	66	<i>t</i> =-1.50	.149
Consequences	14.3(3.7)	14.7 (4.9)	35	$t =456^{*}$.650	12.9 (3.0)	12.7 (2.1)	.238	<i>t</i> =39	.696
Personal Control	18.2 (4.5)	17.6 (3.8)	.58	t=1.06*	.293	16.0 (4.7)	18.1 (3.6)	-2.04	<i>t</i> =-4.13	.001
Treatment Control	15.6 (2.4)	14.8 (2.6)	.82	$t=2.54^{*}$.013	17.2 (1.5)	16.5 (1.6)	.714	t=1.39	.179
Illness Coherence	13.5 (7.6)	17.2 (5.7)	-3.77	$t = -5.28^{*}$	<.001	17.6 (6.9)	21.9 (.83)	-4.23	<i>t</i> =-2.50	.021
Emotional	11.8 (3.4)	12.2 (3.0)	-3.28	$t =71^{*}$.477	13.3 (3.7)	10.6 (1.8)	2.66	<i>t</i> =3.71	.001
Representation										
PHQ-9										
PHQ Summary	4.7 (5.8)	2.7 (2.5)	2.02	$t = 2.75^*$.007	2.8 (1.8)	2.5 (1.3)	.285	<i>t</i> =.90	.379

TABLE XXII

Subscale Comparisons:	Stable CAD Mean Scores (SD)	MI Mean ^a Scores (SD)	Chronic^a Kidney Disease (SD)
IPQ-R Baseline	<i>n</i> =180	<i>n</i> =204	<i>n</i> =42
Timeline (acute/chronic) Stable CAD comparison	17.0 (4.7)	20.0 (5.3) <i>p</i> < .01	24.5 (4.8) <i>p</i> < .01
Timeline (cyclical)	7.0 (2.7)	10.8 (2.8) <i>p</i> < .01	11.9 (2.9) <i>p</i> < .01
Consequences	14.3 (3.6)	18.8 (4.6) <i>p<.</i> 01	23.5 (3.9) <i>p</i> < .01
Personal Control	17.8 (4.5)	21.2 (3.9) <i>p</i> < .01	21.9 (4.2) <i>p</i> < .01
Treatment Control	15.3 (3.2)	18.0 (3.2) <i>p</i> < .01	15.4 (3.1) .854
Illness Coherence	15.5 (7.6)	17.1 (3.0) <i>p</i> =.005	13.8 (4.6) <i>p</i> =.165
Emotional Representation	12.8 (4.0)	16.6 (4.8) <i>p<.</i> 01	20.2 (5.4) <i>p</i> < .01

SUBSCALE COMPARISONS WITH IPQ-R PUBLISHED MEANS

Abbreviations: IPQ-R, Illness Perception Questionnaire- Revised; MI, Myocardial Infarction, ^a Published means by Alsen et al. (2010).

TABLE XXIII

SUBSCALE COMPARISONS WITH PROFILE OF MOOD STATES FOR PUBLISHED MEANS

Subscale Comparisons:	Stable CAD Mean Scores (SD)	MI Mean ^a Scores (SD)	Healthy ^b Sample Males (SD)	Healthy ^b Sample Females (SD)
POMS Baseline Fatigue (POMS-F) Stable CAD comparison	<i>n</i> =180 12.8 (6.4)	n=116 13.0 (7.4) p=.78	<i>n</i> =204 7.4 (5.7) <i>p</i> <.01	<i>n</i> =42 8.7 (6.1) <i>p</i> <.01
Vigor (POMS-V)	7.0 (2.7)	15.0 (6.9)	19.8 (6.8)	18.9 (6.5)
Stable CAD comparison		<i>p</i> < .01	<i>p</i> < .01	<i>p</i> < .01
Depressive Mood (POMS-D)	7.7 (9.4)	10.3 (9.9)	7.5 (9.2)	8.5 (9.4)
Stable CAD comparison		<i>p=.012</i>	<i>p</i> =.111	<i>p</i> =.073

Abbreviations: CAD, Coronary Artery Disease; MI, Myocardial Infarction; POMS, Profile of Mood States, ^a Published means by Fennessy et al. (2010), ^b Published means by Neyenhuis (1999).

TABLE XIV

Subscale Comparisons:	Stable CAD Mean Scores (SD)	COURAGE ^a Stable CAD PCI/OMT Sample Scores (SD)	COURAGE ^a Stable CAD OMT Sample Scores (SD)	AMI ^b Sample Scores (SD)
SF-36 Baseline	<i>n</i> =180	<i>n</i> =987	<i>n</i> =974	<i>n</i> =111
Vitality	44.5 (9.3)	47 (24)	47 (23)	46.1 (11.5)
Stable CAD comparison		<i>p</i> =.168	<i>p</i> =.151	<i>p</i> =.194
Physical Functioning	40.9 (11.0)	58 (27)	59 (27)	41.7 (12.3)
Stable CAD comparison		<i>p<.01</i>	<i>p<.01</i>	<i>p</i> =.565
General Health	43.2 (8.8)	57 (20)	55 (20)	42.3 (10.5)
Stable CAD comparison		<i>p<.</i> 01	<i>p<.</i> 01	<i>p</i> =.432

SUBSCALE COMPARISONS WITH SF-36 PUBLISHED MEANS

Abbreviations: PCI/OMT, Percutaneous Coronary Intervention with Optimal Medical Therapy; OMT, Optimal Medical Therapy; MI, Myocardial Infarction, ^a Published means by Weintraub et al. (2008), ^b Published means by Fennessy et al. (2010).

E. Research Purpose and Specific Aims

The purpose of this research was to examine the influence of illness representation, fatigue, and depressive symptoms for participation in cardiac rehabilitation, smoking, and medication use related to dual antiplatelet therapy and lipid lowering agents in patients with stable. This convenience sample was recruited from an interventional cardiology practice located at a large, academic medical center in Maywood, Illinois. Therefore, all patients in this sample underwent coronary angiography (n=180); however, only n=90 underwent PCI, with n=90 receiving OMT as part of their CAD treatment plan.

1. <u>Specific Aim 1</u>

To compare group differences in illness representation (identity, cause, time-line, consequences, and cure/control) between patients with obstructive CAD receiving PCI (PCI group- stents/angioplasty) and patients with nonobstructive CAD receiving medical management

An independent samples *t* test was used to detect differences between PCI/OMT and OMT treatment groups for the IPQ-R subscales measured at baseline and 30-days. At baseline, there were no significant differences in the IPQ-R subscales between the PCI/OMT and OMT groups (see table XII). At 30-days (see table XIII), the timeline acute/chronic (t=2.14, df=92, p=.035) and timeline cyclical subscales (t=3.69, df=92, p<.05) were significantly different between PCI/OMT and OMT treatment groups. When comparing IPQ-R differences at 30-days, patients treated in the OMT group tended to have a more chronic illness timeline (M=18.8, SD=4.9; PCI/OMT M=16.4, SD=5.5) and viewed their illness with a more cyclical timeline (M=10.2, SD=4.5; PCI/OMT M=7.1, SD=3.3), which suggests that patients treated with OMT

continued to experience symptoms within 30-days after treatment, with the exception of fatigue. Items on the IPQ-R associated with the Timeline cyclical subscale reflect items such as, "my symptoms change a great deal from day-to-day", "my illness is very unpredictable", and "my symptoms come and go in cycles". Since patients who underwent OMT had higher timeline cyclical scores, it is likely that they continued to experience ongoing symptoms within 30-days after treatment.

Further differences were also observed between gender groups. At baseline, females tended to view their illness using a chronic illness model, as demonstrated by increased timeline (acute/chronic) scores (females M=18.8, SD=4.2) when compared to males (M=16.3, SD=4.7, t=-3.28, p=.001). Additional gender differences were observed for the treatment control (t=-3.62, p<.01), illness coherence (t=-3.75, p<.01) and emotional representation subscales (t=-2.75, p=.006). Females reported greater treatment control (females M=16.9, SD=1.7; males M=14.8, SD=3.3) and perceived themselves to have a greater understanding of the illness (Illness Coherence subscale; females M=18.8, SD=6.1; males M=14.2, SD=7.7), but with greater emotional representation subscale; females M=14.1, SD=3.7; males M=12.3, SD=4.1) when compared to males.

