

CORONARY REVASCULARIZATION STRATEGIES AND THE EFFECTS OF
DIABETES COMPLICATIONS ON POOR HEALTH

by

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ABSTRACT

BOLARINWA FUNGBE EKEZUE. Coronary revascularization strategies and the effects of diabetes complications on poor health outcomes (Under direction of Dr. SARAH B. LADITKA, and Dr. JAMES N. LADITKA)

Objectives: This research assessed the effect of comorbid diabetes complications on short-term adverse outcomes: in-hospital mortality, postoperative stroke, postoperative renal failure and readmissions within 30 days of discharge after coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) among patients age 45 and older who have diabetes. The analysis compared differences in outcomes for CABG and PCI and for off-pump and on-pump CABG. The analysis also focused on assessing associations between structure and process factors and the study outcomes. Specifically for readmissions, the effect of discharge disposition was evaluated, including discharge to home without home health care (HHC), to home with HHC, and to a transitional care facility. *Methods:* In-hospital mortality, postoperative stroke, and postoperative renal failure were assessed using the 2007 Nationwide Inpatient Sample (NIS) database. Readmission was categorized into early (≤ 10 days) and late (11 to 30 days), and assessed using the 2007 State Inpatient Databases (SIDs) for Arizona, California, and Florida. Analyses included chi-square, t-test, propensity adjusted multivariate logistic regression, multilevel regression, and Cox proportional hazard regression. Analyses using the NIS data accounted for the survey design and were weighted for national representation. Covariates included age, race/ethnicity, health insurance, median household income, gender, 30 comorbidities, illness acuity measure, procedure volume and hospital characteristics. *Results:* In adjusted analyses, patients with comorbid diabetes

complications were more likely to have in-hospital mortality with both CABG (Odds Ratio, OR 1.60; 95% Confidence Interval, CI 1.22-2.10) and PCI (OR 1.59, CI 1.27-1.99) than those without diabetes complications. Their odds of renal failure were higher with PCI than CABG (OR 4.27 vs. 2.25, $p < 0.05$). Further, they were more likely to have postoperative stroke with off-pump CABG (OR 1.69, CI 1.10-2.60). For readmissions, the adjusted hazard of early (Hazard Ratio, HR 1.24, CI 1.08-1.42) and late (HR 1.27, CI 1.11-1.39) readmissions for those with comorbid diabetes complications and early (HR 4.16, CI 3.53-4.91) and late (HR 1.88, CI 1.69-2.10) readmissions for patients discharged to a transitional care facility were higher. Discharge to home with HHC (HR 1.24, CI 1.12-1.36) was associated only with late readmission. *Discussion:* Regardless of the revascularization strategy, patients with comorbid diabetes complications may have higher risks of in-hospital death after coronary revascularization. Effects of comorbid diabetes complications on poor outcomes should be considered when making clinical decisions about CABG and PCI for patients with diabetes. Comprehensive discharge planning may be needed to identify potential vulnerabilities, such as a predisposition to poor diabetes management for patients with comorbid diabetes, to reduce their risk for readmission. Further research should examine the association between termination of HHC services and late readmission for patients using HHC services after discharge.

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CHAPTER 1: INTRODUCTION

Statement of Problem

In the past two decades, health care expenditures in the United States have more than tripled, exceeding \$2.3 trillion in 2008, representing over 16% of the national gross domestic product in 2008 (Kaiser, 2011). Cost associated with the treatment of chronic conditions is one of the key drivers of health care cost increases. With the aging of the baby boomers in the United States, and increased life expectancy, the prevalence of age-related diseases, which are often chronic in nature, has markedly increased (Kung, Hoyert, Xu, & Murphy, 2008; Thrall, 2005). Heart disease and diabetes are among the top five causes of mortality and morbidity in the United States. The estimated direct and indirect costs of coronary artery disease (CAD) were about \$177 billion in 2010 (CDC, 2010); costs of diabetes were about \$174 billion in 2007 (ADA, 2011). Among the 25% of Medicare beneficiaries with the highest health care costs, 72% have CAD or diabetes (CBO, 2005). Diabetes is often a comorbid condition of CAD; diabetes is associated with greater severity of CAD and poorer prognosis (Flaherty & Davidson, 2005; Resnick, Shorr, Kuller, Franse, & Harris, 2001). Specifically, diabetes is associated with coronary calcification, diffuse CAD, narrow arterial vessels, and abnormal electric cardiographic measurements (Oei, Vliegenthart, Hofman, Oudkerk, & Witteman, 2004; Vaccaro et al., 2004; Zornitzki et al., 2007). The established treatment for CAD is coronary

