THE RELATIONSHIP BETWEEN SELF-EFFICACY AND CLINICAL RISK FACTORS IN THE BYPASS ANGIOPLASTY REVASCULARIZATION INVESTIGATION 2 DIABETES (BARI 2D) STUDY

by

Veronica V. Sansing

BA, University of Chicago, 1999

Submitted to the Graduate Faculty of

Graduate School of Public Health in partial fulfillment

of the requirements for the degree of

Master of Science

University of Pittsburgh

2008

UNIVERSITY OF PITTSBURGH

GRADUATE SCHOOL OF PUBLIC HEALTH

This thesis was presented

by

Veronica V. Sansing

It was defended on

January 25, 2008

and approved by

Thesis Advisor:
Gale A. Richardson, Ph.D.
Associate Professor
Psychiatry
Graduate School of Public Health
University of Pittsburgh

Committee Members:
Maria Mori Brooks, Ph.D.
Assistant Professor
Epidemiology
Graduate School of Public Health
University of Pittsburgh

Nancy L. Day, Ph.D.
Professor
Psychiatry
Graduate School of Public Health
University of Pittsburgh

Stephen B. Thomas, Ph.D.
Philip Hallen Professor
Behavioral and Community Health Sciences
Graduate School of Public Health
University of Pittsburgh

Gale A. Richardson, Ph.D.

THE RELATIONSHIP BETWEEN SELF-EFFICACY AND CLINICAL RISK FACTORS IN THE BYPASS ANGIOPLASTY REVASCULARIZATION INVESTIGATION 2 DIABETES (BARI 2D) STUDY

Veronica V. Sansing, MS

University of Pittsburgh, 2008

Objectives: Although prior research has shown that self-efficacy (SE), the belief that one has the ability to create change through behaviors, is associated with better clinical outcomes for Type 2 diabetes (DM) and coronary artery disease separately (CAD), little research has examined the role of SE in patients with both DM and CAD. The goal of this cross-sectional analysis was to describe the association between SE and glycosylated hemoglobin (HbA1c), systolic blood pressure (SBP), and low density lipids (LDL) in patients with comorbid CAD and DM. In addition, this analysis examined the demographic and clinical factors that are associated with SE in the management of DM and CAD.

Methods: Bivariate and multivariate analyses were conducted with 1,447 patients in the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) study who completed a self-efficacy assessment. Only patients recruited at U.S. sites were included in the analyses. The majority of the patients were White non-Hispanic, male, and had a post high school education. The average age at enrollment was 63 years. The models were adjusted for sex, age, race/ethnicity, and education.

Results: Better HbA1c was positively associated with SE, even after adjusting for race/ethnicity, age, sex, and education. Better SBP was positively associated with SE, however this association

was only marginally significant when adjusting for race/ethnicity, age, sex, and education. LDL was not associated with SE. Hispanic ethnicity, history of congestive heart failure, number of hypertension drugs, probable neuropathy, and insulin use were factors negatively associated with SE. A post high school education and history of cancer were positively associated with SE.

Conclusions: Psychosocial factors, such as self-efficacy, are of public health significance because they play a considerable role in the management of diabetes and cardiovascular disease. Self-efficacy was positively associated with better cardiac and diabetic factors in the BARI 2D population. Literacy skills, cardiac history, number of medications, and neuropathy are several other factors doctors should take into consideration when assessing and building up patients' confidence in being able to manage their medical conditions.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1.0 INTRODUCTION

A large number of Americans suffer from preventable and treatable diseases, two of which are Type 2 diabetes mellitus (DM) and coronary artery disease (CAD). DM accounts for 90 – 95% of the 15.8 million diabetes cases diagnosed in the United States (CDC, 2005). Additionally, CAD is the leading cause of death in the U.S., with more than a half million people dying from CAD annually (NHLBI, 2007). In order to treat these diseases, patients with both DM and CAD must engage in daily treatment regimens to regulate blood glucose levels and balance diet and exercise. These regimens can include, but are not limited to, monitoring of blood glucose with a blood glucose monitor, complex drug regimens including oral hypoglycemic drugs as well as lipid and blood pressure drugs, use of insulin, proper care of feet, dieting, and exercise. These steps are essential for health maintenance and the management of these chronic diseases (Anderson, Funnell, Fitzgerald, & Marrero, 2000).

Several studies have documented the difficulty of DM management even under the care of the best physician (Jerant, Friederichs-Fitzwater, & Moore, 2005; Nelson, McFarland, & Reiber, 2007). The patient's motivation, ability, and social support needed to adhere to medication and lifestyle regimens are key in controlling the diseases and reducing the risk of complications of DM, including CAD. One must also consider how well the person believes they are able to carry out the steps needed to keep their DM and

cardiovascular disease under control. Research defines this belief as self-efficacy (SE) and many studies have documented the significance of SE in reducing an individual's risk for adverse health outcomes and morbidities (Bandura, 1977; Chlebowy & Garvin, 2006).

According to findings from the Bypass Angioplasty Revascularization Investigation (BARI) study, patients with DM had a significantly higher incidence of morbidities and mortality after cardiovascular revascularization compared to patients without diabetes (BARI Investigators, 1997). This led to the proposal of the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) study, which investigates the effect of glycemic control and cardiovascular intervention in patients with DM and mild to moderate CAD (Brooks et al., 2006). Using baseline data from the BARI 2D study, the primary aims of the current analyses are to 1) describe the association between SE and risk factor control; and 2) identify the factors that are associated with SE in the management of DM and CAD in BARI 2D patients. It is hypothesized that SE will be positively associated with glycemic control, blood pressure, and lipids. In addition, it is hypothesized that after controlling for sex, age, race/ethnicity, and education, both cardiovascular and diabetic clinical factors will be associated with SE. Results of this analysis may provide a better understanding of the relationships among clinical, demographic, and psychosocial factors shaping health outcomes. The results may help healthcare professionals incorporate SE motivational methods into treatment, management, and patient education materials designed for patients with DM and CAD.

1.1 LITERATURE REVIEW

The objective of this literature review is to identify studies focused on SE as a psychosocial factor in populations with the co-morbid conditions of DM and CAD. A search for articles related to this topic was undertaken to include both historical and current research. This was supplemented by additional searches of article reference lists and scans of cardiovascular, diabetes, and psychiatric journals. The search for appropriate articles was undertaken using the MEDLINE database through the PubMed and Ovid search engines with keywords: cardiovascular, coronary, Type 2 diabetes, self-efficacy, and self-management. Search results were limited to English publications, full text (Ovid only) and adult samples (age 19 and over; PubMed only). There were no specifications for the years in which the articles were published. The first part of the literature review describes Bandura's theory of SE (1977) and its implications for health management, followed by an exploration of SE in relation to DM and CAD management. Studies selected by their specific focus on SE and DM/CAD will be described in terms of the operational definition of SE, effect size, study design, diversity of study population, and research methods.

1.2 SELF-EFFICACY: ORIGINS AND MEASUREMENT

The concept of "readiness to change" was coined by Bandura (1977) as one construct in his social cognitive theory of human behavior. Over time, consensus emerged around the term "self-efficacy" to define a person's confidence in being able to make change

(Bandura, 1977, 1982). Within the concept of SE, mastery of a required skill gives one confidence to continue to utilize this skill. SE arises from 1) performance accomplishments (how well they have controlled their DM and CAD), 2) vicarious experience (fellow patients' experiences in self-management), 3) verbal persuasion (medical advice), and 4) physiological states (emotional arousal in coping with threatening situations) (Bandura, 1977, 1982). SE differs from outcome expectancies in that it focuses on the belief in one's skills in performing an act, rather than the outcome of the act itself (Figure 1) (Bandura, 1977, 1982). A person can believe that an act will produce a desired outcome, but if s/he does not believe the act can be mastered, then the behavior will not be executed.

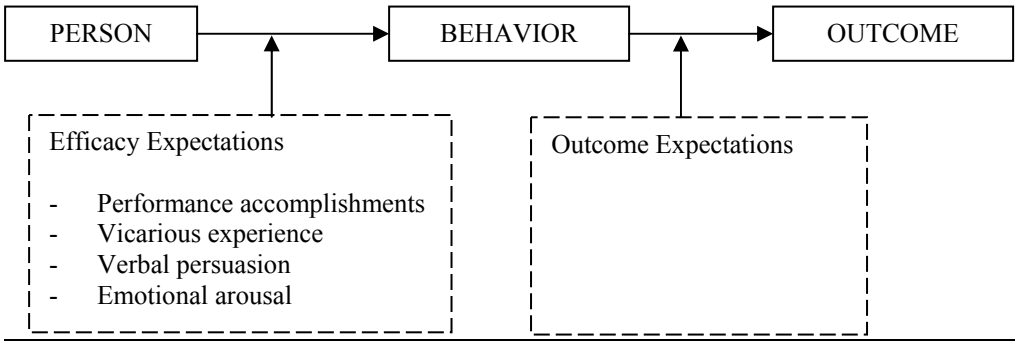


Figure 1. Bandura's conceptual model of self-efficacy (Bandura, 1997)

Expectations of SE determine whether or not the self-management behaviors will commence, how long they will be done, and whether or not they will persist during obstacles and difficult circumstances (Bandura, 1977, 1982). This is of importance to the medical field because one's belief that s/he is able to effectively manage his/her health mediates change, and these beliefs are readily stimulated and formed by one's successes with self-management of his/her diseases (Anderson et al., 2000; Bandura, 1977). More

often than not, patients perceive barriers to active self-management of chronic conditions. Depression, difficulty exercising, poor communication with healthcare professionals, low family support, physical pain, and financial problems are the most commonly noted barriers (Jerant et al., 2005). Furthermore, the lack of drive to fully engage in the regimens related to chronic conditions can result in poor outcomes and additional utilization of the medical system (Jerant et al., 2005). The relationship between drive and outcomes is consistent among age groups, literacy levels, and races (Nakahara et al., 2006; Sarkar, Fisher, & Schillinger, 2006).

Bandura's model was the theoretical context for development of the Chronic Disease Self Management Program launched by researchers at Stanford University (Lorig, 1996). They realized that the effectiveness of chronic disease management is highly contingent on the self-care behaviors of the patients. This program has been shown to improve SE, self-management behaviors, and health outcomes, as well as reduce hospitalizations. Therefore, it is important to understand the interaction between chronic conditions such as DM and CAD and the patients' self-management behaviors in order to improve their health outcomes (Deaton et al., 2006). Part of the program included the development of a global assessment tool that could measure SE in patients.