At 30-days, females continued to perceive their illness with higher levels of treatment control, suggesting the perception of improved control of their prescribed treatment plan (M=21.9, SD=.83) when compared to males (M=17.2, SD=5.7, t=-3.55, p=.001). However, male perceptions shifted at 30-days, with a tendency to view their illness as more cyclical (male M=9.1, SD=4.3; females M=6.9, SD=3.2, t=2.15, p=.034), with greater consequences (males M=14.7, SD=4.9; females M=12.7, SD=2.1, t=2.71, p=.008), greater perceived understanding of their illness (males M=19.1, SD=5.4; females M=17.4, SD=5.2, t=6.68, p<.01), and had a

increased emotional response (males M=12.2, SD=3.0; females M=10.6, SD=1.8, t=2.83, p=.006) when compared to females.

2. <u>Specific Aim 2</u>

To compare temporal changes in illness representation (identity, cause, time-line, consequences, and cure/control) from baseline (post-procedure) to 30-days for patients treated with PCI/OMT and OMT.

A paired *t* test was used to assess for change in the IPQ-R subscales from baseline to 30days (see table XVIII). Significant changes (see table XXI) over time were demonstrated in the Timeline (cyclical) (*t*=-4.35, *df*=93, *p*<.05), Treatment Control (*t*=2.90, *df*=93, *p*=.005), and Illness Coherence (*t*=-5.81, *df*=93, *p*<.05) subscales. In this sample, Timeline (cyclical) scores increased suggesting continued symptoms despite treatment. Additionally, treatment Control scores decreased from M=16.0 (*SD*=2.3) at baseline to 15.2 (*SD*=2.5; *p*=.005) at 30-days, suggesting that patients had less confidence in the treatment or recommendations during followup. Illness Coherence scores were significantly increased across time (baseline *M*=14.43, *SD*=7.6; 30-days *M*=18.30, *SD*=5.4, *t*=-5.81, *p*<.01), which suggests greater understanding following treatment for stable CAD.

Further subgroup analyses were conducted for patients treated with PCI/OMT and OMT (see table XIV). Patients treated with PCI/OMT and OMT demonstrated a significant increase in perceived understanding of illness (Illness Coherence subscale) from baseline (PCI/OMT: M=14.7, SD=7.2, t=-4.43, p<.001; OMT: M=14.1, SD=8.0, t=-3.74, p=.001) to 30-days (PCI/OMT: M=.19.1, SD=5.4; OMT: M=17.4, SD=5.2). Patients treated with OMT demonstrated a significant increase in Timeline (cyclical) scores from baseline (M=7.1, SD=2.4,

t=-4.57, *p*<.001) to 30-days. Additionally, patients treated with OMT demonstrated a significant reduction in Treatment Control scores from baseline (M=16.1, SD=1.9, *t*=3.26, *p*=.002) to 30-days (M=15.2, SD=2.2). Finally, interactions (see Figures I and II) were noted, which demonstrates that the effect of the Timeline (acute/chronic) and Personal Control subscales were not the same for the treatment groups from baseline to 30-days.

TABLE XXV

CHANGES IN ILLNESS REPRESENTATION: BASELINE AND 30-DAYS, n=94

Subscale	Baseline	30-Day	t	P Value	95% CI
	Mean (SD)	Mean (SD)	Value		
Timeline (acute/chronic)	17.03 (4.2)	17.61 (5.3)	981	.329	±-1.76599
Timeline (cyclical)	6.83(2.6)	8.67 (4.2)	-4.53	<.01	±-2.63- 1.03
Consequence	14.0 (3.6)	14.28 (4.5)	359	.720	\pm -1.44- 1.00
Personal Control	17.78 (4.6)	17.78 (4.6)	014	.989	±906893
Treatment Control	16.02 (2.3)	15.22 (2.5)	2.90	.005	± .252-1.34
Illness Coherence	14.43 (7.6)	18.30 (5.4)	-5.81	<.01	±519- ⁻ 2.55
Emotional Representation	12.21 (3.5)	11.87 (2.9)	.829	.409	±474- 1.15

FIGURE III

IPQ-R SUBSCALE: TIMELINE (ACUTE/CHRONIC) INTERACTION BASED ON TREATMENT

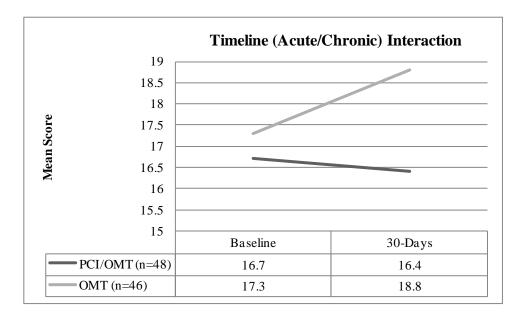
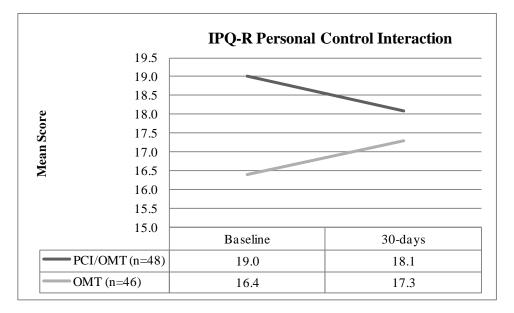


FIGURE IV

IPQ-R SUBSCALE PERSONAL CONTROL INTERACTION BASED ON TREATMENT GROUP



3. <u>Specific Aim 3</u>

To determine if secondary prevention behaviors are influenced by illness representation, fatigue, and depressive symptoms as measured at 30-days post-procedure.

Secondary preventions was based on behaviors such as cardiac rehabilitation participation, medication use (aspirin, thienopyridines, and lipid lowering agents), and smoking/tobacco use. The relations between the independent and dependent variables were examined using Pearson correlation coefficients. Spearman's Rho correlation coefficients were used to examine significant correlations between the IPQ-R subscales and secondary prevention behaviors at 30-days (see table XXII). Those IPQ-R subscales with significant correlations for secondary prevention behaviors were included in the regression models. Independent variables were inspected for multicollinearity prior to conducting the regression analyses. For this analysis, individual logistic regression models were used to examine whether illness representation (based on subscales with significant correlations), fatigue (POMS-Fatigue), and depressive symptoms (PHQ-9) predicted secondary prevention behaviors at 30-days. The PHQ-9 summary score was included for regression models rather than the POMS-Depression Dejection score to reflect depressive symptoms versus depressed mood. Considering the overwhelming use of the PHQ-9 instrument in prior cardiovascular related research, the decision was made for the PHQ-9 to be included as the key depressive symptoms variable in the logistic regression models. Individual logistic regression models (see tables XXIII, XIV, XXV, XXVI and XXVII), tested the prediction of secondary prevention behaviors at 30-days.

Significant models were demonstrated for secondary prevention behaviors related to cardiac rehabilitation participation (n=93, B=-.894, Wald=15.3, P<.001, Exp (B) .409) and use

of medications such as, lipid lowering agents (n=87, B=1.65, Wald 32.03, P<.001, Exp (B) 5.21), aspirin (n=87, B=1.49, Wald 31.15, P<.001, Exp (B) 4.47) and thienopyridines (n=80, B=1.38, Wald 24.59, P<.001, Exp (B) 4.00) within 30-days after treatment for stable CAD. No significant models could be produced for smoking/tobacco use (p=.162).

The regression model for cardiac rehabilitation participation demonstrates that when controlling for the independent variables (see table XXIII), there was predictive likelihood of the occurrence of cardiac rehabilitation participation. Therefore, when all the other independent variables were kept constant, for each 1 unit increase in Years with prior CAD diagnosis (B=-.218, p=.024, Exp(B)=.804), 30-day IPQ-R Personal Control (B=-.406, p=.003, Exp(B) .666), and 30-day IPQ-R Illness Coherence (B=-.186, p=.007, Exp(B)=.830), the odds of cardiac rehabilitation attendance was reduced by 4.4%, 3.9%, and 4.5% respectively. Furthermore, independent variables related to gender (B=4.44, p=.002, Exp(B) 85.50) were predictive of odds for participation in cardiac rehabilitation. Male gender resulted in increased odds for cardiac rehabilitation attendance by 9.8%. The model explained 45.8% to 65.4% of the variance for cardiac rehabilitation participation (Cox and Snell R^2 =.458, Nagelkerke R^2 =.654).

The regression model for lipid lowering use 30-days after treatment for CAD supports the influence of years with prior CAD diagnosis (see table XIV). Therefore, with all other independent variables in the model kept constant, each 1 unit increase in the number of years with prior CAD diagnosis resulted in decreased odds of 3.8% for consistent lipid lowering use within the first 30-days (B=-.482, p<.001, Exp(B) .617). The model explained 29.3% to 50.0% of the variance for consistent lipid lowering use (Cox and Snell R^2 =.293, Nagelkerke R^2 =.500).