revascularization, primarily coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI) (Eagle et al., 2004; Smith et al., 2001). Outcomes of these procedures for patients with diabetes are often worse than those without diabetes (Berry, Tardif, & Bourassa, 2007; Bravata et al., 2007).

As CABG and PCI are not equally optimal for all patients, research has sought to identify patients who will be more likely to benefit from CABG or PCI. Research suggests that PCI may be more appropriate for persons with diabetes if CAD is less severe and affects only one or two vessels (Patel, Dehmer, Hirshfeld, Smith, & Spertus, 2009b; Smith, 2009). For patients with diabetes who have severe CAD, characterized by stenosis of the left main artery or three or more diseased vessels, studies suggest that CABG may be a more appropriate option (Patel, et al., 2009b; Smith, 2009). The off-pump rather than on-pump procedure for those undergoing CABG has been suggested for patients with diabetes, as these patients are in a high-risk group (Puskas et al., 2005). Patients with diabetes are in a high-risk group because of anatomical, physiologic and metabolic dysfunctions. Among individuals with diabetes, the development of diabetes complications are also risk factors for poor outcomes after revascularization (Barsness, Holmes, & Gersh, 2005; Creager, Lüscher, Cosentino, & Beckman, 2003; Jiménez-Quevedo et al., 2009; Nesto, 2004; Reeder, Holmes, Lennon, Larson, & Frye, 2002).

Understanding how the presence of comorbid diabetes complications influences the outcomes of coronary revascularization can help to further clarify the benefits of revascularization strategies among patients with diabetes. However, subgroup analyses in many observational studies and trials including patients with diabetes lack information about the presence of diabetes complications; thus, the effectiveness of PCI and CABG in

patients with diabetes complications is inclusive (Berry, et al., 2007; Bravata, et al., 2007; Serruys et al., 2009; Shroyer et al., 2009). Findings from this study can help to identify factors that predispose patients with diabetes to adverse outcomes, and provide opportunities for clinicians to provide necessary interventions. Understanding factors that contribute to poor outcomes can also help clinicians to select patients for the appropriate revascularization strategy. Reducing readmissions is important in improving the quality of life for patients after discharge. Patients with diabetes have consistently been suggested to have greater risk of readmissions (Hannan et al., 2003; Slamowicz, Erbas, Sundararajan, & Dharmage, 2008; Stewart et al., 2000; Sun et al., 2008). Identifying characteristics that predict readmission risk in patients with diabetes can help to inform patients and care providers on factors to target in reducing readmissions.

Background

The two surgical treatments of choice for people with severe coronary artery disease are coronary artery bypass grafts (CABG) and percutaneous coronary intervention (PCI). CABG was the only surgical treatment until Andreas Gruentzig introduced coronary angioplasty in 1977, as a non-surgical substitute for treating CAD (Smith, et al., 2001). More recently, technological advancements such as use of the drug eluting stent (DES) in PCI have improved the safety and effectiveness of PCI, leading some researchers to suggest that the two techniques may be equally effective (Bravata, et al., 2007; Smith, et al., 2001). CABG is a more invasive procedure than PCI requiring a sternotomy and temporary stoppage or reduced blood flow to the heart. Artery or vein harvested from the legs or breast bone is used to bypass blocked artery and restore normal blood flow to the heart (AHA, 2011b). The CABG procedure can be performed