Assessment of SE can be either global or disease-specific. Global assessments such as the one by Lorig (1996) can be altered and used in multiple fields such as disease management, education, or webpage development. However, disease-specific assessments, such as the Cardiac Self-Efficacy Scale and Diabetes-Related Self-Efficacy assessment from the Multidimensional Diabetes Questionnaire, utilize questions that target specific self-management behaviors based on the disease.

Although many studies have used different SE assessments, it is often shown that SE is positively associated with one's cardiac and diabetic health status and management in studies that have investigated the diagnoses separately (Nakahara et al., 2006; Sarkar et al., 2006; Sol, van der Graaf, van der Bijl, Goessens, & Visseren, 2006). Numerous published studies have investigated the role of SE as a factor in DM or CAD, but these studies have been limited by focusing on one disease. Far fewer studies have investigated the role of SE in patients with both DM and CAD, a population at increased risk of premature morbidity and mortality. Therefore, more research is needed to disentangle the risk factors associated with the co-morbidities of DM and CAD.

1.3 TYPE 2 DIABETES MELLITUS

A total of 88 articles in PubMed and 74 articles in Ovid were identified that focused on DM and SE. DM is a condition in which the body either does not produce enough insulin or becomes insulin resistant. It begins with the body's resistance to insulin production. As a result, the pancreas over-secretes insulin to the point at which it can no longer effectively produce enough. Complications resulting from DM include neuropathy, CAD, hypertension, renal disease, and amputation of the limbs (Chlebowy & Garvin, 2006). In order to keep DM under control, patients must make a number of daily decisions regarding medication, glucose monitoring, nutrition, physical activity, and stress management (Anderson et al., 2000). DM self-management is strongly related to disease control and outcomes (Franz et al., 2002). However, the literature presents evidence of mixed results regarding the relationship between glycemic control and SE with some

studies documenting no association and others showing a strong association. This may be due to the types of SE assessments used.

A study by Chlebowy and Garvin (2006) utilized a two-group comparative descriptive design to examine the relationships between social support, SE, and outcome expectations to DM self-care behaviors and glycemic control in Caucasian and African American participants (N=91). Instruments used were the Social Support Questionnaire, Self Efficacy Questionnaire (SEQ), Outcome Expectancy Questionnaire, and the Diabetes Activities Questionnaire. All scales were found to be highly reliable including the SEQ (α coefficient for overall score=0.92). SE was not significantly related to glycemic control for either race, while outcome expectation was significantly related to glycemic control.

In a one-year prospective study, Nakahara et al. (2006) examined the causal relationship between psychosocial factors and DM in 256 Japanese men. SE was measured by the Diabetes-Related Self-Efficacy section of the Multidimensional Diabetes Questionnaire, which has high internal consistency (Crohnbach's α=0.80). This is a 0-100 Likert scale ranging from "0=not at all" to "100=very." Additional instruments used were the Problem Areas in Diabetes, Life and Health Related Questionnaires, and Profile of Mood States. SE was significantly related to good regimen adherence ($r=0.56$, $p<0.01$), and adherence had a direct association with glycosylated hemoglobin A1c (HbA1c) over time. HbA1c six months post-baseline was both directly and indirectly associated with adherence, SE, social support, daily burden, DM-related distress, and emotion-focused coping.

Sarkar et al. (2006) examined the relationship between SE and DM management in a racially diverse, low-income population with limited ability to read and comprehend written health materials (health literacy). Patients (N=408) with DM were given an oral questionnaire in either English or Spanish. SE was measured with a 4-point Likert scale from "1=not sure at all" to "4=very sure." SE was significantly associated with diet, exercise, self-monitoring of blood glucose, and foot care, even after controlling for DM factors, race, and health literacy. Medication adherence was not significantly associated with SE (OR=1.04, 95% CI=0.93-1.17), but a self-report may not be the best measure for assessing medication adherence as patients are prone to recall bias.

A study by Nelson et al. (2007) assessed factors associated with the self-management of DM among veterans with poor glycemic control (HbA1c≥8.0%). Surveys were mailed to patients of the Washington State Veteran Affairs Medical Centers, yielding a 57% response rate (N=717). The surveys contained assessments of SE, readiness to change, physician's advice, and DM self-management. SE was assessed using the 4-item Perceived Competence in Diabetes Scale (Crohnbach's $\alpha \approx 0.80 - 0.94$), which accounts for the stages of change (Bandura, 1977). They noted that individuals with higher SE scores were more likely to follow their medication therapy, maintain proper nutrition, adhere to a blood glucose-monitoring schedule, and be physically active ($p<.001$). The data collected were self-reported so it may be limited by recall bias and non-response bias.

There are several issues one must consider with SE and DM research. One, although different assessments of SE were used in each study, results consistently showed that SE was positively associated with behaviors related to DM management.

Whether or not HbA1c is related to SE is still to be determined. Two, DM management may be based on the participant's exposure to DM education. Patients with DM education may be more likely to perform the needed daily tasks regarding health maintenance and they may also be of high socioeconomic status, thereby having a more positive DM profile (Chlebowy & Garvin, 2006). Furthermore, DM has high comorbidty with depression (10-15%), which has been shown to affect SE, adherence to self-care regimens, and quality of health (Ciechanowski, Katon, & Russo, 2000; Katon et al., 2004). Some of the symptoms of major depression are lack of interest, psychomotor agitation, and fatigue which may result in people with DM and depression being less motivated to exercise, adhere to their diet, and take their medications (DSM-IV-TR American Psychiatric Association, 2000). Additionally, few studies reported their patient's cardiac status. Patients with a comorbid cardiac condition have poorer SE than those without (Deaton et al., 2006).

1.4 CORONARY ARTERY DISEASE

A total of 211 articles in PubMed and 147 articles in Ovid were found relating to CAD and SE. CAD occurs when the coronary arteries become hardened and narrowed due to atherosclerosis. Blood flow to the heart muscle is reduced, resulting in angina, myocardial infarction (MI), cardiac arrest, or arrhythmias. CAD is also one of the main causes of activity limitations, besides arthritis (Sullivan, LaCroix, Russo, & Katon, 1998). Although the studies have shown a relationship between CAD and functional capacity as measured by the Duke Activity Status Index (DASI) and the Medical

Outcomes Study 36-Item Short Form (SF-36), SE has been shown to be related to *behaviors* that affect CAD prevention and outcomes (Sullivan et al., 1996). SE has been shown to predict adherence to exercise and dietary regimens (Robertson & Keller, 1992; Sullivan et al., 1998).

A study by Sullivan et al. (1998) prospectively examined the role of SE in patients with CAD (N=198), controlling for anxiety and depression. Like the BARI 2D study (Brooks et al., 2006), patients were eligible for elective surgery. Instruments used were the 13-item Cardiac Self-Efficacy Scale, which looked at function maintenance and symptom control, the SF-36 (physical functioning), and the Sheehan Family/Home and Social Interference Scales (disability). CAD was measured by the number of coronary vessels with >70% stenosis, because it showed the strongest relation to self-reported physical function compared to any other angiographic measure in their past studies on the same cohort (as cited by Sullivan et al., 1998). The effect of left main stenosis, a measure of CAD severity, on SE was not found to differ from the effect of stenosis of the other principal arteries. Patients with ST segment depression (cardiac ischemia) were also found to have better self–reported function than those with less ST segment depression. SE was found to be a good predictor of physical function and role function after controlling for CAD severity, anxiety, and depression. This study is limited in that the validity of the SE assessment scale that was used is still to be determined.

The goal of a study by Sarkar et al. (2007) was to examine the relationship between cardiac SE and health status in 1,024 patients with congestive heart disease in the Heart and Soul Study, controlling for severity of congestive heart disease and depression. Cardiac SE was measured using Sullivan's 5-item scale (Crohnbach's α =

0.80) (Sullivan et al., 1998). Lower SE was found to be independently associated with greater cardiac symptom burden, greater physical limitations, worse quality of life, and worse overall health. Since the study is cross-sectional, directionality and causality cannot be established. Furthermore, the majority of the patients were older, low-income White males, limiting the generalizability of the results.

In a longitudinal study of a Turkish cohort, 60 cardiac patients were randomized to a home-based cardiac exercise program (HBCEP) or no intervention (control) in order to study each group's lipids, exercise tolerance, and SE (Senuzun, Fadiloglu, Burke, & Payzin, 2006). Grounded in the theory of SE, the HBCEP included exercise information (vicarious experience) and regular counseling sessions over the telephone, which were meant to monitor the patients' exercise diaries (performance accomplishments), provide physiological feedback (physiological states), and boost SE through social persuasion (verbal persuasion). Blood samples were collected pre-entry and 12 weeks later to measure the 12-hour fasting lipid profiles. SE was measured by the Cardiac Self-Efficacy Index (CESEI), whose test-retest reliability was 0.97 (Crohnbach's α=0.87). At the end of the 12 weeks, the HBCEP group significantly improved in comparison to the control group in total cholesterol ($p=0.004$), low density lipid cholesterol (LDL; $p=0.04$), high density lipid cholesterol (HDL; $p<.001$), systolic blood pressure ($p=0.04$), diastolic blood pressure ($p=0.04$), and SE ($p<.001$). Senuzun et al. (2006) concluded that exercise along with SE might have improved the patients' exercise capacity, thereby improving their clinical outcomes. However, this conclusion may be premature in that the control group did not receive any intervention. An additional control group that would warrant such a

conclusion would be composed of patients who received an exercise program that was not grounded in the SE theory.

There are several issues that previous research findings raise for future investigation into CAD and SE. There are multiple measures of CAD that overlap. For instance, CAD can be measured by either extent (number of lesions with ≥50% stenosis) or severity (Myocardial Jeopardy Index). Furthermore, since both exercise and medications have been found to improve the status of several variables such as lipid values and blood pressure, special care must be taken to disentangle the interaction between drugs and medications on these variables.