The regression model (see table XXVI) for aspirin use 30-days after treatment for CAD supports the influence of illness representation, specifically related to the IPQ-R Timeline (acute/chronic) subscale. Therefore, with all other independent variables in the model kept constant, each 1 unit increase in the 30-Day IPQ-R Timeline (acute/chronic) score resulted in increased odds of 5.6% for aspirin use. This model explained 26.3-42.8% of the variance for regular use of aspirin within the first 30-days after treatment for CAD (Cox and Snell R^2 =.263, Nagelkerke R^2 =.428).

The regression model (see table XXVII) for thienopyridine use 30-days after treatment for CAD supports the influence of illness representation (B=.321, p=.005, Exp(B) 1.37) and depressive symptoms (B=.529, p=.008, Exp(B) 1.69). Therefore, with all other independent variables in the model kept constant, each 1 unit increase in the 30-Day IPQ-R Timeline (acute/chronic) score resulted in increased odds of 5.7% for regular use of thienopyridine agents. For the influence of depressive symptoms, each 1 unit increase in the 30-day PHQ-9 Summary score resulted in an increased odds of 6.2% for thienopyridine use. This model explained 21.6-34.2% of the variance for regular use of thienopyridine agents within the first 30-days after treatment for CAD (Cox and Snell R^2 =.216, Nagelkerke R^2 =.342).

TABLE XXVI

IPQ-R SUBSCALES AND SECONDARY PREVENTION CORRELATIONS AT 30-DAYS^a

	Cardiac Rehabilitation	Smoking/Tobacco Use	Medication:	Medication:	Medication:
	Attendance		aspirin	thienopyridine	lipid lowering
1. 30-Day IPQ-R Timeline (acute/chronic)	.06	15	.35**	.37**	08
2.30-Day IPQ-R Timeline (cyclical)	.09	.11	.26*	.18	07
3. 30-Day IPQ-R Consequences	.08	.21*	.07	16	19
4. 30-Day IPQ-R Personal Control	41**	.11	09	.03	12
5. 30-Day IPQ-R Treatment Control	14	.03	23*	.18	20
6. 30-Day IPQ-R Illness Coherence	27**	11	06	.01	39
7. 30-DayIPQ-R Emotional Representation	.23*	21	.14	09	.39**

* < .05, **< .01, ^a Spearman Correlation, r_s

TABLE XXVII

PREDICTING CARDIAC REHABILIATION PARTICIPATION 30-DAYS AFTER TREATMENT, (n=93)

Variables	В	Wald (SD)	<i>P</i> Value	Exp(B) (95% CI)
Years with CAD diagnosis	218	5.06	.024	.804 (±.664972)
30-Day IPQ-R Personal Control	406	8.63	.003	.666 (±.508874)
30-Day IPQ-R Illness Coherence	186	7.34	.007	.830 (±.725950)
30-Day IPQ-R Emotional Representation	.213	2.34	.125	1.23 (±.942-1.62)
30-day PHQ-9 Summary Score	103	.267	.605	.903 (±.612-1.33)
30-day POMS-Fatigue	220	3.38	.066	.802 (±.634-1.01)
Age	.031	.420	.517	1.03 (±.940-1.13)
Gender (1=male)	4.44	9.80	.002	85.50 (±5.28-1383.98)
Constant	6.67			
Model χ2=56.9, df=8, p<.001 ; r2 Cox &	snell $r^2 =$.	458 ; Nagel	kerke $r^2 = .6$	654.

TABLE XXVIII

PREDICTING LIPID LOWERING THERAPY USE 30-DAYS AFTER TREATMENT, (n=87)

Variables	В	Wald (SD)	<i>P</i> Value	Exp(B) (95% CI)
Years with CAD diagnosis	482	13.7	<.001	.617 (±.478797)
30-Day IPQ-R Emotional Representation	229	1.89	.169	.795 (±.573-1.10)
30-day PHQ-9 Summary Score	.441	3.56	.059	1.55 (±.983-2.45)
30-day POMS-Fatigue	.126	1.05	.305	1.13 (±.892-1.44)
Age	.060	1.60	.205	1.06 (±.968-1.16)
Gender (1=male)	-1.29	1.69	.193	.275 (±.039-1.92)
Constant	4.12			· · · · ·

Model $\chi 2=30.1$, df=8, p<.001; r2 Cox Snell $r^2=.293$; Nagelkerke $r^2=.500$.

TABLE XXIX

PREDICTING SMOKING/TOBACCO USE 30-DAYS AFTER TREATMENT, (*n*=92)

Variables	В	Wald (SD)	<i>P</i> Value	Exp(B) (95% CI)
	011			000 (. 000 1 10)
Years with CAD diagnosis	011	.025	.875	.989 (±.863-1.13)
30-Day IPQ-R Consequences	035	.194	.660	.966 (±.826-1.12)
30-Day PHQ-9 Summary Score	.332	4.57	.032	1.39 (±1.02-1.88)
30-Day POMS-Fatigue	142	2.22	.136	.867 (±.719-1.04)
Age	.053	1.92	.165	1.05 (±.979-1.13)
Gender (1=male)	.518	.556	.456	1.67 (±.430-6.54)
Constant	-4.95			

Model χ 2=9.21, *df*=8, *p*=.162 ; *r*2 Cox & Snell *r*²=.095 ; Nagelkerke *r*²=.162.

TABLE XXX

PREDICTING ASPIRIN USE 30-DAYS AFTER TREATMENT, (*n*=93)

Variables	В	Wald (SD)	<i>P</i> Value	Exp(B) (95% CI)
Years with CAD diagnosis	092	1.26	.261	.912 (±.776-1.07)
30-Day IPQ-R Timeline (acute/chronic)	.282	4.65	.031	1.32 (±1.02-1.71)
30-Day IPQ-R Timeline (cyclical)	.201	2.45	.117	$1.22(\pm .951-1.57)$
30-Day IPQ-R Treatment Control	.152	.609	.435	1.16 (±.795-1.70)
30-day PHQ-9 Summary Score	.383	2.97	.084	1.46 (±.949-2.26)
30-day POMS-Fatigue	050	.261	.610	.951 (±.785-1.15)
Age	062	1.07	.300	.940 (±.836-1.05)
Gender (1=male)	809	.932	.334	.445 (±.086-2.30)
Constant	6.70			

Model $\chi 2=28.35$, df=8, p<.001; r2 Cox Snell $r^2=.263$; Nagelkerke $r^2=.428$.

TABLE XXXI

PREDICTING THIENOPYRDINE USE 30-DAYS AFTER TREATMENT, (*n*=80)

Variables	В	Wald (SD)	P Value	Exp(B) (95% CI)
Years with CAD diagnosis	087	1.11	.290	.917 (±.781-1.07)
30-Day IPQ-R Timeline (acute/chronic)	.321	7.82	.005	1.37 (±1.10-1.72)
PHQ-9 30-days Summary Score	.529	7.06	.008	1.69 (±1.14-2.50)
POMS-Fatigue 30-days	055	.331	.565	.946 (±.784-1.14)
Age	056	1.14	.285	.946 (±.854-1.04)
Gender (1=male)	706	.797	.372	.493 (±.105-2.32)
Constant	109			

Model $\chi^2=19.50$, df=8, p=.003; $r^2 \text{ Cox \& Snell } r^2=.216$; Nagelkerke $r^2=.342$

V. DISCUSSION

A theory-driven approach to research provides a way to classify situations, relating events, or experiences and serves as a basis for predicting or explaining a particular phenomenon (Omery, Kasper, & Page, 1995). This study is important because it is the first theory-driven study to examine the influence of illness representation, fatigue, and depressive symptoms for secondary prevention behaviors in patients living with stable CAD. Leventhal's Self-Regulation Model provided a theoretical perspective on the proposed set of relationships to guide the exploration of the key concepts used in this study. Although this study is descriptive in nature, the findings provide support for the influence of illness representation towards secondary prevention behaviors. Depressive symptoms were found to be significant predictors towards the regular use of thienopyridine agents. These findings have implications towards developing tailored interventions to facilitate secondary prevention behaviors for patients living with CAD.

A. Overview

Leventhal et al. (Leventhal et al., 1984) describe self-regulation as a theoretical approach, which views the patient as an active problem solver. Within the model, patients develop meanings of past and present experiences to promote self-regulating behaviors. Essentially, the response to illness is dynamic, which results in various coping responses towards self-regulating behaviors. Response to illness involves a cognitive representation, formation of an action plan, and a follow-up appraisal process to evaluate outcomes related to the specific health threat. For purposes of clarity, this study focused on the phase associated with cognitive representation.