with or without cardiopulmonary machine. It is an off-pump CABG when the cardiopulmonary machine is not used and the heart remains beating during the procedure (Shekar, 2006). Percutaneous coronary intervention refers to various angiographic techniques used to relieve coronary narrowing. The early techniques involved using balloon to expand the artery whereas recent advancements include the use of stents with or without additional pharmacological treatment (Smith, et al., 2001). While the surgical revascularization of atherosclerotic heart disease is a modern day success story, the improvement of the procedure achieved over time was through focused dedication and continued research. Coronary artery disease is characterized by a gradual buildup of plaques in coronary arteries, restricting blood flow to the heart (AHA, 2011a). Patients with coronary artery diseases experience chest pain as the heart is deprived of vital oxygen and in some cases a heart attack when there is complete blockage of blood flow to the heart (AHA, 2011a; Eagle, et al., 2004). Coronary revascularization provides a means of restoring blood flow to the heart either by bypassing a blocked artery or expanding a narrow artery (Eagle, et al., 2004; Smith, et al., 2001). The benefits of coronary revascularization include relief of angina, survival and improvement in quality of life (Eagle, et al., 2004; Hunt, Hendrata, & Myles, 2000; Sjoland et al., 1997; Smith, et al., 2001). However, the success of coronary revascularization procedure: CABG and PCI is also measured in terms of absence of procedural complications such as death, and morbidities that adversely affect the quality of life or increase the likelihood of death, such as myocardial infarction, stroke and renal failure. Thus, a number of studies have examined ways to improve CABG and PCI techniques and also to identify factors that increase patient's risks for adverse outcomes (Curtis et al., 2009; Do et al., 2002; Fuchs et

al., 2002; Gupta, Gurm, Bhatt, Chew, & Ellis, 2005; Pell et al., 2001; Peterson, Coombs, DeLong, Haan, & Ferguson, 2004). Some of these factors include the surgical process; such as preoperative evaluation, anesthesia technique, perioperative monitoring of hemodynamic and physiological functions, the hospital environment; such as surgeon skills, procedure volume, staffing adequacy and patient's characteristics. Patient risk factors that are associated with poor outcomes include advanced age, female gender, severe CAD, diabetes, impaired renal function, congestive heart failure and multiple comorbidities (Brooks et al., 2000; Cantor et al., 2002; Eagle, et al., 2004; Smith, et al., 2001). Research has indicated worse short-term and long-term outcomes after coronary revascularization for patients with diabetes (Brooks, et al., 2000; Cruz-Gonzalez et al., 2010; Sun, et al., 2008; Whang & Bigger, 2000). Patients with diabetes are particularly at risk for adverse outcomes because the changes caused by diabetes are antecedents to adverse outcomes independent of coronary revascularization (Beckman, Creager, & Libby, 2002; Creager, et al., 2003). These changes can manifest as microvascular and macrovascular complications of diabetes.

Overview of the Nationwide Inpatient Sample (NIS) and the State Inpatient Sample SID Databases

The Nationwide Inpatient Sample (NIS) and the State Inpatient Database (SID) are hospital discharge databases maintained as part of the Healthcare Cost and Utilization Project (HCUP) by the Agency for Healthcare Research and Quality (AHRQ) (HCUP, 2007). The NIS is nationally representative administrative data representing all inpatient stays from a stratified 20% sample of United States community hospitals (HCUP, 2010). The SID databases contain all inpatient discharges from participating states, (HCUP, 2011). Data obtained from participating states are checked for inconsistencies and

edited; variables are coded so that coding is consistent across states. Many quality assurance procedures are performed on the NIS and SID data to ensure consistent internal and external validity (HCUP, 2009). The NIS database sampling used five nested stratification variables based on the characteristics of hospitals from the participating states; discharge sample weights were calculated as the probability of sampling within each stratum (HCUP, 2006). Both NIS and SID databases have similar core data elements; de-identified inpatient discharge-level data with information about demographics, admission information, length of stay, payer information, diagnoses and procedures. In addition, the NIS has information on hospital-level data such as location, ownership, bed size, staffing ratio, hospital state, and teaching status. The SID database has medical and demographic information for patients, information about patients' discharge status, and information to identify multiple hospitalizations. A limitation of the SID databases used for this research is that hospital characteristics such as teaching status and location were not included.