1.5 DIABETES AND CARDIOVASCULAR DISEASE COMORBIDITY

A total of 22 articles in PubMed and 5 articles in Ovid were found relating to CAD, DM, and SE. CAD is a major complication in patients with DM, resulting in an increased risk of morbidity and mortality compared to patients with CAD alone (Deaton et al., 2006). The risk of CAD-related complications in those with DM is two to four times greater compared to those without DM (Stamler, Vaccaro, Neaton, & Wentworth, 1993). Patients with DM and CAD experience far worse clinical outcomes than patients with no DM as a result of CAD events and cardiac revascularization attempts (Sobel, Frye, & Detre, 2003). In fact, approximately 75% of most White populations with DM will die of cardiovascular disease (Laasko & Lehto, 1997). To date, there is limited research on SE in patients with both DM and CAD. The following article by Deaton et al. (2006) was chosen for review based on its specific focus on SE and DM/CAD. Most of the articles

found in the literature search did not look at this topic in depth and they referenced the Deaton article.

Deaton et al. (2006) studied symptom distress, self-management, and general and cardiac health status in 1,013 congestive heart disease patients with and without DM in the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation Trial (COURAGE). Self-management was measured by the Self-Management Difficulties Scale, which was adapted from a similar tool used to measure diabetic self-management (Crohnbach's α=0.89). Researchers found the effects of both diseases to be synergistic. Patients with DM and a greater severity of DM had more self-management difficulty regarding medication, exercise, and diet (DM severity only). They also had more physical limitations that promoted the difficulties in self-management. Congestive heart disease was the most important comorbid factor in explaining a poorer risk factor profile for disability in patients with DM. DM was independently associated with increased odds of disability in this patient population. Variables found to be associated with self-management were age, angina status, severity of DM, renal disease, symptom distress, and social support (R^2=0.12, p=0.03). This study was limited in that it was cross-sectional and used mainly White male patients. However, it is similar to BARI 2D in that it was composed of patients with congestive heart disease suitable for revascularization.

Thus, the limited literature has shown that both the management and outcomes of DM and CAD in terms of adherence to medications, exercise, glucose monitoring, ST segment depression, lipids, blood pressure, and foot care are highly related to SE. Future research must be done on a more demographically diverse population, because racial minorities such as Blacks and Native Americans are disproportionately affected by DM

and CAD (AHA ASA, 2007; CDC, 2005). Future research on the association between SE and DM/CAD management is needed.

The current analysis will examine 1) how SE is related to the following DM and CAD risk factor outcome measures: HbA1c, LDL, and systolic blood pressure, and 2) examine which clinical factors are related to SE in a diverse cohort of patients with both DM and CAD. It is hypothesized that SE will be positively associated with better HbA1c, LDL, and systolic blood pressure, and that both DM and CAD variables will be associated with SE.

2.0 METHODS

2.1 STUDY DESIGN

The Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) study is a National Institutes of Health (NIH) sponsored randomized clinical trial designed to examine optimal treatment strategies for patients with DM and documented stable CAD (Brooks et al., 2006). This study has 49 clinical sites in the United States, Brazil, Canada, Mexico, the Czech Republic, and Austria, and the Coordinating Center is located at the University of Pittsburgh Graduate School of Public Health (Pittsburgh, PA). Using a 2x2 factorial design (Table 1), BARI 2D patients are randomized to immediate elective revascularization combined with aggressive medical therapy versus initial aggressive medical therapy alone, and to an insulin-providing versus an insulin-sensitizing strategy of glycemic control (target HbA1c <7.0% for all patients). BARI 2D is an on-going IRB approved study. This secondary data analysis has been approved by the University of Pittsburgh IRB (IRB# PRO07090264).

Table 1. BARI 2D study design by randomized treatment assignment

Percentage of Patients Per Treatment Assignment		Revascularization Strategy	
		Revascularization	Medical Management
Glycemic Control Strategy	Insulin-Providing	579	585
	Insulin-Sensitizing	568	589

Randomization is stratified by BARI 2D site and by intended revascularization -- either percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG). Patients who are randomized to immediate revascularization receive surgery by a BARI 2D certified technician within four weeks of randomization. Patients randomized to initial aggressive medical therapy may receive revascularization at a later stage in the trial, in the event of worsening symptoms or a cardiac event. All patients receive aggressive medical therapy for health complications associated with DM and CAD, such as dyslipidemia, hypertension, and angina, based on the BARI 2D protocol. The protocol also includes a non-pharmacologic Lifestyle Program aimed at smoking cessation, weight loss, foot care, and proper exercise.

Randomization to either insulin-sensitizing drugs or insulin-providing drugs requires that patients adopt the assigned form of drug therapy, regardless of their prior form of therapy. If over the course of the study, a patient's HbA1c remains >8.0%, s/he is mandated to receive glucose-lowering drugs from the other arm. Additional control of HbA1c is based on an algorithm for optimal glycemic control through combination therapy (Magee & Isley, 2006).

Recruitment began January 1, 2001 and ended March 31, 2005. At the baseline visit, extensive clinical, demographic, and psychosocial data are collected including

education, employment status, body mass index (BMI), HbA1c, duration of DM, history of MI, blood pressure, lipid values, and number of medications. Study participants also complete a comprehensive battery of self-reported psychosocial measurements including four questions regarding SE.

Follow-up visits occur monthly for the first six months and quarterly thereafter, until the end of the study in 2008. At each follow-up visit, information about clinical risk factors, diabetes complications, clinical events, and medications is collected. The projected mean follow-up per patient is 5.2 years. The BARI 2D primary endpoint is all-cause mortality. The composite secondary endpoint is death, stroke, or MI (heart attack). Although this is a prospective longitudinal study, only cross-sectional data at study entry were available at the time of this analysis.

2.2 SUBJECTS

BARI 2D participants were enrolled from clinical sites in the United States, Canada, Brazil, Mexico, the Czech Republic, and Austria (N=2,368). Eligible patients have a "diagnosis of DM and angiographically documented CAD for which revascularization was not required for prompt control of severe or unstable angina" (Brooks et al., 2006, p. 10G). A physician/investigator at each site determined if the patients were eligible for the study based on inclusion/exclusion criteria. Based on the BARI 2D Manual of Operations (BARI 2D Coordinating Center, 2002-2005), inclusion criteria were as follows: diagnosis of Type 2 diabetes mellitus, coronary arteriogram showing one or more vessels amenable to revascularization (≥50% stenosis), objective documentation of

ischemia or subjectively documented typical angina with ≥70% stenosis in at least one artery, suitability for coronary revascularization by at least one of the available methods, ability to perform all tasks related to glycemic control and risk factor management, age 25 or older, and informed written consent (Brooks et al., 2006). Exclusion criteria were as follows: definite need for invasive intervention as determined by a cardiologist, any prior CABG (bypass surgery) within the past twelve months, prior PCI (stent placement) within the past 12 months, class III or IV congestive heart failure, creatinine > 2.0 mg/dl., HbA1c > 13%, need for major vascular surgery concomitant with revascularization (e.g., carotid endarterectomy), left main stenosis ≥ 50%, non-cardiac illness limiting mortality, hepatic disease, fasting triglycerides > 1000 mg/dl in the presence of moderate glycemic control (HbA1c <9.0%), current alcohol abuse, chronic steroid use, known/planned/suspected pregnancy, geographically inaccessible or unable to return for follow-up, enrolled in a competing randomized trial or clinical study, and unable to understand or cooperate with protocol requirements (Brooks et al., 2006).

The recruitment pattern for patients differed according to site. Patients were generally recruited through screenings conducted in the cardiac catheterization laboratory, stress test laboratory, and outpatient clinics both inside and outside of the study site. Since DM and CAD affect racial/ethnic minorities disproportionately (AHA ASA, 2007; CDC, 2005), there was a strong aim to recruit at least 30% minority participants. A minority recruitment and retention committee was established at the BARI 2D Coordinating Center to provide technical assistance. Before randomization, it is required that all patients give signed informed consent which also contained Health Insurance Portability and Accountability Act (HIPAA) information.

Of the 2,368 randomized BARI 2D patients, 2,321 had <20% missing baseline data and these patients form the BARI 2D baseline population used for cross-sectional correlation analyses. Due to the discernible social and cultural differences and to the differences in the administration of the self-efficacy assessments (verbal versus on paper) across the clinical sites outside the U.S., subjects at non-U.S. sites were not included in the present analysis. This resulted in a sample of 1,447 patients for this analysis. Hispanic ethnicity was self-reported if the person was of Latin/Spanish culture or origin, regardless of race. Race was self-reported based on the U.S. Census Classification System as either 1) American Indian/Alaskan Native, 2) Asian, 3) Black/African American, 4) Native Hawaiian/Pacific Islander, 5) White, or 6) Other (including those of multiple races).

2.3 VARIABLES

Self-efficacy is the key measurement of one's self-confidence in medical self-management. Thereby, it serves as the main psychological measure for this proposal. At study entry, BARI 2D participants completed the SE questionnaire, as well as a comprehensive battery of psychosocial quality of life measures regarding their own health, self-rated health, energy, health distress, and ability to do different activities. Demographic information, clinical history, prescribed pharmaceuticals, and quality of life data were also collected.

HbA1c is used as a measure of diabetic severity, while LDL and systolic blood pressure are used as measures of cardiovascular risk. One-minute resting blood pressure was measured with participants in the seated position. The systolic blood pressure and diastolic blood pressure reported are based on an average of the two sitting blood pressures. Hypertension is defined as a blood pressure level >140/90 mmHg (BARI 2D Coordinating Center, 2002-2005). Fasting total, low density lipid (LDL) cholesterol, and high density lipid (HDL) cholesterol, fibrinolytic factors, insulin, and HbA1c levels were measured from blood samples collected at baseline and were analyzed at the BARI 2D core Biochemistry Laboratory. LDL was calculated using the Friedwald equation (Friedwald & Frederickson, 1972). Urine specimens were assayed at the Biochemistry Laboratory for albumin and creatinine in order to diagnose micro- and macroalbuminuria. Medication adherence was not measured in BARI 2D, only the types of medication prescribed. Patients with a history of health problems may be clinically under control, because of the medications they are using. Therefore, the medications used

could serve as a surrogate for a history of medical problems for which they are taken (e.g., high LDL or high blood pressure).

2.3.1 Assessments

2.3.1.1 Self-efficacy.

The self-efficacy assessment of the quality of life section (Appendix A) attempts to measure how confident the patient is in his/her ability to do tasks and activities that relate to managing his/her DM and CAD in general and specific ways. The ambiguous term "management" may be interpreted as something as simple as trying to monitor glucose regularly or to a more complex regimen of a specific diet with regular exercise. Patients were encouraged to personally consider what tasks and activities they do on a day-to-day basis, in order to measure confidence in the ability to keep DM and CAD "under control."