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Patients in this sample were diagnosed with stable CAD. The primary goals for treating this population of patients includes; relief of symptoms and ischemia, prevention of future cardiovascular death, and reduction in the progression of CAD that could lead to AMI (Pfisterer, Zellweger, & Gershm, 2010). Patients were recruited to examine the influence of illness representation, fatigue, and depressive symptoms towards secondary prevention behaviors measured at 30-days. Additionally, group differences in illness representation were evaluated between treatment and across time.

Overall, the results from this study lead to three key findings. First, significant differences were noted for the Timeline (acute/chronic) and Timeline (cyclical) subscales between treatment groups within 30-days after treatment. Patients treated with PCI/OMT reported lower scores on the Timeline acute/chronic scales, which suggest a more acute illness perception when compared to those patients treated with OMT. Differences in the Timeline cyclical subscales were observed for patients treated with OMT. Higher Timeline cyclical score (Timeline Cyclical- items reflecting continuing symptoms) demonstrate that patients treated with OMT tended to view their illness as unpredictable and it is likely that this group tended to experience more issues with symptoms than those patients who were treated with PCI/OMT.

Secondly, the OMT group was noted to have a reduced belief in the effectiveness of their treatment plan (Treatment Control) and may also be associated with the belief that their disease was unpredictable with continued symptoms 30-days after treatment. Both treatment groups were noted to have significant improvements in their beliefs related to illness coherence, which suggest that patients believe that they understand their illness better within 30days after treatment regardless of whether they were treated with interventional and/or medical therapies.

Finally, secondary prevention behaviors related to cardiac rehabilitation participation and

regular use of lipid lowering agents, aspirin, lipid lowering and thienopyridines were found to be significantly predicted by models used in this study. One important finding relates to the impact of the Timeline acute/chronic scale for the regular use of antiplatelet medications. These medications remains a priority for those treated with stable CAD. However, the models in this study suggest that an acute illness perspective may mislead patients in believing that their disease process is "fixed" and result in early discontinuation of regular therapy. Fatigue and depressive symptoms were not found to be significant contributors for secondary prevention behaviors related to cardiac rehabilitation attendance and aspirin or lipid lowering therapy. However, depressive symptoms were found to influence the regular lipid lowering medications.

The majority of patients were white (78%), married (67%), and well-educated, with at least 53% reporting a college level of education or higher. Patients were noted to have a prior history of CAD for at least 8 years. Over half (58%), had a prior history of AMI, with 71% undergoing PCI in the past. Over a third of patients (38%) previously underwent CABG surgery. Given the chronic nature of CAD, it was not surprising to see the presence of additional cardiovascular related co-morbidities such as peripheral arterial disease (34%), heart failure (30%), hypertension (82%), and diabetes mellitus (57%). From a physical functioning standpoint, patients from the current study reported greater physical limitations compared to physical functioning scores reported by the COURAGE trial (Weintraub et al, 2008), which reported results using stable CAD patients (n=2287) undergoing similar therapies. A greater incidence of cardiovascular related comorbidities was observed in this study compared to those from COURAGE. Strict selection criteria in the COURAGE trial limited patients with multiple cardiovascular related conditions, compared to those observed in this study. It is

estimated that over 40% of patients with stable CAD are under treatment and these patients are likely to present with multiple co-morbidities compared to what was reported in the COURAGE trial (Lloyd-Jones et al., 2009).

B. <u>Illness Representation</u>

Multiple studies have reported variations in illness representation after diagnosis of CAD; however, those findings evolved from studies using an AMI sample. This is problematic because not all CAD patients are treated in the setting where ischemic symptoms may require emergent therapy. Hospitalization is rapid and overall recovery for AMI is different from those presenting with stable CAD. In the case of those with a prior history of CAD, patients may present with cardiac symptoms or abnormal stress testing, but in a more stable fashion with a hospitalization that is planned, systematic, and all within an outpatient setting. Furthermore, many patients presented for treatment with past medical histories that often included prior PCI or CABG. It is likely that these prior cardiac experiences influenced illness representation patterns after repeated treatment for CAD. Nevertheless, the implications for long-term management of CAD remain the same for both AMI and stable CAD patients (Smith et al., 2006b); however, data from this study suggests that differences in illness representation exist between these diagnoses. Additionally, results from this study suggest that differences in illness representation go even further to distinguish between stable CAD patients who are treated with percutaneous and/or optimal medical therapy. For example, patients treated with OMT tended to experience changes over time which suggests continued symptoms after treatment (Timeline Cyclical), reduced beliefs in the prescribed treatment plan (Treatment Control) and the perception of an improved overall understanding of their illness (Illness Coherence). Additionally, for those patients treated

with PCI/OMT, changes were observed with perceptions of improved understanding for their illness (Illness Coherence).

Prior researchers have examined timeline differences between groups of patients with CAD; however, comparisons were often done using AMI or groups of patients initially diagnosed with CAD (Broadbent et al., 2009; Devcich et al., 2008; Petrie, Buick, Weinman, & Booth, 1999; Petrie et al., 2002; Petrie et al., 1996; Zerwic et al., 1997). In the current study, the AMI sample was excluded, to reflect only those patients with a prior history of CAD who present in an outpatient setting for treatment. Zerwic et al. (1997) reported that 41% patients perceived their illness to be short-lived or acute in nature; although, this was done using comparisons between AMI and stable CAD group. Results from this study are consistent with those reported by Zerwic et al., (1997) and further clarifies differences in timeline perceptions for patients with stable CAD compared to those diagnosed with AMI.

For the current study, the concept of timeline was quantified using the timeline (acute/chronic) and timeline (cyclical) subscales within the IPQ-R instrument. Overall, patients with stable CAD in this study reported lower timeline scores at baseline and 30-days, suggesting a more acute or short-lived disease process when compared to those patients diagnosed with AMI (Alsen et al., 2010; Cherrington et al., 2004; Petrie et al., 2002) . Of particular interest in this study were the lower timeline scores for the PCI/OMT group at 30-days. Overall, patients who were treated with PCI tended to perceive a more short-lived illness at 30-days compared to those treated with OMT, which suggests that patients treated with PCI/OMT may view themselves as "fixed" or "cured" following hospital discharge. The higher Timeline (cyclical) scores for those treated with OMT suggest that these patients continue to experience symptoms. Furthermore, results from this study supports prior research (Barnason et al., 2006) which suggests an inverse relationship between physical functioning and symptom management; for example, as symptoms increased, functioning decreased. For the patients treated with PCI/OMT in this study, symptoms were much improved at 30-days, and physical functioning increased over time, perhaps adding to the more acute or "fixed" perception of illness.

Patterns of recovery have been examined for patients undergoing coronary angiography (Devcich et al., 2008) and PCI (Astin & Jones, 2006; Barnason et al., 2006). Significant changes across time were previously reported for the emotional representation and consequences subscales (Astin & Jones, 2006; Devcich et al., 2008); however, measurement of these constructs differed according to the IPQ version used in prior studies. Furthermore, changes across time were often done using either a short time span (before and after treatment) (Devcich et al., 2008) or several months following care (6-8 months) (Astin & Jones, 2006). Timeline scores were over 50% lower (Astin & Jones, 2006; Devcich et al., 2008) at both measured time points compared to scores reported in this study at baseline and 30-days, which suggests potential differences in illness representation based on the type of CAD diagnosis and time points used in analyses. The present study extends what is known about changes in illness representation across time by delineating changes within the initial 30-day timeframe after treatment. The specific changes in Timeline (cyclical) reported in this study lends support for continued monitoring of symptoms in patients with stable CAD, specifically for those treated with OMT.

Illness Coherence, or how much the illness "makes sense" overall, was increased from baseline to 30-days in patients treated for CAD. All patients in this study underwent treatment for CAD, which included patient education by nurses and physicians. Therefore, the increase in illness coherence at 30-days may reflect patient education that was received during hospitalization. Moss-Morris et al. (2002) reported in their analysis that illness coherence was unrelated to illness severity; however, this finding was based on a sample of patients with multiple sclerosis. Results from this study support this conclusion, with small correlations reported between Illness Coherence and Timeline (acute/chronic). However, an inverse relationship (see table XIII) was noted between Illness Coherence and Timeline (cyclical) scores (r=-.287, p=.005), which may indicate that as symptoms continued during the recovery period, then patients' overall understanding of CAD was reduced by 30-days.