Objective of Research

This research has three objectives. The first objective is to examine the effect of diabetes complications using three measures of adverse outcomes: in-hospital mortality, postoperative stroke, and renal failure among individuals with diabetes having CABG or PCI. A related study objective is to compare outcomes for patients with comorbid diabetes with CABG and PCI. The second objective is to compare in-hospital mortality, postoperative stroke, and postoperative renal failure for patients with diabetes who underwent off-pump or on-pump CABG. A related study objective is to determine patient and hospital characteristics associated with off-pump CABG outcomes, and to

examine contextual factors that may be associated with outcomes for patients with comorbid diabetes complications. The third objective is to assess readmissions that occurred within 30-day of discharge in patients with diabetes who had coronary revascularization. Related to the third objective, I evaluated early readmissions, defined as readmissions that occurred within 10 days after discharge, and late readmissions, defined as readmissions that occurred after 10 days of discharge. For early and late readmissions, I examined the effect of comorbid complications and discharge disposition. Although the literature suggests that poorer revascularization outcomes are associated with metabolic changes resulting from suboptimal glycemic control, little research has focused on the response of individuals with diabetes complications to revascularization procedures. By quantifying adverse outcomes of diabetes complications among patients having either CABG or PCI, this research helps to identify the revascularization strategy that may offer better outcomes among patients with CAD and diabetes complications. Few studies have examined readmissions among patients with diabetes having coronary revascularization. No study has assessed the effect of comorbid diabetes complications on readmissions among patients with diabetes after coronary revascularization. Findings from research will expand on our understanding of how comorbid diabetes complications at the time of an index coronary revascularization hospitalization affect the likelihood of readmission. Results will also help to identify patient characteristics that should be considered when planning post-discharge care for individuals who have diabetes undergo CABG or PCI, and provide information about potentially modifiable patient characteristics, which clinicians may be able to address to enhance outcomes.

CHAPTER 2: LITERATURE REVIEW

Introduction

Diabetes is a major health problem in the United States. It affects about 24 million people, with great costs (ADA, 2010). Coronary artery disease (CAD), a major vascular complication of diabetes, is prevalent in adults with diabetes. (Hammoud, Tanguay, & Bourassa, 2000; Resnick, et al., 2001) Diabetes elevates the risk for coronary artery disease, and accelerates its progression (Resnick, et al., 2001). With a projected increase in diabetes prevalence, health care needs associated with the disease are also likely to grow, along with their costs (Mokdad et al., 2003). Heart disease care costs represent the largest single category of health spending in the United States, 8.3% of total health expenditures during 1997-2002 (Olin, 2005). Of the 1.5 million revascularization procedures performed annually to treat coronary artery disease, about 25% are for people with diabetes; these individuals experience more unfavorable outcomes than people without diabetes (Flaherty & Davidson, 2005). Coronary artery disease (CAD), characterized by blockages in the coronary artery due to atherosclerosis, accounts for a large proportion of spending for heart disease. Among the 25% of Medicare beneficiaries with the highest health care costs, 72% have CAD or diabetes (CBO, 2005). Thus, it is useful to identify individual characteristics associated with adverse outcomes among patients with CAD and diabetes having revascularization.

In addition, it is useful to understand treatment options and care processes that are associated with better outcomes for individuals with CAD and diabetes. This information can help to reduce health care costs related to CAD and diabetes, reduce the burden of secondary illnesses, and improve quality of life for persons with CAD and diabetes.