The SE assessment used in BARI 2D is originally from the Chronic Disease Self-Management Study (Lorig, 1996) and was found to have high internal consistency in that study (Crohnbach's α=0.92). The sample used to test this instrument was mostly White non-Hispanic (nH; 91.1%) and female (68.0%), with a mean age of 64.4 years (Lorig, 1996). It should be noted that the original SE assessment has five items, however the BARI 2D assessment used only four (Crohnbach's α=0.89). The fifth question regarding the patient's ability to visit a health care professional was omitted since the patients are closely monitored and managed within the BARI 2D clinical trial with a high level of professional care and oversight. The questions have also been modified from disease management in general to address heart disease and DM specifically. Each question

consists of a 10-point Likert scale with "1=not at all confident" and "10=totally confident." Interest lies in the patients' confidence in 1) doing all day-to-day things necessary to manage their conditions, 2) doing activities for their DM and CAD in order to reduce doctor visits, 3) reducing emotional stress associated with their diseases through acts such as prayer, meditation, art, and social contact, and 4) doing activities besides medication adherence, such as exercise, hobbies, and diet, to reduce the impact of the diseases on their daily life.

2.3.1.2 Additional quality of life assessments.

With self-rated health, patients are asked to rate their general health as either "Excellent," "Very Good," "Good," "Fair," or "Poor" (Ware & Sherbourne, 1992). Health distress and energy are assessed by a 9-item questionnaire in which patients report how they have felt during the past four weeks (Stewart & Ware, 1992). Patients are read five answer options which range from "All of the Time" to "None of the Time." The Duke Activity Status Index (DASI) is a 12-item questionnaire that measures the functionality of the patients in daily and recreational activities (Crohnbach's α=0.67) (Dorian et al., 2002).

2.3.2 Statistical Analyses

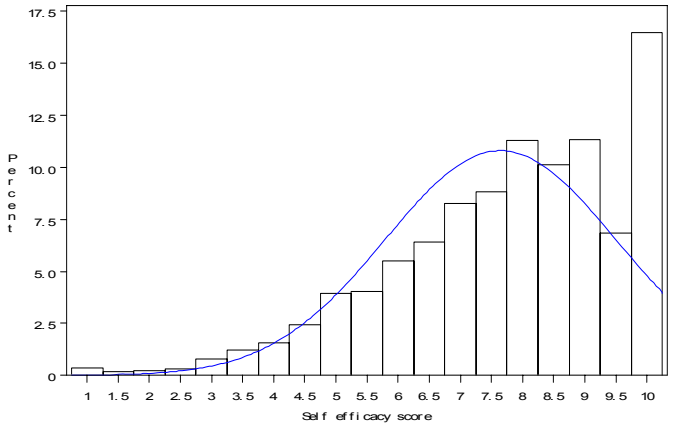
The first step was to assess the normality of the distribution of the continuous baseline variables: SE score, HbA1c, LDL, and systolic blood pressure. For each of these variables, the hypothesis of normality was formally rejected (Kolmogorov-Smirnov $p<0.01$). However, given the large sample size in this analysis (N=1,447), there was power to detect small departures from normality based on skewness, kurtosis, and visual

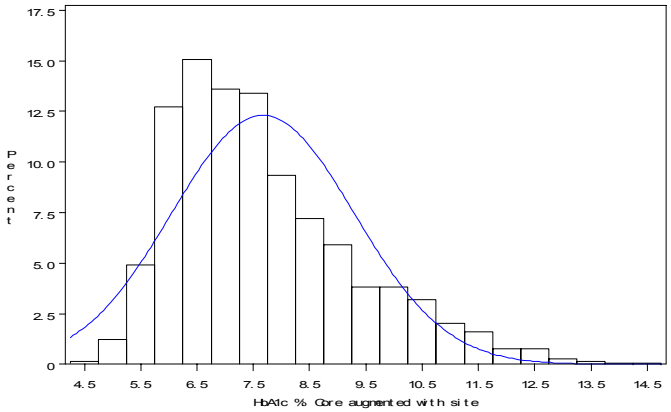
inspection. The distributions of the SE score (mean=7.7, s.d.=1.8, skewness=-0.75, kurtosis=0.23), HbA1c (mean=7.67, s.d.=1.62, skewness=0.94, kurtosis=0.60), LDL (mean=96.8, s.d.=34.0, skewness=1.01, kurtosis=2.80) and systolic blood pressure (mean=131.7, s.d.=20.0, skewness=0.79, kurtosis=1.13) can be considered approximately normal (Figures 2 and 3). SE was used a continuous variable (0-10) in this analysis. Previous literature that investigated SE as a continuous measure did not transform the SE variable and used non-parametric statistics to account for the non-normal distributions. Lowess smoothed plots (bandwidth=0.2 and bandwidth=0.4) of the explanatory risk factor variables versus SE were examined, and it was determined from visual inspection that linear forms of the variables were appropriate for the current analyses. Therefore, the SE variable was not transformed.

Cut-off points for clinical variables such as ankle brachial index and diastolic blood pressure were based on a review of literature for their clinical thresholds. The SE scores of baseline demographic and clinical categories were compared using chi-square statistics for categorical variables and Wilcoxon non-parametric statistics for continuous variables. Non-parametric statistics were used for between group comparisons of categorical variables (i.e., men vs. women, history of congestive heart failure vs. no congestive heart failure) for the SE score. The p-values were based on the Wilcoxon signed-rank test (2 groups) or the Kruskal-Wallis test (more than 2 groups). P-values for the group variables of race/ethnicity, albuminuria, and angina status are reported. Variables to be considered included demographics and clinical characteristics presented in Table 2. Based on the literature, candidate variables of interest for the analysis also included drug use, marital status, duration of DM, and ST segment depression.

Regression models with the outcome of SE were constructed, both unadjusted and adjusted for age, race/ethnicity, education, and sex. Risk factors were stratified by race/ethnicity, sex, and education. Two-way ANOVAs were performed to test within category differences of the demographic variables and interactions between the independent variables.

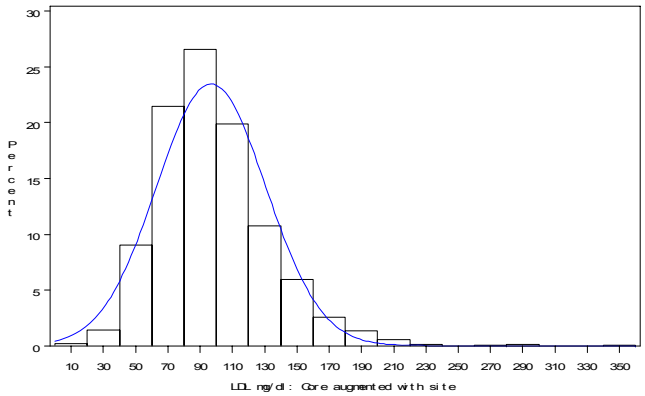
A multivariate model with the outcome of SE was created. First, a stepwise linear regression model ($p<0.10$) was created from the following domains in the following sequence: *demographics* – sex, age, race/ethnicity, education, marriage status, BMI; *clinical history* – HbA1c, duration of diabetes, current insulin use, history of hypoglycemia, albumin creatinine ratio >30, probable neuropathy as indicated by a Michigan Neuropathy Screening score ≥7 (Feldman et al., 1994), LDL ≥100, systolic blood pressure >130, diastolic blood pressure <70, history of congestive heart failure, non-coronary artery disease, angina status, total cholesterol ≥200, low HDL, ankle brachial index ≤0.90, ST segment depression >.5mm; and *medications* – number of hypertension drugs, number of lipid drugs, number of diabetes drugs, and no diabetes drugs. In order to create a parsimonious model of factors associated with SE, variables that entered the resulting model with a $p\geq0.05$ were individually removed from the model until the final model contained only variables with $p<0.05$. All analyses were performed using SAS version 9.1.



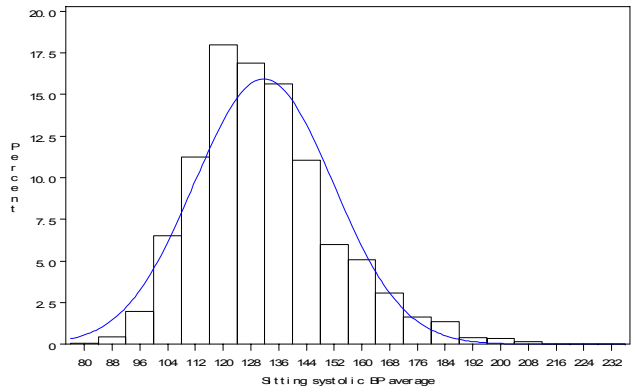


HbA1c
(Skewness=0.94, Kurtosis=0.60)

Figure 2. Histograms of Self-efficacy score and HbA1c



Low density lipids
(Skewness=1.01, Kurtosis=2.80)



Systolic blood pressure
(Skewness=0.79, Kurtosis=1.13)

Figure 3. Histograms of low density lipids and systolic blood pressure

3.0 RESULTS

3.1 BASELINE DEMOGRAPHICS AND CLINICAL HISTORY

In the U.S. sites, 1,447 patients completed the SE questionnaire. The characteristics of these patients at study entry are shown in Table 2. Patients were predominately male (68.3%), with an average age of 62.8 years. The patients were racially and ethnically diverse, with 59.4% White non-Hispanics (nH), 22.9% Black nH, 14.2% Hispanic, and 3.5% Other (including Asian and Native American). Half of the patients had an education beyond high school, including associate degrees, bachelor degrees, and advanced degrees. The mean body mass index (BMI) was 32.9 kg/m^2, which is considered obese.

The average duration of diabetes in the BARI 2D patients was 10.9±8.9 years. Patients had a mean HbA1c of 7.6% ±1.6% and probable neuropathy was screened in 18.1% of patients. Few patients were not taking any diabetes drugs (6%) and about a third were taking insulin at the time of randomization. The mean SE score was 7.7±1.8. Most of the patients (39.8%) rated their health as "Good." However, the patients rated their energy and their ability to carry out daily activities as low.