Gender differences in illness representation were found, with females demonstrating a more chronic course of illness, greater treatment control, greater perceived illness coherence, and a greater emotional response at baseline. At 30-days, gender differences continued with males reporting experiencing symptoms after treatment, greater illness consequences, greater perceived illness coherence, and a greater emotional response at 30-days. The cyclical episodes reflect continued experience with symptoms as determined from the IPQ-R items related to "my symptoms change a great deal from day to day", "my symptoms come and go in cycles" and "my illness is very unpredictable". Gender differences associated with illness representation were previously reported in patients with acute coronary syndrome (Grace et al., 2005), AMI (Martin et al., 2005), and in those undergoing CABG surgery (Dunkel, Kendel, Lehmkuhl, Hetzer, & Regitz-Zagrosek, 2011); although, these differences were predominately associated with causal attributions related to CAD, and not the specific concepts associated with illness representation. Grace et al. (2005b) found females with acute coronary syndrome to have a more chronic course of illness, which appears to resemble the higher timeline (acute/chronic) scores obtained in this study. Although, the shift in gender differences for illness representation at 30-days were not reported elsewhere in the literature. Therefore, results from this study extend what is known

about gender differences and demonstrate adjustments in illness representation within the first 30-days after treatment.

C. <u>Fatigue</u>

Findings from this study suggest that males and females differ in the experiences of fatigue associated with stable CAD. Prior studies evaluated the symptom of fatigue; however, this was done using samples consisting predominately of females (McSweeney, 1998; McSweeney et al., 2001; McSweeney et al., 2003; McSweeney & Crane, 2000) and inclusion criteria specific for AMI patients (Appels et al., 2005; Appels & Mulder, 1988; Fennessy et al., 2010; Kop et al., 1994). In this study, higher fatigue scores were noted for females at baseline. By 30-days, fatigue scores were reversed, with females reporting lower fatigue scores compared to males. Additionally, increased fatigue scores in females at baseline were associated with reduced vigor, reduced vitality, and poor physical functioning when compared to males.

Results from Fennessy et al. (2010), reported similar gender-based findings related to fatigue, particularly with moderate to high fatigue in males 30-days after treatment for AMI. Fatigue has previously been reported to be a prodromal symptom for females with AMI; and based on results from this study, remains a problem before and after treatment for the stable CAD population. Results from Fennessy et al. (2010) and McSweeney et al. (2003) used a sample with a diagnosis of AMI and reported fatigue experienced prior to diagnosis. In this study, higher fatigue scores were reported for females, which suggest the possibility for prodromal symptoms for those presenting with stable CAD. Prior research has also shown fatigue to be present across various stages of CAD (Smith et al. 2008), and lends support to the finding from this study that fatigue is prominent even within a stable CAD sample. In this study,

patients were recruited with a diagnosis of stable CAD and were asked to reflect on the symptom of fatigue using the POMS instrument, which instructs respondents to answer items based on their experiences within the prior seven day period. These data extend what is known about fatigue by identifying prodromal symptoms that might suggest the need for early treatment for a stable CAD in females, as well as the role of continued fatigue symptoms in males after treatment.

D. <u>Depressive Mood and Symptoms</u>

Males were found to have higher depressed mood scores (POMS) at baseline and 30-days when compared to females. The PHQ-9, which focuses predominately on depressive symptoms, was not found to be significant between gender groups. No differences in depressive mood/symptoms were reported between patients treated with PCI and those prescribed optimal medical therapy. Previous researchers reported higher rates of depressive symptoms in females (Grace et al., 2005b; Whooley et al., 2008). For this study, two measures (POMS Depression Dejection and PHQ-9) were used to assess construct validity for depression-related measures. However, these results demonstrated inverse findings at baseline, with higher depressive symptom scores (PHQ-9) for females compared to higher depressed mood (POMS) for males. Higher depressed mood scores for males at baseline may reflect a situational bias. In this case, the recent hospitalization or procedural experiences associated with stable CAD may have resulted in higher depressed mood scores for males. These findings are consistent with Eng et al. (2007), which demonstrated moderate and higher levels of depressed mood immediately following PCI and was attributed to the procedural environment required to treat CAD. Since patients undergoing PCI are administered light sedation, compared to general anesthesia used for surgical approaches, it is likely that their experiences and memory while in the cardiac

catheterization laboratory may have added to the increased levels of depressed mood, further lending support to the conclusion of a situational bias. Additionally, the PHQ-9 includes items that may tap into the concept of fatigue. Since females had higher fatigue levels at baseline, the higher PHQ-9 scores for females at baseline may actually reflect fatigue-specific symptoms compared to depressed mood as measured in the POMS.

Mild levels of depressive symptoms were found in this study. Cut-points are generally used with the PHQ-9 for diagnosing or identifying high risk groups (Cannon et al., 2007; Kroenke et al., 2001). Within the cardiovascular community, PHQ-9 scores between 4-6 are associated with adverse health outcomes in high-risk patients recovering after AMI (Buchanan et al., 2010). Based on these cut-points, PHQ-9 scores for patients (n=47, 26.1%) in this study resulted in a high risk classification for future cardiovascular events.

E. <u>Secondary Prevention</u>

The results of the logistic regression models from this study support the concept of illness representation. Specific models were found to be significantly influenced by illness representation concepts used in this study. These models included secondary prevention behaviors related to cardiac rehabilitation participation (personal control β =-.406, *p*=.003 and illness coherence β =-.186, *p*=.007) as well as for the regular use of aspirin (timeline acute/chronic β =.282, *p*=.031), and thienopyridine medications (timeline acute/chronic β =.321, *p*=.005). However, a significant regression model was not produced for smoking/tobacco use at 30-days following treatment.

For cardiac rehabilitation participation, the beta weights in the regression model suggests the greatest influence based on gender (β =4.44, Exp(B)=85.50, *p*=.002), with males

demonstrating the greater likelihood of participation at 30-days. Illness Representation concepts specific to the personal control (Personal Control subscale; β =-.406, Exp(B)=.666, *p*=.003) and perceived understanding of CAD (Illness Coherence; β =-.186, Exp(B)=.830, *p*=.007) were associated with cardiac rehabilitation participation at 30-days. As the level of personal control and perceived understanding increased, the odds of cardiac rehabilitation were reduced by 3.9% and 4.5%, respectively. Therefore, as patients viewed greater self control of their disease process, they were also more likely perceive a greater understanding of their disease process and have reduced participation in cardiac rehabilitation participation within 30 days after treatment. The total numbers of years with prior CAD diagnosis was also a significant contributor (β =-.218, Exp(B)=.804, *p*=.004), with reduced participation by 4.4% as the number of years increased. The number of years with a prior CAD diagnosis may conceptually represent the same effect observed with the Personal Control and Illness Coherence subscales. These variables all involve some level of prior experience with CAD and may ultimately affect how self-directed patients may be in the management of what is essentially a chronic illness.

Based on results in this study, the beta weights for personal control (β =-.406, p=.003) and illness coherence (β =-.186, p=.007) were negative and were found to be only significant illness representation contributors to model. In this study, higher levels of personal control and illness coherence may have impeded cardiac rehabilitation participation at 30-days. Therefore, patients who perceived themselves as having greater personal control and overall understanding of their illness were more likely to have reduced participation in cardiac rehabilitation programs. From a practical standpoint, patients who viewed themselves as having more personal control and an improved understanding of their disease process may have been less inclined to attend cardiac rehabilitation services because they had a more independent perspective on the management of

their disease process. No other prior studies have reported this particular phenomenon towards cardiac rehabilitation participation; however, recall this sample included only stable CAD patients, which also reflects a more long-term experience in living with CAD.

Given the physical nature associated with cardiac rehabilitation, it is surprising that fatigue and depressive symptoms were not significantly correlated with cardiac rehabilitation attendance. Results from this study contradict previous research which demonstrated the influence of depression and cardiac rehabilitation participation for post AMI patients (Cooper et al., 1999). Both fatigue and depressive symptoms were not found to be significant contributors to model and this may be due to issues related to low response rate at 30-days. It is likely that these variables were not significant due to lack of statistical power. Therefore, lack of power and high attrition are limitations of the study.