Coronary artery disease (CAD) is a leading cause of mortality in the U.S. In 2006, CAD caused 425,425 deaths, representing a sixth of all deaths (Heron et al., 2009). As a result of the gradual build-up of cholesterol and plaque in the coronary artery, the artery of patient with CAD may become narrow or blocked (AHA, 2011a; Lloyd-Jones et al., 2010). Consequently, blood flow to the heart is restricted, or stopped if the artery is blocked. Often CAD is not diagnosed until a person suffers a heart attack (NHLBI, 2009b). CAD is more common in older adults because the incidence of CAD increases with age. About 8% of adults age 20 and over in the United States have CAD (Pleis, Lucas, & Ward, 2009), with most incident CAD occurring in persons 60 years and older (Lloyd-Jones, et al., 2010). Across all age groups, CAD death rates were highest for Blacks and lowest for Asians (NHLBI, 2009a). Among non-Hispanic Whites (hereafter Whites), the prevalence is higher among men (9.4%) than women (6.9%). Among non-Hispanic Blacks (hereafter Blacks) CAD rates are higher for women than men (8.8% versus 7.8%); this is also true among Mexican Americans (6.6% for women versus 5.3% for men) (Pleis, et al., 2009). CAD occurs at earlier ages among men than among women; the lifetime risk of developing CAD for men at age 45 is 11% higher than the comparable risk for women (Lloyd-Jones, Larson, Beiser, & Levy, 1999). In a follow-up study of adults aged 45 to 64, the incidence of CAD per 1000 person-years was 12.9% for White men, 10.6% for Black men, 5.1% for Black women and 4.0% for White women.

When CAD cases from revascularization procedures were excluded, CAD rates were higher for Black men than for White men (Jones et al., 2002).

Diabetes is a major risk factor for CAD, accelerates CAD progression (Resnick, et al., 2001), and is an indicator of worse outcomes after medical procedures (Vaccaro, et al., 2004; Zornitzki, et al., 2007). People with diabetes are more likely to have more coronary calcification than others (Oei, et al., 2004), which is a marker for heart attack and coronary death (Detrano et al., 2008). Some studies suggest that people with CAD and diabetes are less likely to report chest pain, have more significant coronary stenosis, and more abnormal electric cardiographic measurements than those without diabetes (Cariou et al., 2000; Ledru et al., 2001). These differences may be due to greater microvascular vessel damage (Sobel, 2001). Although factors such as age, hypertension, gender, and hyperlipidemia are strong predictors of CHD severity, diabetes is also a major risk factor, especially among women (Natali et al., 2000).

Surgical treatment is usually preferred for patients with advanced CAD, marked by substantial blockage of the coronary artery and restricted blood flow to the heart. The two surgical treatments of choice for people with severe coronary artery disease are coronary artery bypass grafts (CABG) and percutaneous coronary intervention (PCI). CABG was the only surgical treatment until Andreas Gruentzig introduced coronary angioplasty in 1977, as a non-surgical substitute for treating CAD (Smith, et al., 2001). More recently, technological advancements such as use of the drug eluting stent (DES) in PCI have improved the safety and effectiveness of PCI, leading some researchers to suggest that the two techniques may be equally effective (Bravata, et al., 2007; Smith, et al., 2001). Although CABG was the established surgical treatment for many years, most

revascularization procedures performed in the U.S. annually are PCI procedures. The discharge rate for CABG in 2002-2004 was 25.2% whereas that of PCI was 59.2% (Lloyd-Jones, et al., 2010).

The outcomes of PCI and CABG are well described in the literature (Eagle, et al., 2004; Lloyd-Jones, et al., 2010; Smith, et al., 2001). These outcomes can be beneficial or unfavorable. Unfavorable short-term outcomes include adverse events during hospitalization such as death, stroke, renal failure, and short-term hospital readmission. Studies have suggested that certain patient populations experience better outcomes with CABG, and others with PCI (Eagle, et al., 2004; Patel, et al., 2009b; Puskas, et al., 2005; Smith, et al., 2001). However, there are subgroups for who the optimal revascularization technique is less clear. For example, subgroup analyses in many trials including patients with diabetes lack information about the presence of diabetes complications; thus, the effectiveness of PCI and CABG in patients with diabetes complications is not well supported in the literature (Berry, et al., 2007).

Three Areas of Dissertation Research Focus

The next sections describe the literature review I conducted on the outcomes: in-hospital mortality, postoperative stroke, and postoperative renal failure, and readmissions following coronary revascularization in patients with diabetes; comparing CABG and PCI outcomes, on-pump and off-pump CABG outcomes.