A low percentage of patients had a history of congestive heart failure. A large proportion of the patients had a clinical history of hypertension and hypercholesterolemia requiring treatment. More than a quarter (27.9%) of the patients had non-coronary artery disease and

37.3% of patients reported angina status that was mild to moderate (Canadian Classification System [CCS] 1, 2) (Campeau, 1975). There were 2.6±1.9 lesions per patient on average. Few patients had major Q-wave MI. A quarter of the patients had high blood pressure, as indicated by a blood pressure >140/90 mmHg. The BARI 2D target blood pressure was 130/80. The mean systolic blood pressure was 130.7±19.0, the mean diastolic blood pressure was 72.5±10.4, and the mean LDL was 95.4±34.3 mg/dl. Patients were prescribed an average of 2.3±1.0 drugs for their hypertension.

3.2 SELF-EFFICACY SCORE

Table 3 presents the SE score mean and standard deviation (s.d.) for each category. Variables presented in the table were chosen if they were clinically significant or were shown to be related to SE from past literature. The SE score was significantly different between racial/ethnic groups with the White BARI 2D patients having the highest mean SE score and the Hispanic patients having the lowest. There was no significant difference between the age categories or by BMI. Males and those with higher education had significantly higher SE scores than females and those with less education. Patients who exercised daily had significantly higher SE scores than patients who did not exercise daily. Patients with HbA1c <8% had significantly higher SE scores. Differences between SE scores by systolic blood pressure and LDL categories were not significant.

Patients with a healthier diabetic profile -- no history of hypoglycemia, no neuropathy, no micro-albuminuria (30< albumin creatinine ratio [acr] <300) or macro-albuminuria (acr≥300),

Patients with a healthier cardiac profile -- no additional history of treated congestive heart failure or hypertension, no angina or angina only with MI, no ST segment depression >.5 mm, an ankle brachial index >1.4, and fewer hypertension medications -- had significantly higher mean SE scores that those with a less healthy profile. However, patients who had a history of malignancy had higher SE scores than those without a history of malignancy. The SE scores between diastolic blood pressure categories were not significantly different.

The SE scores by the three risk factors, HbA1c, systolic blood pressure, and LDL, were stratified by race/ethnicity, sex, and education. Figure 4 depicts the results from the two-way ANOVAs in graphical form. The SE difference between HbA1c categories shown in Table 3 remained significant when stratified by race/ethnicity ($p=0.02$), sex ($p=0.03$), and education ($p=0.01$). The relationships between SE and systolic blood pressure and LDL remained non-significant even after stratifying by these demographics. No risk factors met the $p<0.05$ significance for interactions between risk factors and demographic variables. Therefore, the association between the risk factors and SE is the same regardless of the demographic status.

Table 2. Demographic and clinical characteristics

Characteristic	Total (N=1,447)
DEMOGRAPHICS	
Male, %	68.3
Age at study entry (years), mean, s.d.	62.8, 9.1
Race/Ethnicity, %	
White non-Hispanic (nH)	59.4
Black nH	22.9
Hispanic	14.2
Other nH	3.5
Education categories, %	
< High school	23.8
High school graduate	26.5
Some post high school	30.0
Bachelor degree or higher	19.6
Medicare/Public insurance, %	55.1
BMI, mean, s.d.	32.9, 6.2
RISK FACTORS OF INTEREST	
HbA1c %, mean, s.d.	7.60, 1.58
Sitting systolic blood pressure average, mean, s.d.	130.7, 19.0
Low density lipids mg/dl, mean, s.d.	95.4, 34.3
DIABETES	
Duration of diabetes (years), mean, s.d.	10.9, 8.9
Probable neuropathy (Michigan neuropathy screening score ≥7), %	18.1
Albuminuria categories, %	
No albuminuria	66.1
Micro albuminuria, 30<acr<300	23.4
Macro albuminuria, acr ≥300	10.5
No diabetes drugs, %	6.6
Currently taking insulin, %	33.4
CARDIAC	
History of congestive heart failure requiring treatment, %	9.1
Hypertension requiring treatment, %	84.2
Hypercholesterolemia requiring treatment, %	83.7
Non-coronary artery disease, %	27.9
History of malignancy (cancer), %	10.6
Angina category w/i 6 weeks, %	
Angina Only with MI / No Angina nor Angina Equivalents	17.8
Anginal Equivalents	24.9
Stable CCS1, CCS2*	37.3
Stable CCS3, CCS4, Unstable	20.1
Number of lesions with ≥ 50% stenosis, mean, s.d.	2.6, 1.9
Proximal left anterior descending artery (LAD) ≥ 50% stenosis, %	12
Major Q-wave myocardial infarction, %	6
ST segment depression > 0.5 mm, %	14.2
Sitting blood pressure >140/90, %	25.9
Sitting diastolic blood pressure average, mean, s.d.	72.5, 10.4

Table 2 (cont.)

Characteristic	Total (N=1,447)
Total cholesterol mg/dl, mean, s.d.	167.1, 40.5
Triglycerides, mean, s.d.	175.3, 135.0
High density lipids mg/dl, mean, s.d.	38.2, 10.8
Number of hypertension drugs, mean, s.d.	2.3, 1.0
Beta blocker, %	72.8
Calcium channel blockers combined, %	31.7
Angiotensin converting enzyme (ACE) inhibitor, %	66.7
Angiotensin receptor blocker (ARB), %	16
Diuretic, %	44.5
Nonsublingual nitrate, %	29.5
Sublingual nitrate spray, %	27.3
QUALITY OF LIFE	
Self efficacy score (0-10), mean, s.d.	7.7, 1.8
Self rated health category, %	
Poor	13.2
Fair	35.3
Good	39.8
Very good	10.3
Excellent	1.3
Quality of life energy score (0-100), mean, s.d.	45.4, 21.8
Health distress score (0-100), mean, s.d.	56.2, 25.3
Quality of life Duke Activity Score Index (DASI) (0-58.2), mean, s.d.	18.7, 14.2

*Canadian Classification System for angina

Table 3. Mean and s.d. of SE score between variable categories

Variable	Categories (Mean, s.d.)						P-value
DEMOGRAPHICS							
Sex	Female (N=461)	Male (N=995)					
	7.5, 1.9	7.8, 1.8					<.001
Race	White nH (N=866)	Black nH (N=333)	Hispanic (N=207)	Other nH (N=50)			
	8.0, 1.7	7.6, 2.0	7.0, 2.0	7.5, 1.9			<.001
Age	<50 yrs (N=113)	50-59 yrs (N=457)	60-69 yrs (N=533)	≥ 70 yrs (N=353)			
	7.6, 1.9	7.6, 1.9	7.9, 1.8	7.7, 1.8			0.12
Education	Some HS/ Less (N=26)	HS Diploma (N=385)	Some post HS (N=434)	Bachelors/ Higher (N=170)			
	6.3, 2.3	7.5, 1.9	8.0, 1.6	8.3, 1.5			<.001
Marital status	Never married (N=89)	Married/ spouse-like (N=964)	Divorced/ Separated (N=253)	Widowed (N=150)			
	7.5, 2.1	7.8, 1.7	7.4, 2.0	7.7, 1.9			0.01
Exercise daily	No (N=1093)	Yes (N=360)					
	7.6, 1.9	8.3, 1.5					<.001
BMI	Low, <20 (N=3)	Normal, 20-<25 (N=104)	Overwt., 25-<30 (N=405)	C1 Obese, 30-<35 (N=492)	C2 Obese, 35-<40 (N=264)	C3/4 Obese, ≥40 (N=177)	
	8.0, 1.0	7.5, 2.1	7.8, 1.8	7.8, 1.8	7.7, 1.7	7.5, 2.0	0.17
RISK FACTORS OF INTEREST							
HbA1c	<7 (N=564)	7-<8 (N=364)	≥ 8 (N=516)				
	7.8, 1.7	7.9, 1.8	7.5, 2.0				0.01
Systolic blood pressure	<130 (N=740)	(130-140) (N=315)	≥140 (N=392)				
	7.8, 1.8	7.7, 1.7	7.6, 1.9				0.40
LDL	<100 (N=876)	100-<130 (N=355)	≥130 (N=194)				
	7.8, 1.9	7.7, 1.8	7.6, 1.9				0.36
DIABETIC FACTORS							
History of hypoglycemia	No (N=1038)	Yes (N=401)					
	7.8, 1.8	7.6, 1.7					0.04
Probable neuropathy	No (N=1188)	Yes (N=262)					
	7.9, 1.8	7.1, 2.0					<.001
Albuminuria	No albuminuria (N=864)	Micro albuminuria (N=307)	Macro albuminuria (N=136)				
	7.8, 1.8	7.6, 1.8	7.4, 2.0				0.02
Diabetes drugs	None (N=97)	1, no insulin (N=398)	≥2, no insulin (N=476)	Insulin (N=485)			
	8.2, 1.6	7.9, 1.8	7.8, 1.7	7.4, 1.9			<.001

Table 3 (cont.)

Variable	Categories (Mean, s.d.)						P-value
CARDIAC FACTORS							
History of congestive heart failure	No (N=1315)	Yes (N=132)					
	7.8, 1.8	7.0, 2.0					<.001
History of hypertension	No (N=227)	Yes (N=1222)					
	8.1, 1.6	7.7, 1.9					<.001
Non-coronary artery disease	No (N=1048)	Yes (N=408)					
	7.8, 1.8	7.4, 1.9					<.001
History of Malignancy (cancer)	No (N=1300)	Yes (N=156)					
	7.7, 1.9	8.1, 1.6					<.001
Angina status*	Only w/ MI/Neither (N=257)	Angina Equivalent (N=361)	Angina 1, 2 (N=548)	Angina 3, 4 (N=290)			
	8.1, 1.8	7.8, 1.7	7.7, 1.9	7.4, 1.9			<.001
ST segment depression >.5mm	No (N=1122)	Yes (N=185)					
	7.8, 1.8	7.5, 1.9					0.03
Diastolic blood pressure	<70 (N=577)	70-<80 (N=519)	≥80 (N=350)				
	7.6, 1.9	7.7, 1.8	7.7, 1.8				0.18
Ankle brachial index	≤ 0.90 (N=258)	>0.90-1.4 (N=980)	>1.4 (N=36)				
	7.4, 1.8	7.8, 1.8	8.4, 1.2				<.001
Number of hypertension drugs	0 (N=56)	1 (N=226)	2 (N=562)	3 (N=435)	4 (N=164)	5 (N=13)	
	8.3, 1.6	8.1, 1.7	7.8, 1.8	7.6, 1.9	7.4, 2.0	7.3, 2.2	<.001

Key: SE – self efficacy, BMI- body mass index, HS – high school, nH – non-Hispanic, C1–C4: Class 1 – 4 obesity, HbA1c – glycosylated hemoglobin, LDL – low density lipid cholesterol, MI – myocardial infarction