The model for lipid lowering use at 30-days demonstrated the greatest effect by the number of years with prior CAD diagnosis (β =-.482, Exp(B)=.617, *p*<.001). As the number of years with prior CAD diagnosis increased, the odds of taking lipid lowering medications were reduced by 3.8% (years with CAD diagnosis β =-.482, *p*<.001, Exp(B)=.617). Illness representation, fatigue, and depressive symptoms were not significant contributors within the model. Lipid lowering agents remain an important part of the treatment plan; however, many patients are reported to stop taking these medications due to costs, side effects and the inaccurate beliefs in disease consequences (Brewer et al., 2002). In this study, an increase in the number of years living with CAD served as a potential hindrance for maintaining lipid lowering therapy. While the consequences subscale was not a significant predictor for regular use of lipid lowering therapy, the number of years in living with CAD may serve as a potential proxy for this concept. For example, as the number of years with CAD increase, it is likely that patients may have opted

to select other self directed interventions, like diet and exercise, to lower cholesterol values rather than medications. Brewer et al. suggest that inaccurate beliefs in the overall consequences of the disease process may be one of the reasons why patients do not take their lipid lowering agents on a regular basis. Data from this study supports the findings from Brewer et al., such that patients who had higher number of years with a CAD diagnosis may have perceived their disease as progressing regardless of whether or not they take their lipid lowering medications, which represents an inaccurate perception of the disease process.

Brewer et al. (2002) reported on the influence of illness cognition towards self-reported lipid lowering medications using the IPQ in a sample of hypercholesterolemic patients (n=169). Results demonstrated the significant influence of consequences towards improved medication taking; however, the measurement of illness representation was based on a prior version of the IPQ instrument. For the model used in this study, illness representation was not a significant contributor and may have been underpowered to detect an effect, which suggests the need for future research to analyze the impact of illness beliefs impact lipid lowering use after treatment for CAD.

For self-reported use of anti-platelet agents at 30-days, the beta weights in the regression model for aspirin and thienopyridines demonstrated significant influences based on 30-day IPQ-R Timeline (acute/chronic) (aspirin: β =.282, Exp(B)=1.32, *p*=.031; thienopyridine: β =.321, Exp(B)=1.37, *p*=.005). Therefore for both antiplatelet agents, patients who perceived their illness as more chronic (increase Timeline [acute/chronic] scores) had a greater odds of taking their aspirin (5.6%) and thienopyridine medications (5.7%) 30-days after treatment for CAD. These results suggest that patients with acute illness models may view their illness as

short-term, quite possibly due to improved physical functioning and reduced symptoms, resulting in irregular use of these medications.

Dual anti-platelet medications remain one of the primary therapies for treating patients with CAD, in particular for those patients who are treated with PCI. Spertus et al. (2006) reported on the prevalence of premature discontinuation of thienopyridines after drug-eluting stent implantation and found an increased mortality rate (7.5% versus 0.7%, p<.00001) in post-AMI patients who stop this medication prematurely. Current guidelines recommend dual anti-platelet therapy (aspirin and clopidogrel or prasugrel) for at least 1 month after a bare metal stent, 3 months after a sirolimus-eluting stent, and 6 months after a paclitaxel-eluting stent; however, it is typical for thienopydirine therapy to be continued up to 12 months if patients are not classified as high risk for bleeding (Smith et al., 2005). Prior studies have reported on the frequency and clinical predictors associated with early discontinuation of thienopyridine agents (Pasceri et al., 2003; Spertus et al., 2006); however, this study is the first to report on the influence of acute versus chronic illness models for regular use of aspirin and thienopyridine medications after treatment for stable CAD.

Similarly, other researchers have reported on the modest effects of illness representation related to secondary prevention behaviors (Stafford, Jackson, & Berk, 2008); although, there are conflicting results which suggest that illness representation was not helpful in predicting these behaviors (Byrne et al.,2005). It is possible that differences in the measurement of illness representation, as well as the lack of specific health-behavior outcomes in previously published studies, places limits on how well we understand what the true impact is towards secondary prevention. For example, beyond these results, there are two other studies (Cherrington et al., 2004; Juergens, Seekatz, Moosdorf, Petrie, & Rief, 2010) that reported illness representation

using an Illness Representation Summary Score, which used a summary of the total scores versus individual subscales. Therefore, additional research will need to be conducted to better understand the predictive influence of illness representation on secondary prevention behaviors.

Considering the direct impact of smoking/tobacco use associated with heart disease, it was hypothesized that illness representation would have some level of influence towards this behavior. More specifically, it was thought that patients with higher perceptions of consequences associated with CAD and greater beliefs in personal control would influence smoking/tobacco use at 30-days following treatment. However, no significant models could be produced for behaviors related to smoking/tobacco abuse (χ^2 =9.21, df=8, p=.162). Despite these results, the reported incidence of smoking was 16.3% (n=15). Of note, increased depressive symptoms scores was still significant (β =.332, p=.032) when compared to all other variables within the model for tobacco abuse. Therefore, it is likely that this model was underpowered to predict overall smoking/tobacco abuse at 30-days. Additionally, the model used to predict smoking/tobacco use did not account for the fact that this behavior reflects a true addiction, with biologic components that were not included in the analysis. Nevertheless, smoking cessation is absolutely necessary for patients who have undergone PCI and has been shown to reduce future cardiovascular events and mortality (Smith et al., 2006b; Spertus et al., 2006). As a result, future research will need to ensure adequate power to examine the influences of illness representation, fatigue, and depressive symptoms towards specific secondary prevention behaviors.

F. Strengths

The major strength of this study is that is provides a theory-driven approach to examine secondary prevention behaviors after treatment for CAD. The use of theory in this study allowed

for a more targeted analysis of data to assess the extent to which key variables influenced the secondary prevention behaviors of cardiac rehabilitation participation, smoking, and medication use. Secondly, this study incorporated the use of two time points and is one of the first studies to examine temporal changes in illness representations between treatment and gender groups within the initial 30-day recovery period. Finally, the symptom of fatigue was examined with specific differences noted between gender groups and supporting previous findings from patients diagnosed with AMI. This finding may extend the prodromal symptom pattern of fatigue to include those patients who present with early ischemic symptoms consistent with stable CAD.

G. Limitations

Some limitations should be considered when interpreting the results of this study. First, missing data were noted, in particular within the illness representation scales. Despite the use of missing value analyses and imputation rules, several scores were not reported due to a number of missing data points, which suggests a potential threat to statistical conclusion validity. With missing data, scores were either imputed based on pre-established instrument rules or left missing if more than 10% of items in a particular subscale were missing. Missing data may have influenced statistical conclusion validity by resulting in an underpowered analysis for a subscale or attenuation of the effects based on subscale calculations.

Secondly, the response rate at 30-days was less than 60%, which is the recommended rate by survey research experts (Salant & Dillman, 1994). Therefore, attrition may have added to the low internal consistency for some of the reported IPQ-R subscales. The use of a predominantly mailed survey without a built in mechanism for subject follow-up may have added to the issues related to attrition. Additionally, higher PHQ-9 scores were found to be significantly associated (p<.05) with lower responses rate at 30-days. With this finding, higher levels of depressive symptoms were associated with lower response rates and are therefore a possible threat to internal validity.

Finally, secondary prevention behaviors were collected via self-report, which also serves as a threat to internal validity. In these instances, self-reported data may be susceptible to potential response effects, with specific attention to the social desirability of select behaviors related to smoking/tobacco use and regular use of medications. The use of a convenience sample at a single center site also serves a threat to generalizability due to possible selection bias.

H. Recommendations for Future Research

Findings from this descriptive, correlational study provide initial evidence for the influence of illness representation, fatigue, and depressive symptoms towards secondary prevention in patients treated with stable CAD. Therefore, partial support was demonstrated for the use of Leventhal's Self Regulation model as a framework within the field of illness representation research. Future research will require improvements in illness representation measures that are adaptable for patients with stable CAD. Finally, focus groups using this population of patients may help in clarifying perceptions related to control (treatment/personal) and timelines (acute/chronic).

I. <u>Conclusion</u>

A number of important results were demonstrated in this study. First, shifts in illness representation occur for patients treated with percutaneous or medical therapies. Similar shifts were in illness representation were also demonstrated between gender groups. Various components of illness representation were found to be significantly different, particularly for areas related to the overall perceived understanding of CAD, the level of disease control by the prescribed treatment, and the view that CAD is cyclical with ongoing symptoms even after treatment. Findings from this study and other studies imply that a tailored approach for promoting secondary prevention may be advantageous for patients living with stable CAD. Therefore, by targeting shifts in components related to illness representation, healthcare providers may be in a better position to help patients to better cope with their disease process and improve outcomes long after they have been treated for CAD.

Secondly, fatigue was found to be more frequently reported in females compared to males in this sample. These results were similar to other published reports about the symptom of fatigue and offer promising opportunities in terms of early intervention for identifying those patients with non-specific symptoms like fatigue, who require treatment for CAD. Currently, fatigue is reported to be a prodromal symptom in females diagnosed with AMI and may possibly be extended to those previously diagnosed with CAD who present with symptoms suggesting the reoccurrence of occlusive level disease. However, further research is needed to understand the role of fatigue in the stable CAD population and to understand how treatment differences, in an outpatient rather than acute AMI setting, impacts treatment seeking decision making for this population of patients. Additionally, higher fatigue levels in females at baseline suggests the need to conduct additional studies to evaluate the role of inflammatory biomarkers to determine the etiology of this symptom as it relates to stable CAD.