CABG and PCI Outcomes

Considerable research is focused on the long-term effects of revascularization with regards to diabetes, such as restenosis and repeat revascularization (Berry, et al., 2007; Bravata, et al., 2007; Kip et al., 2002; Kurbaan, Bowker, Ilesley, Sigwart, &

Rickards, 2001). Much less research is focused on short-term outcomes of revascularization in patients with diabetes. Common short-term outcomes include procedural adverse events, such as in-hospital mortality, postoperative stroke, and renal failure requiring hemodialysis. The rate of in-hospital mortality after CABG varies across studies, in part due to methodological differences (Bittner & Savitt, 2002; Ellis et al., 1988; O'Connor et al., 1991). Common risk factors for in-hospital mortality among CABG and PCI patients include being older or female, having a history of peripheral vascular disease or heart surgery, or having renal dysfunction, postoperative stroke, or diabetes (Gruberg et al., 2001; Stamou et al., 2001). The incidence of adverse neurological effects due to cerebral vascular accidents (CVA) ranges between 0.05% to 0.38% for PCI (Brown & Topol, 1993; Fuchs, et al., 2002), and 0.40% to 0.80% for CABG (Breuer et al., 1983; McKhann et al., 1997). The wide ranges for these rates may be attributable in part to differences in the definition of CVA, or differences in study designs or research samples. The CVA definition may be restrictive, as in cerebral infarction detected by imaging techniques. Alternatively, CVA may be defined broadly to include transient ischemic attacks and loss of neurological function (McKhann, Grega, Borowicz, Baumgartner, & Selnes, 2006; Smith et al., 2006). Stroke and renal dysfunction are sequelae of microvascular and macrovascular complications of diabetes and are major complications of coronary revascularization, particularly for individuals with compromised physiologic and metabolic status associated with diabetes complications, such as vessel shrinkage and reduced creatinine clearance (Beckman, et al., 2002; Fuchs, et al., 2002; Rosolova et al., 2008; Schachner, Zimmer, Nagele, Laufer, & Bonatti, 2005; Vlassara, 1997). Despite the link between diabetes complications and

poorer outcomes after CABG and PCI, this relationship has received little attention in prior research.

CABG and PCI Outcomes among Patients with Diabetes

Epidemiological evidence suggests that the physiologic and metabolic dysfunction associated with diabetes contributes to worse outcomes among individuals with diabetes and comorbid atherosclerotic disease (Nesto, 2004; Yan, Ramasamy, Naka, & Schmidt, 2003). Chronic hyperglycemia, dyslipidemia, and vascular inflammation cause arterial dysfunction, severity of arterial stenosis, and more diffuse CAD (Nesto, 2004; Yan, et al., 2003). In addition, hyperglycemia causes glycosylation of protein, a precursor to diabetes microvascular complications (Vlassara, 1997). Hyperglycemia is also associated with platelet abnormalities, evident in a higher number of pro-coagulating platelets, a risk factor for thrombolytic events (Creager, et al., 2003). Diabetic nephropathy, reduced creatinine clearance, and proteinuria are indicators of long-term poor glycemic control, and are associated with adverse short and long-term outcomes after coronary revascularization (Reeder, et al., 2002). In addition to metabolic dysfunction, studies have suggested coronary artery remodeling, where the vessel dimension compensates to changes in atherosclerotic plaque build-up (Barsness, et al., 2005). This compensation is less than optimal in individuals with diabetes (Jiménez-Quevedo, et al., 2009; Vavuranakis et al., 1997). Coronary arteries of individuals with diabetes lack the tendency to compensate for changes caused by atherosclerosis, which is linked with vessel shrinkage, a major risk factor for restenosis and adverse cardiac events after PCI (Cantor, et al., 2002; Jiménez-Quevedo, et al., 2009; Mazeika, Prasad, Bui, & Seidelin, 2003). Some studies have suggested the optimal control of blood glucose may

reduce both mortality and illness severity. Several studies found a significant reduction in mortality due to strict perioperative glucose control among patients having CABG (Díaz et al., 1998; Furnary et al., 2003; Malmberg et al., 1996). Anatomical, physiologic and metabolic dysfunctions that affect individuals with diabetes are antecedent to diabetes complications, and are risk factors for severe CAD and for adverse short-and long-term outcomes of CABG and PCI.