*Canadian Classification System for angina

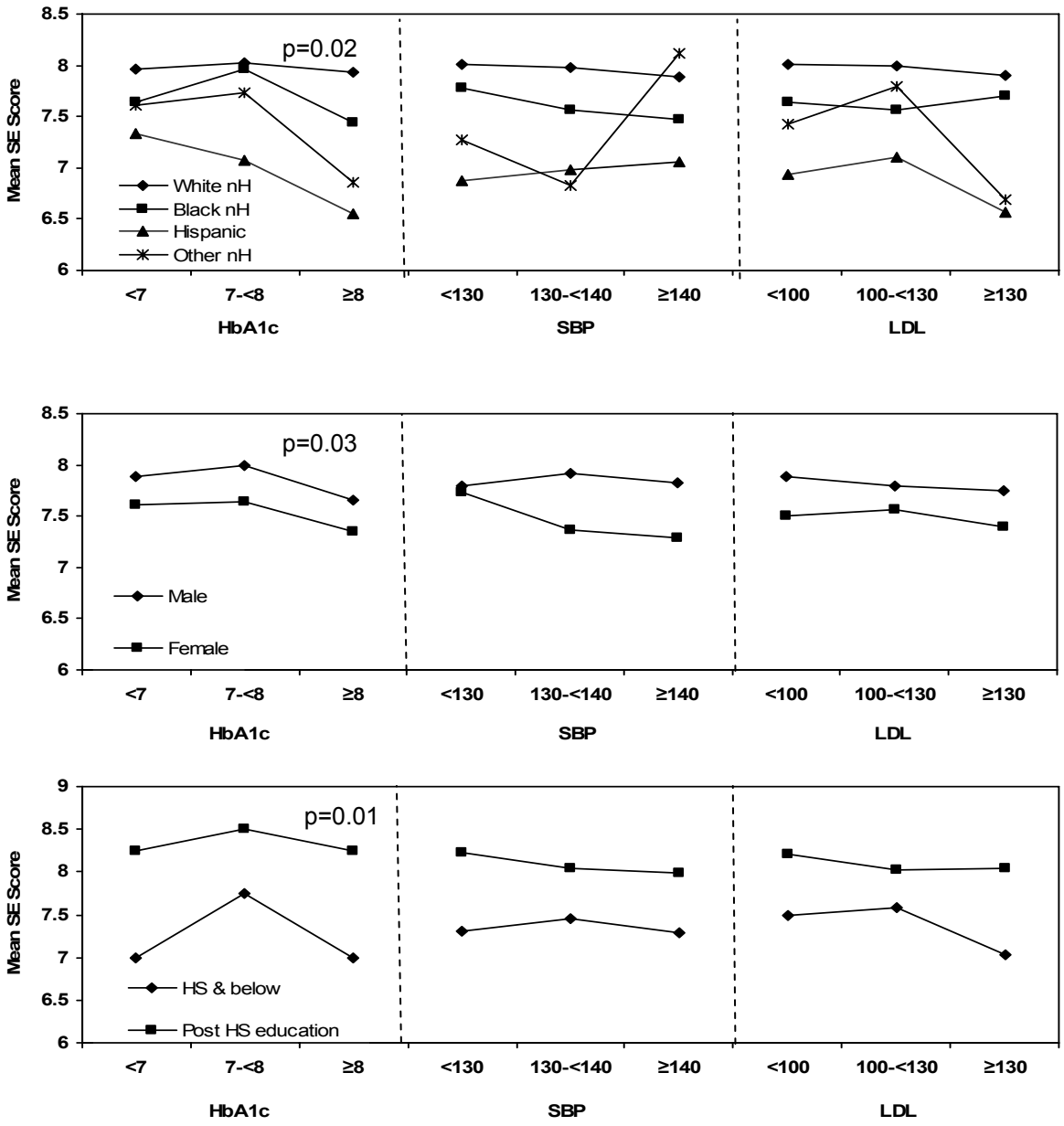


Figure 4. Mean SE Scores for risk factors by race/ethnicity, sex, and education

Key: SE – self efficacy, HbA1c – glycosylated hemoglobin, SBP – systolic blood pressure, LDL – low density lipid cholesterol, HS – high school, nH – non-Hispanic

No values met the $p<0.05$ significance for interactions between risk factors and demographics for SE based on two-way ANOVAs.

P-values presented represent the difference in SE scores between HbA1c categories.

3.3 BIVARIATE AND MULTIVARIATE MODELS

Table 4 shows the bivariate and multivariate regression models for SE. Model 1 is unadjusted and Model 2 is adjusted for sex, age, race/ethnicity, and education. In Model 1, female, Black and Latino race/ethnicity, and a post high school education (high school diploma and above) were significantly associated with SE. Age and Other race/ethnicity were not significantly associated with SE. Race/ethnicity was related to SE ($p<.001$), and minority racial/ethnic groups compared to White patients had lower SE scores. Compared to White patients, Black patients scored 0.34 lower, Hispanics scored 1.02 lower, and Other racial/ethnic patients scored 0.52 lower (non-significant) on the SE score. A post high school education was positively associated with SE. Regular exercise and being married were both positively associated with SE.

HbA1c, defined both continuously and dichotomously (≥8%), was significantly negatively associated with SE score, as was systolic blood pressure per 10 mmHg. LDL, continuously and dichotomously (≥100), was not significantly associated with SE.

Diabetic factors that were negatively associated with SE were duration of diabetes per 5 years, history of hypoglycemia, probable neuropathy, albuminuria, and current insulin use. Patients who were not on diabetes drugs had significantly higher SE scores than patients on diabetes drugs.

Cardiac factors that were negatively associated with SE were a history of congestive heart failure, hypertension, ankle brachial index ≤.90, non-coronary artery disease, angina CCS 3, 4 or unstable angina, ST segment depression, and number of hypertension drugs. Surprisingly, a history of malignancy (cancer) at baseline was positively associated with SE. Diastolic blood

pressure <70, low HDL, total cholesterol, and number of lipid drugs were not significantly related to SE.

In Model 2, sex, age, race/ethnicity, and education serve as the reference model. Each demographic variable is adjusted for the other demographic variables. For example, age is adjusted for sex, race/ethnicity, and post high school education. Latino, Other race/ethnicity, and a post high school education were significantly associated with SE. The Black nH, female, and age variables were not significantly associated with SE. BMI was not significantly associated with SE, but regular exercise and being married were significantly related to a higher SE score. HbA1c was the only risk factor of interest that was significantly negatively associated with SE score.

Additional diabetic factors that were negatively associated with SE were duration of diabetes per 5 years, history of hypoglycemia, probable neuropathy, albuminuria, current insulin use, and no use of diabetes drugs. Cardiac factors that were negatively associated with SE were a history of congestive heart failure, hypertension, ankle brachial index ≤.90, non-coronary artery disease, no diagnosis of malignancy, angina status, ST segment depression, and number of hypertension drugs. Low HDL, total cholesterol, and number of lipid drugs were not significantly related to SE after adjusting for confounders. Diastolic blood pressure <70, which showed no significant association in the unadjusted bivariate model, was significantly negatively associated with SE in the adjusted model.

A multivariate linear regression model was also created to examine the contribution of baseline risk factors in determining the level of SE (Table 5). This analysis is different from that in Table 4 in that it looks at a variable's association with SE controlling for sex, age, race/ethnicity, post high school education, and additional clinical variables. Variables that

entered the model were probable neuropathy, current insulin use, history of congestive heart failure, number of hypertension drugs, and a history of cancer. Probable neuropathy, current insulin use, a history of treated congestive heart failure, and hypertension drugs were significantly associated with a decrease in SE. A history of cancer was associated with an increase in SE. This model explains 12% of the variance in the SE score as indicated by the adjusted R^2.

Table 4. Unadjusted bivariate and adjusted models: outcome SE score (0-10)

Variable	Model 1: Unadjusted Coefficient	P-value	Model 2: Adjusted* Coefficient	P-value
DEMOGRAPHICS			*reference model in italics*	
Female	-0.33	<.001	*-0.20*	*0.06*
Age (per 5 years)	0.05	0.06	*0.05*	*0.06*
Black nH (vs. White nH) **	-0.34	<.001	*-0.16*	*0.19*
Hispanic or Latino (vs. White nH) **	-1.02	<.001	*-0.80*	*<.001*
Other nH (vs. White nH) **	-0.52	0.05	*-0.53*	*0.04*
Post HS education and above (vs. ≤HS education)	0.78	<.001	*0.68*	*<.001*
BMI (per 5 points)	-0.05	0.18	-0.06	0.14
Exercise regularly	0.74	<.001	0.59	<.001
Married	0.34	<.001	0.26	0.01
RISK FACTORS				
HbA1c %	-0.10	<.001	-0.07	0.02
HbA1c ≥ 8.0%	-0.30	<.001	-0.22	0.03
Sitting systolic blood pressure (per 10 mmHg)	-0.06	0.03	-0.01	0.06
Sitting systolic blood pressure >140	-0.16	0.14	-0.13	0.22
LDL per 10 mm/dl	-0.02	0.46	-0.01	0.68
LDL ≥ 100	-0.10	0.35	0.01	0.91
DIABETIC				
Duration of diabetes (per 5 years)	-0.06	0.03	-0.05	0.04
History of hypoglycemic episode	-0.22	0.04	-0.23	0.02
Probable neuropathy	-0.79	<.001	-0.66	<.001
Micro albuminuria 30<acr ≤300 mg/g (vs. none)	-0.20		-0.19	
Macro albuminuria acr>300 mg/g (vs. none)	-0.44	0.02	-0.37	0.04
Currently taking insulin	-0.51	<.001	-0.47	<.001
No diabetes drugs	0.46	0.02	0.39	0.04
CARDIAC				
History of congestive heart failure requiring treatment	-0.77	<.001	-0.72	<.001
Hypertension requiring treatment	-0.48	<.001	-0.40	0.00
Ankle brachial index ≤.90	-0.27	0.01	-0.21	0.04
Non-coronary artery disease	-0.41	<.001	-0.37	0.00
History of malignancy (cancer)	0.42	0.01	0.37	0.02
Angina equivalent (vs. no angina)	-0.26		-0.19	
Angina CCS 1, 2 (vs. no angina)	-0.42	<.001	-0.30	0.02
Angina CCS 3, 4, Unstable (vs. no angina)	-0.65		-0.48	
ST segment depression >.05mm	-0.31	0.03	-0.36	0.01
Diastolic blood pressure <70	-0.14	0.15	-40.23	0.02
HDL < 40 males, < 50 mg/dl females	-0.01	0.96	-0.03	0.76
Total cholesterol ≥ 200 mg/dl	-0.19	0.15	-0.09	0.50
Number of hypertension drugs	-0.23	<.001	-0.24	<.001
Number of lipid drugs	-0.10	0.20	-0.16	0.05

Key: SE – self-efficacy, nH – non-Hispanic, BMI – body mass index, HbA1c – glycosylated hemoglobin, LDL – low density lipids, acr – albumin creatinine ratio, CCS 1-4 – Canadian Classification System, HDL – high density lipids

* Sex, age, race/ethnicity, and post high school education serve as the reference model for which the latter variables are adjusted.