Next, as more research is conducted, it may be possible to design interventions based on Leventhal's Self-Regulation Model, to promote the use of key medication therapies and other secondary prevention strategies that are shown to effectively improve outcomes in this population of patients. In this study, a key finding related to dual antiplatelet therapy suggests that patients' views of a CAD as an acute or chronic illness may serve as an early indicator as to whether or not these patients continue with this important medication regimen. Considering that stent thrombosis remains a key issue for patients who undergo drug-eluting stent implantation, these patients are typically required to take their dual antiplatelet medications for a minimum of 12 months. Therefore, it is important to consider illness representation as one of the factors that may lead to early discontinuation of this therapy.

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VITA

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EDUCATION

University of Illinois at Chicago, Chicago, Illinois Doctorate of Philosophy in Nursing Science, May, 2011

Medical University of South Carolina, Charleston, South Carolina Master of Science in Nursing received May, 2002

College of the Albemarle, Elizabeth City, North Carolina Associate of Applied Science in Nursing received May, 1997

CREDENTIALS

Illinois RN Licensure Illinois APN Licensure South Carolina RN Licensure North Carolina RN Licensure Illinois APN Controlled Substance Licensure DEA Certification

CERTIFICATIONS

Board Certified ANCC Advanced Practice Registered Nurse/ CNS Board Certified AACN Adult Critical Care Registered Nurse Basic Cardiac Life Support Provider Advance Cardiac Life Support Provider

PROFESSIONAL EXPERIENCE

Loyola University Medical Center, Maywood, Illinois Cardiovascular Advanced Practice Registered Nurse, Adult Cardiac Catheterization Lab, Interventional Inpatient Service (May 2009—Current) Coordinator Structural Heart Disease Outpatient Clinic (March 2011—Current) Coordinator Acute Myocardial Infarction Program (May 2009—March 2011) Interventional Cardiology Outpatient Clinic (May 2009—December 2010)

University of Chicago Medical Center, Chicago, Illinois Cardiovascular Advanced Practice Registered Nurse, Adult Cardiac Catheterization Lab (January 2006—May 2009)

University of Chicago Medical Center, Chicago, Illinois Cardiovascular Advanced Practice Registered Nurse, Department of Professional Development (May 2005—January 2006)

Roper Saint Francis Health Care, Charleston, South Carolina Nursing Clinical Director- Chest Pain Center, Cardiac Intensive Care Cardiovascular Administration (May 2002—May 2005)

Trident Medical Center, Charleston, South Carolina Registered Nurse- Critical Care Department Full Time/ Flex Pool (April 1998—May 2002)

Albemarle Hospital, Elizabeth City, North Carolina Registered Nurse- Telemetry Flex Pool (December 1997—May 1998)

Chowan Medical Center, Edenton, North Carolina Registered Nurse- Critical Care Full time (March 1997—May 1998)

PEER REVIEWED PUBLICATIONS

Borden, W.B., O'Conner, A., Mulliken, R.A., **Fennessy, M**., Lee, L., Nichols, J. & Lopez, J.J. (2011). Quality Improvement in the Door-to-Balloon Times for ST-Elevation Myocardial Infarction Patients Presenting Without Chest Pain. *Catheterization and Cardiovascular Interventions*. **Accepted paper 4/19/2011

Fennessy, M. M., Fink, A., Eckhardt, A., Jones, D. R., Kruse, D., VanderZwan, K., Ryan, C., & Zerwic, J.J. (2010). Gender Differences in Fatigue Associated with Acute Myocardial Infarction. Journal of Cardiopulmonary Rehabilitation and Prevention, 30(4), 224-229.

Fink, A. M., Eckhardt, A. L., **Fennessy, M. M**., Jones, J., Kruse, D., VanderZwan, K. J., Ryan, C. & Zerwic, J.J. (2010). Psychometric properties of three instruments to measure fatigue with myocardial infarction. *Western Journal of Nursing Research*, 32(7), 967-983.

Fennessy, M. & Borden, W. (2006). Clinical benefits of drug-eluting stents: Results from RAVEL and Beyond. Journal of Cardiovascular Nursing, 21(6), 442-450.

PUBLISHED ABSTRACTS

Haque, M., Gottam, N., **Fennessy**, M., Dajani, K. (2010). Assessing the Prevalence of Non-Diagnostic Studies in 64-MDCT Coronary Angiography Over a 36 month Period. *Journal of Cardiovascular Computed Tomography*. 4(4), S1-S81.

Eckhardt, A., **Fennessy, M.**, Fink, A., Ryan, C., Cruse, D., Vanderzwan, K., & Zerwic, J.J. (2008). Fatigue as a Symptom of Acute Myocardial Infarction. National Teaching Institute. Chicago, IL, *American Journal of Critical Care*, *17*, 287.

Eckhardt, A., **Fennessy, M.,** Fink, A., Jones, J., Szigetvari, K., Cruse, D., Tucco, L., Ryan, C. & Zerwic, J. (2007). Fatigue as a Symptom of Acute Myocardial Infarction. *Circulation*, *116*(16), 676.

Fennessy, M., Grayson, M., & Walter, J. (2005). Chest Pain Centers—A Novel Approach to Caring for the Acute Coronary Syndrome Patient. *Journal of Cardiovascular Management*, 16(3), 37.

COMMUNITY-BASED PUBLICATIONS

Fennessy, M. & Zerwic, J. (2006). Stroke: Remains the silent killer in your community. *Chicago Gazette*, *24*(4), 70-71.

POSTER PRESENTATIONS

Havey, J., **Fennessy**, **M**., and Glenn, J. Evaluating Electronic Tools to Meet Information Systems Infrastructure Data Needs. <u>2011 Ruth K. Palmer Research Symposium</u>, <u>Loyola</u> <u>University Medical Center</u>. Maywood, Illinois.

Fennessy, M., Ryan, C., Lopez, J., Klein, W., Lewis, B., Steen, L., Leya, F., and Zerwic, J.J. (2011) Illness Perceptions in Patients with Stable Coronary Disease. <u>2011 Ruth K. Palmer</u> <u>Research Symposium, Loyola University Medical Center</u>. Maywood, Illinois.

Haque, M., Gottam, N., **Fennessy**, **M**., Dajani, K. (2011) Effect of Body Mass Index as a Non Diagnostic Determinant in 64-MDCT Coronary Angiography over a 36-Month Period. <u>American College of Cardiology Scientific Sessions 2011</u>. New Orleans, Louisiana.

Haque, M., Gottam, N., **Fennessy, M.**, Dajani, K. (2011) Impact of Heart Rate on Image Quality and Radiation Exposure in Coronary Computed Tomographic Angiography. <u>American</u> <u>College of Cardiology Scientific Sessions 2011</u>. New Orleans, Louisiana.

Nowak, W., Leya, F., **Fennessy, M**., Dieter, R., Lewis, B., Steen, L., Cichon, M., Probst, B., Ryan, M., Liu, J., Smith, C., Jarotkiewicz, M., Wilber, D., Lopez, J.J. (2011). Impact of a Novel 24/7 In-House Interventional Team Program on Workflow Times for STEMI: First-year experience. <u>American College of Cardiology Scientific Sessions 2011</u>. New Orleans, Louisiana.

Fennessy, M., Ryan, C. and Zerwic, J. (2011) Illness Representation, Fatigue, and Depressive Symptoms in Patients with Stable Coronary Artery Disease. <u>Midwest Nursing Research Society</u>. Columbus, Ohio.

Haque, M., Gottam, N., **Fennessy, M.**, Dajani, K. (2011) Effect of Body Mass Index as a Non Diagnostic Determinant in 64-MDCT Coronary Angiography over a 36 Month Period. <u>American Heart Association: Nutrition, Physical Activity and Metabolism / Cardiovascular</u> <u>Disease Epidemiology and Prevention 2011 Scientific Sessions</u>. Atlanta, Georgia.

Haque, M., Gottam, N., **Fennessy, M**., Dajani, K. (2011) Impact of Heart Rate on Image Quality and Radiation Exposure in Coronary Computed Tomographic Angiography. <u>American</u> <u>Heart Association: Nutrition, Physical Activity and Metabolism / Cardiovascular Disease</u> <u>Epidemiology and Prevention 2011 Scientific Sessions</u>. Atlanta, Georgia.