On-pump and Off-pump CABG Outcomes

Although research has not quantified the proportion of adverse outcomes attributable to use of the cardiopulmonary machine, there is evidence that patients having the on-pump procedure may be more likely to have complications, including postoperative stroke, renal failure, and mortality (Chen-Scarabelli, 2002). The in-hospital mortality rate after on-pump CABG in patients aged 45 and older is between 3.5% to 4.3%, a risk that is influenced by comorbidities, and perioperative and postoperative morbidities (Holmes, Kozak, & Owings, 2007). For example, the mortality risk was twenty times greater for CABG patients who had acute renal failure that required hemodialysis compared to those without acute renal failure (Conlon et al., 1999). Similarly, stroke following on-pump CABG surgery is a serious complication associated with mortality (McKhann et al., 2002; Stamou, et al., 2001). Further, hemodynamic changes due to cardiopulmonary bypass make the kidney susceptible to embolic damage and renal failure (Baker, Andrew, & Knight, 2001).

On-pump and Off-pump Outcomes and Diabetes

Diabetes is an independent risk factor for CAD. It accelerates the progression of CAD, and coronary artery stenosis, often making patients with diabetes candidates for

coronary revascularization (Barsness, et al., 2005). The interest in off-pump CABG has grown because of its potential to minimize the risks associated with the bypass process. The majority of CABG procedures are performed using the on-pump technique because there is still a debate on the superiority of off-pump over on-pump CABG, although some studies have suggested that patients with certain risk factors are likely to have better outcomes with off-pump CABG (Ascione et al., 2002; D'Ancona et al., 2003; Newman et al., 1996). These risk factors include advanced age, comorbid diabetes, and left ventricular dysfunction (Puskas, et al., 2005). Patients with diabetes are considered high-risk because CAD in patients with diabetes is more diffuse, involves multiple vessels, and often results in more severely occluded vessels with more rupture prone plaques (Cariou, et al., 2000; Ledru, et al., 2001; Moreno et al., 2000). In addition, metabolic and hematologic abnormalities, such as platelet aggregation and poor creatinine clearance, elevate the risks for complications and adverse events (Reeder, et al., 2002).

Considering these risk factors, patients with diabetes may benefit from the off-pump CABG strategy compared to on-pump CABG (Puskas, et al., 2005). However, results from a small number of studies that have examined the efficacy of off-pump CABG for individuals with diabetes are mixed and inconclusive (Magee et al., 2001; Srinivasan, Grayson, & Fabri, 2004). In a prospective study using the Society of Thoracic Surgeons (STS) database, including 2,891 patients with diabetes who had CABG, the off-pump procedure was not associated with lower mortality among those with diabetes; patients without diabetes did have lower mortality with off-pump CABG than those with diabetes (Magee, et al., 2001). Similarly, in a recent study examining outcomes of off-pump and on-pump CABG in patients with diabetes, there was no

reduction in mortality for those undergoing the off-pump procedure; however, those with the off-pump procedure had significantly shorter length of stay, fewer blood transfusions, and less postoperative stroke (Srinivasan, et al., 2004). Srinivasan and colleagues suggested that the lack of a significant association between the CABG procedure used and mortality may have been due to inadequate statistical power. They also suggested that unmeasured factors, such as staffing issues and hospital characteristics, may have contributed to the results. In addition, effects of comorbid complications of diabetes such as uncontrolled diabetes, retinopathy and nephropathy were not assessed, although studies have suggested these complications as risk factors for morbidity and mortality after coronary revascularization (Jones et al., 2008; Ono et al., 2006). Patients with diabetes complications are a high-risk group that may benefit from off-pump CABG (Abraham et al., 2001; Magee, et al., 2001).