** Test for significance of race/ethnicity unadjusted p<.001, adjusted p<.001

Table 5. Multivariate linear regression model- SE score (0-10)

Variable	Coefficient	P-value
Intercept*	7.71	<.001
Female	-0.09	0.37
Age (per 5 years)	0.04	0.12
Black nH (vs. White nH)	-0.04	0.75
Hispanic or Latino (vs. White nH)	-0.74	<.001
Other nH (vs. White nH)	-0.46	0.07
Post HS education and above (vs. ≤HS education)	0.67	<.001
Probable neuropathy	-0.46	<.001
Currently taking insulin	-0.33	<.001
History of congestive heart failure requiring treatment	-0.50	<.001
Number of hypertension drugs	-0.20	<.001
History of malignancy (cancer)	0.36	0.02
Adjusted R^2=0.12		

Key: nH – non-Hispanic, HS – high school

* Sex, age, race/ethnicity, and education were forced into the model.

4.0 DISCUSSION

Type 2 diabetes and coronary artery disease continue to be growing problems in the U.S., and the control of the diseases' risk factors is not simply a measure of prescribed healthcare regimens as given by one's physician (Jerant et al., 2005). Psychosocial factors play a considerable role in the management of these comorbid diseases. In this analysis of BARI 2D patients with both Type 2 diabetes and known CAD, self-efficacy was independently and positively associated with better profile for cardiac and diabetic risk factors and measures. Better HbA1c was positively associated with SE, which is consistent with the past literature that looked at DM both separately and in conjunction with CAD (Deaton et al., 2006; Nakahara et al., 2006). HbA1c was significantly associated with SE, even after adjusting for sex, age, race/ethnicity, and education. Consistent with the results of the study by Senuzun et al. (1996), systolic blood pressure was associated with SE when there was no adjustment for clinical and demographic confounders. However, in the current analysis, this association was not significant when adjusting for demographic confounders only. LDL was not associated with SE, which is counter to the results by Senuzun et al. (1996), which showed LDL to be significantly improved in a group of patients who received SE-improving skills compared to a control group. The relationship between SE and the risk factors did not differ by race/ethnicity, sex, and education.

The clinical and demographic factors that were examined in BARI 2D account for an important proportion of one's SE. Like the study by Deaton et al. (2006), the multivariate model

in this analysis accounted for 12% of the variance of the SE score. This suggests that one's clinical status is not the sole component in SE regarding one's health.

Education and literacy are important factors in SE. In this analysis, BARI 2D Hispanic patients were more likely than non-Hispanic patients to have lower SE. This may be a reflection of cultural differences or a matter of English literacy. Limited English skills can impair one's health literacy. Poor literacy has been associated with worse DM outcomes and poor SE has been found to be negatively associated with self-management across race/ethnicity and health literacy levels (Kim, Love, Quistberg, & Shea, 2004; Sarkar et al., 2006). Furthermore, less educated BARI 2D patients had significantly lower SE, emphasizing the role that health education and literacy have on a patient's confidence to effectively manage their chronic conditions. The SE assessment in BARI 2D was designed to be self-reported. Patients had to read a list of questions regarding their ability to manage their conditions. In the case that a person indicated that they were not able to read the questions, the assessment was administered by a BARI 2D staff member.

In this analysis, probable neuropathy and insulin use were diabetic factors strongly associated with SE, both unadjusted and adjusted for confounders. The impact of neuropathy on quality of life has been well documented (Argoff, Cole, Fishbain, & Irving, 2006; Barrett et al., 2007). Neuropathy is a clinical complication in which there is numbness, tingling, and/or pain in the body's extremities, such as the hands and feet. The painful symptoms have been found to significantly diminish one's quality of life. In a meta-analysis by Argoff et al. (2006), diabetic neuropathy was associated with the impairment of emotions, enjoyment of life, energy, pain, physical mobility, employment, and recreational and social activities. These impairments can affect the daily regimens needed to properly manage the chronic diseases. Insulin use is

indicative of more severe diabetes and is also a more complex regimen requiring intense management. Current insulin use was independently and negatively associated with SE, even after controlling for confounding demographic variables. Compared to patients with no current use of insulin, patients who were currently using insulin rated their estimated SE score close to a half-point lower.

The cardiac factors mainly associated with SE were history of congestive heart failure and use of hypertension drugs. Self-efficacy expectations are shaped by successful and failed outcomes (Bandura, 1977), and therefore, congestive heart failure can impair a persons' belief that they are able to effectively mange their CAD. Congestive heart failure can be seen as the negative outcome of a failed attempt to manage one's disease, thereby lowering one's SE in prospective self-management. In other words, because congestive heart failure is seen as "failure," the person then believes that s/he is no longer able to effectively manage his/her disease. Also, low SE can result in poor cardiac health management, which results in congestive heart failure. The symptoms of congestive heart failure can be very painful, and the level of pain may serve as a measure of how well or poorly a patient is taking care of his/herself. The association between SE and the number of hypertension drugs indicates that the management of the disease affects SE, and not the disease per se. Hypertension is commonly known as the "silent killer" because it has no immediate painful symptoms. However, the use of hypertension drugs serves as a reminder to the patient that they are indeed suffering from a potentially deadly condition, and number of drugs taken is representative of the magnitude of this condition. Similar to the results by Sullivan et al. (1998), ST segment depression was also negatively associated with SE.

A history of malignancy was found to be positively associated with SE. This relationship may be indicative of a form of empowerment. If a patient feels they can survive cancer, then their positive outlook on life, as well as self-efficacy for health management behaviors, increases (Andrykowski, Beacham, Schmidt, & Harper, 2006; Park & Gaffey, 2007). DM and CAD may seem manageable in comparison. Furthermore, these patients' bodies may have been relatively physically fit, enabling them to survive cancer.

The main strengths of this analysis are the large sample size and the extent of clinical, demographic, and pharmaceutical data collected on each patient. This study adds to the sparse amount of literature that investigates SE in patients with two conditions that are highly comorbid. This sample is racially and ethnically diverse. BARI 2D surpassed its goal of recruiting 30% of the study participants from minority populations. In this analysis, over 40% of the U.S. patients were self-identified as racial/ethnic minorities. Furthermore, this study also collected data on history of malignancy, which was found to be significantly associated with SE. No other studies in the examined literature looked at cancer's relationship to SE in patients with CAD and/or DM. Another strength of the study is that the longitudinal design will allow future analyses to further explore the temporal relationship between SE, DM and CAD control, clinical outcomes, and risk factors at multiple time points. The level of SE can be seen over time in relation to clinical measures.

There are several limitations to this analysis. First, these analyses are cross-sectional so causation and directionality cannot be established. It is unclear whether or not a controlled medical profile is the successful result of high SE or if high SE is attained through the successful management of less severe disease. Second, SE is not constant over time. It can increase or decrease based on the failures and successes in goal attainment (Gist & Mitchell, 1992). BARI

2D is a longitudinal study so this analysis sets the starting point for an in-depth longitudinal analysis of SE over time. Third, the BARI 2D patient population is a select one (see inclusion/exclusion criteria for this clinical trial); therefore, the results of this analysis may not be generalizable to patients with DM or CAD only.

An additional limitation is that the baseline data of BARI 2D do not contain an assessment of depression, another condition that is highly comorbid with DM and CAD (Ciechanowski et al., 2000; Katon et al., 2004). Follow-up BARI 2D data collection includes the Center for Epidemiological Studies Depression Scale (CES-D), an epidemiological measurement of the severity of depression symptoms (Radloff, 1977). This will provide an opportunity to look not only at the role depression plays in SE, but in clinical risk factors as well.

It is of note that SE is specific based on the behavior in question; it is not a generalized response or a trait (Clark & Dodge, 1999). An additional point to keep in mind is that this is a modified SE assessment which contains four out of the five questions from the original assessment by Lorig (1996). The questions in the modified version of the SE assessment mention both diabetes and cardiovascular disease (Appendix A). This may be confusing to patients who are able to manage one disease properly, but not the other. For instance, a patient whose HbA1c is under control, but has high blood pressure may have difficulty answering question 4.2 (Appendix A). The dual nature of these questions may cloud the independent effects of the comorbid diseases on SE.

The results of this analysis have several implications. Clinical measures account for a proportion of what affects self-efficacy, and additional research can be done to describe additional influential factors such as family situations, living conditions, and additional chronic diseases. Health care providers should strongly take into consideration the patient's clinical

history and SE when assessing the patient's ability to follow the prescribed healthcare regimens. Patient-provider communication must further emphasize building up the patient's confidence, especially addressing physical pain and medication schedules. As indicated by the Bandura model, measures of past successes and failures in diabetes and cardiac control can affect one's SE. Diabetes educators should have the patients recognize their past management of DM and CAD collectively, and let patients know that a poor outcome should not negatively shape their outcome expectations. This can be done through counseling and examining what may have gone wrong in the past and how it can be changed in the future. Furthermore, culturally appropriate and comprehensible healthcare materials should be widely and readily available to those who may not fully understand English or have low literacy levels. Access to comprehensible healthcare information may lessen the disparities in the health profiles between people with different levels of literacy, education, and English.

APPENDIX A

SELF EFFICACY ASSESSMENT *

(Adapted from Lorig, 1996)

SECTION E: QUALITY OF LIFE

4. We would like to know how confident you are in doing certain activities. For each of the following questions, please circle the number that corresponds to your confidence that you can do these things regularly at the present time.

4.1 Having diabetes and heart disease often means doing different tasks and activities to manage your condition. How confident are you that you can do all the things necessary to manage your condition on a regular basis?