Haque, M., Gottam, N., **Fennessy, M**., Dajani, K. (2010). Assessing the Prevalence of Non-Diagnostic Studies in 64-MDCT coronary angiography over a 36 month period. <u>5th Annual</u> <u>Scientific Meeting of Society of Cardiovascular Computed Tomography</u>. Society of Cardiovascular Computed Tomography. Las Vegas, Nevada. Eckhardt, A., **Fennessy, M.,** Fink, A., Ryan, C., Cruse, D., Vanderzwan, K., & Zerwic, J.J. (2008). Fatigue as a Symptom of Acute Myocardial Infarction. <u>National Teaching Institute</u>. American Association of Critical Care Nurses, Chicago, Illinois.

Borden, W.B, O'Connor, A., Mulliken, R.A., **Fennessy, M.M.**, Nichols, J., Wildon, G.N, & Lopez, J.J. (2008). Effect of Chest Pain as the Presenting Symptom on Door-to-Balloon Times for ST-Elevation Myocardial Infarction in a University Hospital Setting. <u>American Heart</u> <u>Association 9th Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular</u> <u>Disease and Stroke</u>. American Heart Association, Washington, D.C.

Fink, A., Eckhardt, A., **Fennessy, M.M**, Jones, J., Szigetvari, K., Tucco, L., Kruse, D., Ryan, C., Zerwic, J.J. (2008). Psychometric Properties of Measures of Fatigue During AMI. <u>University of Illinois, College of Nursing Research Day</u>, Chicago, Illinois.

Fink, A., Eckhardt, A., **Fennessy, M.**, Jones, J., Szigetvari, K., Tucco, L., Kruse, D., Ryan, C., Zerwic, J.J. (2007). Psychometric Properties of Measures of Fatigue During AMI. <u>Midwest</u> <u>Nurses Research Society</u>, Indianapolis, Indiana.

Eckhardt, E., **Fennessy, M.,** Fink, A., Jones, J., Kruse, D., Ryan, C., Tucco, L., VanderZwan, K., Zerwic, J.J. (2007). Fatigue as a Symptom of Acute Myocardial Infarction. <u>2007 American Heart</u> <u>Association</u>, Orlando, Florida.

Fennessy, M., Borden, W.B., O'Connor, A., Mulliken, R., O'Grady, J., Wells, T., Greer, S., Nichols, J., Floreza, A., & Lopez, J.J. (2007). Identifying Barriers and Solutions to Reduce Door-to-Balloon Times: A Quality Improvement Initiative. <u>3rd Annual University of Chicago Medical</u> <u>Center Quality Fair</u>, Chicago, Illinois.

Fennessy, M., Grayson, M., & Walter, J. (2005). Chest pain centers—A Novel approach to caring for the acute coronary syndrome patient. <u>Society of Chest Pain Centers</u>, Orlando, Florida.

ACADEMIC PRESENTATIONS

Eckhardt, E., **Fennessy, M.,** Fink, A., Jones, J., Kruse, D., Ryan, C., Tucco, L., VanderZwan, K., Zerwic, J.J. (2007). Fatigue as a Symptom of Acute Myocardial Infarction. <u>American Heart</u> <u>Association</u>. Orlando, Florida.

PAPERS/ABSTRACTS IN PROGRESS

Comparison of Clinical and Procedural Outcomes of Primary Percutaneous Coronary Intervention in Patients with ST-Elevation Myocardial Infarction During and Prior to Availability of 24/7 In-House Program. *Submitted to Circulation: Cardiovascular Quality and Outcomes*.

INTELLECTUAL PROPERTY

Invention: Novel System for Improving the Efficiency of Programmatic Cardiovascular Data Collection by Integrating and Coupling Clinically Required Data Creation with Systems for National Registry Data Collection. Inventors: John J Lopez MD, **Michelle Fenessey, APN**, Susan Zelisko. Patent Pending. April, 2011.

HONORS AND AWARDS

January 2006	University of Illinois Board of Trustees Scholarship
November 2004	South Carolina League for Nursing Award for Excellence
September 2004	Roper St. Francis Healthcare Leadership Academy Graduate
April 2004	South Carolina Palmetto Gold Nursing Excellence Nomination
May 1997	Dr. L. Everett Sawyer Award for Excellence
September 1996/97	Henry H. Arnold/ Air Force Aid Scholarship Award
September 1996	Dr. Zachary D. & Martha Owens Nursing Scholarship

PROFESSIONAL ASSOCIATIONS

June 2006- Present	American College of Cardiology, Cardiac Care Associate
February 2006- Present	Midwest Nursing Research Society
February 2006- Present	American Heart Association
May 2002-Present	Sigma Theta Tau

ORGANIZATION SERVICE

November 2010-Present	Metro Chicago Mission: Lifeline Taskforce Data and Quality Committee
January 2010- Present	Chicago Healthcare Council- Regionalized STEMI Care
May 2009- Present	American Heart Association- Mission lifeline Metro Chicago task force
February 2006-2010	American Heart Association- Council on Cardiovascular Nursing

February 2006-2007	American Heart Association- Quality of Care and Outcomes
March 2004-2005	National Association of Clinical Nurse Specialists- Co-Chair, Communications and Marketing Committee
May 2002-2003	American Association of Critical Care Nurses- Advanced Practice Advisory Team
May 2002-2003	American Association of Critical Care Nurses- Board Advisory Team

ACADEMIC SERVICE

January 2008- Present	Loyola University , College of Nursing, Preceptor- Graduate nursing students Teaching Assistant- College of Nursing, Spring 2010 Nursing Measurement, GNUR 581
January 2005- Present	University of Illinois Chicago , College of Nursing, Preceptor- Graduate nursing students Teaching Assistant- College of Nursing, Fall 2009 Nursing Measurement, NUSC 581
July 2004- December 2004	Lander University, College of Nursing, Adjunct Nursing Faculty
July 2003-December 2004	Medical University of South Carolina, College of Nursing Alumni Board of Directors

RESEARCH EXPERIENCE

- 2011-Current Medtronic CoreValve U.S. Pivotal Trial. Clinical Site: Loyola UniversityMedical Center, Adult Cardiac Catherization Lab, PI- Fred Leya, MD and Mamdouh Bakhos, MD
- 2010-Current Creation of ACTION Acute Myocardial Infarction Registry at Loyola University Medical Center. Database represents first program in the country to electronically submit de-identified data directly to National Cardiovascular Data Registry (NCDR) using an electronic medical record to capture over 350 variables for submission to NCDR, PI-John Lopez, MD
- 2010- Current Illness Representation, Fatigue, and Depressive Symptoms in Patients Undergoing Coronary Angiography, University of Illinois at Chicago, College of Nursing, Doctoral Dissertation Proposal. PI- Michelle Fennessy, APN, John Lopez, MD, and Julie Zerwic, PhD

- 2010- Current Early Experience of a Tertiary Medical Center with 24/7 In-House Myocardial Infarction Program: Comparison of Clinical and Procedural Outcomes of Primary Percutaneous Coronary Intervention in Patients with ST Elevation Myocardial Infarction During and Prior to Availability of 24/7 In-House Program, Loyola University Medical Center, Section of Cardiology. PI- John Lopez, MD, Coinvestigator- Michelle Fennessy, APN
- 2009-Current Alcohol Septal Ablation in Hypertrophic Obstructive Cardiomyopathy: Mid and Long-tern Follow-up in Loyola Registry, Loyola University Medical Center, Section of Cardiology, PI- Fred Leya, MD
- 2009-2010 Assessing the Prevalence of Non-Diagnostic Coronary Computed Tomographic Angiography Over a 48-Month Period, Loyola University Medical Center, Section of Cardiology. PI- Khaled Dajani, MD
- 2007-2009 Symptom of Fatigue Before and After Acute Myocardial Infarction, University of Illinois at Chicago, College of Nursing. PI- Julie Zerwic, PhD
- 2007-2008 Effect of Chest Pain as the Presenting Symptom on Door-to-Balloon Times for ST-Elevation Myocardial Infarction in a University Hospital Setting, University of Chicago Medical Center, Section of Cardiology. PI- John Lopez, MD, Coinvestigator- Michelle Fennessy

COMMUNITY SERVICE

Chicago Go Red for Women, 2011 Town Hall Panelist representing Loyola University Medical Center, Heart & Vascular Center. Palmer House Hilton, February 25, 2011.

PRESS RELEASES

Plunkett, Nora (2011, April 7). Loyola's on-site cardiology team dramatically improves care for heart attack patients. Retrieved from

http://www.loyolamedicine.org/News/News_Releases/news_release_detail.cfm?var_news_release_e_id=973441427.