Not at all Confident 1 2 3 4 5 6 7 8 9 10 Totally Confident

How confident are you that you can…

4.2 Do the different tasks and activities needed to manage your diabetes and heart disease so as to reduce your need to see a doctor?

Not at all Confident 1 2 3 4 5 6 7 8 9 10 Totally Confident

4.3 Reduce the emotional distress caused by your diabetes and heart disease so that it does not affect your everyday life?

Not at all Confident 1 2 3 4 5 6 7 8 9 10 Totally Confident

4.4 Do things other than just taking medication to reduce how much your diabetes and heart disease affect your everyday life?

Not at all Confident 1 2 3 4 5 6 7 8 9 10 Totally Confident

- *Reprinted from BARI 2D Data Forms Manual, (BARI 2D Coordinating Center, 2002-2004).*

APPENDIX B

GLOSSARY OF ABBREVIATIONS

The following terms are listed alphabetically:

acr – albumin creatinine ratio

BARI 2D – Bypass Angioplasty Revascularization Investigation 2 Diabetes

BMI – body mass index

C1, C2, C3, C4 – Class 1, Class 2, Class 3, Class 4 obesity

CCS – Canadian Classification System

DASI - Duke Activity Status Index

DM – Type 2 diabetes mellitus

HbA1c – glycosylated hemoglobin A1c

HBCEP - home-based cardiac exercise program

HDL – high density lipids

HS – high school

LDL – low density lipids

MI – myocardial infarction

nH – non-Hispanic

n.s. – non-significant

QoL – quality of life

RX – drug prescriptions

SBP – systolic blood pressure

s.d. – standard deviation

SE – self-efficacy

SF-36 - Medical Outcomes Study 36-Item Short Form

BIBLIOGRAPHY

AHA_ASA. (2007). Heart Disease and Stroke Statistics. from http://apps.nccd.cdc.gov/ddtstrs/template/ndfs_2005.pdf

Anderson, R. M., Funnell, M. M., Fitzgerald, J. T., & Marrero, D. G. (2000). The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care, 23*(6), 739-743.

Andrykowski, M. A., Beacham, A. O., Schmidt, J. E., & Harper, F. W. (2006). Application of the theory of planned behavior to understand intentions to engage in physical and psychosocial health behaviors after cancer diagnosis. *Psychooncology, 15*(9), 759-771.

Argoff, C. E., Cole, B. E., Fishbain, D. A., & Irving, G. A. (2006). Diabetic peripheral neuropathic pain: clinical and quality-of-life issues. *Mayo Clin Proc, 81*(4 Suppl), S3-11.

Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev, 84*(2), 191-215.

Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist, 32*(2), 122-147.

BARI_2D_Coordinating_Center. (2002-2004). NHLBI Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Data Forms Manual.

BARI_2D_Coordinating_Center. (2002-2005). NHLBI Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Manual of Operations.

BARI_Investigators. (1997). Influence of Diabetes on 5-Year Mortality and Morbidity in a Randomized Trial Comparing CABG and PTCA in Patients With Multivessel Disease : The Bypass Angioplasty Revascularization Investigation (BARI) (Vol. 96, pp. 1761-1769).

Barrett, A. M., Lucero, M. A., Le, T., Robinson, R. L., Dworkin, R. H., & Chappell, A. S. (2007). Epidemiology, public health burden, and treatment of diabetic peripheral neuropathic pain: a review. *Pain Med, 8 Suppl 2*, S50-62.

Brooks, M. M., Frye, R. L., Genuth, S., Detre, K. M., Nesto, R., Sobel, B. E., Kelsey, S. F., & Orchard, T. J. (2006). Hypotheses, design, and methods for the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Trial. *Am J Cardiol, 97*(12A), 9G-19G.

Campeau, L. (1975). Grading of angina pectoris. *Circulation, 54*, 522-530.

CDC. (2005). Diabetes National Fact Sheet. Retrieved September 1, 2007, from http://www.diabetes.org/uedocuments/NationalDiabetesFactSheetRev.pdf

Chlebowy, D. O., & Garvin, B. J. (2006). Social support, self-efficacy, and outcome expectations: impact on self-care behaviors and glycemic control in Caucasian and African American adults with type 2 diabetes. *Diabetes Educ, 32*(5), 777-786.

Ciechanowski, P. S., Katon, W. J., & Russo, J. E. (2000). Depression and diabetes: impact of depressive symptoms on adherence, function, and costs. *Arch Intern Med, 160*(21), 3278-3285.

Clark, N. M., & Dodge, J. A. (1999). Exploring self-efficacy as a predictor of disease management. *Health Educ Behav, 26*(1), 72-89.

Deaton, C., Kimble, L. P., Veledar, E., Hartigan, P., Boden, W. E., O'Rourke, R. A., & Weintraub, W. S. (2006). The synergistic effect of heart disease and diabetes on self-management, symptoms, and health status. *Heart Lung, 35*(5), 315-323.

Dorian, P., Paquette, M., Newman, D., Green, M., Connolly, S. J., Talajic, M., & Roy, D. (2002). Quality of life improves with treatment in the Canadian Trial of Atrial Fibrillation. *Am Heart J, 143*(6), 984-990.

DSM-IV-TR_American_Psychiatric_Association. (2000). *Diagnostic and statistical manual of mental disorders : DSM-IV-TR*. Washington, DC: American Psychiatric Association.

Feldman, E. L., Stevens, M. J., Thomas, P. K., Brown, M. B., Canal, N., & Greene, D. A. (1994). A practical two-step quantitative clinical and electrophysiological assessment for the diagnosis and staging of diabetic neuropathy. *Diabetes Care, 17*(11), 1281-1289.

Franz, M. J., Bantle, J. P., Beebe, C. A., Brunzell, J. D., Chiasson, J. L., Garg, A., Holzmeister, L. A., Hoogwerf, B., Mayer-Davis, E., et al. (2002). Evidence-based nutrition principles and recommendations for the treatment and prevention of diabetes and related complications. *Diabetes Care, 25*(1), 148-198.

Friedwald, W. L., & Frederickson, D. (1972). Estimation of the concentration of low density lipoprotein cholesterol in plasma. *Clinical Chemistry, 18*, 499-501.

Gist, M. E., & Mitchell, T. R. (1992). Self-Efficacy: A Theoretical Analysis of Its Determinants and Malleability. *The Academy of Management Review, 17*(2), 183-211.

Jerant, A. F., Friederichs-Fitzwater, M. M. v., & Moore, M. (2005). Patients' perceived barriers to active self-management of chronic conditions. *Patient Education and Counseling, 57*(3), 300-307.

Katon, W. J., Von Korff, M., Lin, E. H., Simon, G., Ludman, E., Russo, J., Ciechanowski, P., Walker, E., & Bush, T. (2004). The Pathways Study: a randomized trial of collaborative care in patients with diabetes and depression. *Arch Gen Psychiatry, 61*(10), 1042-1049.

Kim, S., Love, F., Quistberg, D. A., & Shea, J. A. (2004). Association of health literacy with self-management behavior in patients with diabetes. *Diabetes Care, 27*(12), 2980-2982.

Laasko, M., & Lehto, S. (1997). Epidemiology of macrovascular disease in diabetes. *Diabetes Research, 5*, 294-315.

Lorig, K. (1996). *Outcome measures for health education and other health care interventions*. Thousand Oaks: Sage Publications.

Magee, M. F., & Isley, W. L. (2006). Rationale, design, and methods for glycemic control in the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Trial. *Am J Cardiol, 97*(12A), 20G-30G.

Nakahara, R., Yoshiuchi, K., Kumano, H., Hara, Y., Suematsu, H., & Kuboki, T. (2006). Prospective study on influence of psychosocial factors on glycemic control in Japanese patients with type 2 diabetes. *Psychosomatics, 47*(3), 240-246.

Nelson, K. M., McFarland, L., & Reiber, G. (2007). Factors influencing disease self-management among veterans with diabetes and poor glycemic control. *J Gen Intern Med, 22*(4), 442-447.

NHLBI. (2007). Retrieved September 9, 2007, from http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD_Summary.html

Park, C. L., & Gaffey, A. E. (2007). Relationships between psychosocial factors and health behavior change in cancer survivors: an integrative review. *Ann Behav Med, 34*(2), 115-134.

Radloff, L. S. (1977). The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. *Applied Psychological Measurement, 1*(3), 385-401.

Robertson, D., & Keller, C. (1992). Relationships among health beliefs, self-efficacy, and exercise adherence in patients with coronary artery disease. *Heart Lung, 21*(1), 56-63.

Sarkar, U., Fisher, L., & Schillinger, D. (2006). Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? *Diabetes Care, 29*(4), 823-829.

Senuzun, F., Fadiloglu, C., Burke, L. E., & Payzin, S. (2006). Effects of home-based cardiac exercise program on the exercise tolerance, serum lipid values and self-efficacy of coronary patients. *Eur J Cardiovasc Prev Rehabil, 13*(4), 640-645.

Sobel, B. E., Frye, R., & Detre, K. M. (2003). Burgeoning dilemmas in the management of diabetes and cardiovascular disease: rationale for the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Trial. *Circulation, 107*(4), 636-642.

Sol, B. G., van der Graaf, Y., van der Bijl, J. J., Goessens, N. B., & Visseren, F. L. (2006). Self-efficacy in patients with clinical manifestations of vascular diseases. *Patient Educ Couns, 61*(3), 443-448.

Stamler, J., Vaccaro, O., Neaton, J. D., & Wentworth, D. (1993). Diabetes, other risk factors, and 12-yr cardiovascular mortality for men screened in the Multiple Risk Factor Intervention Trial. *Diabetes Care, 16*(2), 434-444.

Stewart, A. L., & Ware, J. E. (1992). *Measuring functioning and well-being the medical outcomes study approach*. Durham: Duke University Press.

Sullivan, M., LaCroix, A., Baum, C., Resnick, A., Pabiniak, C., Grothaus, L., Katon, W., & Wagner, E. (1996). Coronary disease severity and functional impairment: how strong is the relation? *J Am Geriatr Soc, 44*(12), 1461-1465.

Sullivan, M., LaCroix, A. Z., Russo, J., & Katon, W. J. (1998). Self-efficacy and self-reported functional status in coronary heart disease: a six-month prospective study. *Psychosom Med, 60*(4), 473-478.

Ware, J. E., Jr., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care, 30*(6), 473-483.