Coronary Revascularization and Readmissions

Outcomes of coronary revascularization have been widely studied due in part to the complexity of the procedures, the volume, costs, and the characteristics of patients who are often candidates for revascularization. Revascularization outcomes are evaluated to identify risks, to minimize adverse events, and to improve quality of care. While considerable efforts have been devoted to outcomes such as mortality, morbidity, and the need for repeat revascularization, research on readmission is limited. Most prior research on readmissions related to coronary revascularization has focused on patients having CABG. Very few studies have examined readmissions following PCI, although the number of PCIs in the U.S. is growing (Smith, et al., 2006).

Readmission rates vary by time interval, with readmission risk increasing with time following the index hospitalization. The rate of 30-days readmission after discharge for CABG was 16% and the rate for 60-days readmission was 18% (Cowper et al., 1997; Stewart, et al., 2000). In contrast, the rate of readmission for PCI patients was 14.6% after 30 days of discharge, and 48% after one year (Curtis, et al., 2009; Halon, Rennert, Flugelman, Jaffe, & Lewis, 2002).

Although readmission rates vary due to the heterogeneity of patients and their measured and unmeasured risk profiles, studies have suggested some factors that are consistently associated with readmissions. These factors include older age, multiple comorbidities, diabetes, illness severity, being female, being African American, and having surgical complications (Beggs, Birkemeyer, Nugent, Dacey, & O'Connor, 1996; Ferraris, Ferraris, Harmon, & Evans, 2001; Hannan, et al., 2003; Slamowicz, et al., 2008; Stewart, et al., 2000). In a follow-up study of patients who had isolated primary CABG, the risk of readmissions was 22% greater for those with diabetes and only 12% greater for others (Stewart, et al., 2000). Further, among low-risk CABG patients, 28% of those with diabetes were readmitted, compared to 21% of others (Sun, et al., 2008). The association of diabetes with readmissions has also been found for PCI patients (Curtis, et al., 2009), especially those with sub-optimal glycemic control (Corpus et al., 2004; Moss, Klein, & Klein, 1999).

Post-discharge care may also influence readmission. Increasingly, patients are discharged to transitional care facilities to reduce inpatient care costs. Facilities providing transitional care include special units within the hospital, post-acute skilled nursing facilities, intermediate care facility and rehabilitation facility (AGS, 2007; Naylor

& Keating, 2008; Naylor, 2006). From 1990-1998 CABG discharge from a medical center to transitional care increased by 40%, discharges with home cares services increased by 32%, and discharge to home without home care decreased by 42% (Lazar et al., 2001). While studies have suggested that readmission rates from transitional care are high (Bini et al., 2010; Nasraway, Button, Rand, Hudson-Jinks, & Gustafson, 2000), few studies have assessed whether discharge to these facilities is associated with readmissions among revascularization patients.

Gaps in the Literature

The literature review highlights the need for more research to address why patients with diabetes are more likely to have adverse outcomes following coronary revascularization. The few studies that reported differences in outcomes between patients with diabetes and those without diabetes after coronary revascularization often lack statistical power (Banning et al., 2010; Jacobs et al., 1998) or did not examine the effect of comorbid diabetes complications (Clough et al., 2002; Mathew et al., 2004). Characteristics of patients included in the sample in a number of studies limit the generalizability of results (Barsness et al., 1997; Niles et al., 2001). For readmissions, assessment has been in the general population of patients with diabetes (Jiang, Andrews, Stryer, & Friedman, 2005; Molina-Corona & Zonana-Nacach, 2010) or broadly among CABG or PCI patients (Curtis, et al., 2009; Hannan, et al., 2003; Stewart, et al., 2000; Sun, et al., 2008). No study has examined the association of comorbid diabetes complications on readmissions among patients with diabetes having coronary revascularization.

New Contributions of this Dissertation Research

This dissertation research focused on examining the effect of comorbid diabetes complications on poor outcomes in patients 45 years and older with diabetes having coronary revascularization. The sample was restricted to patients age 45 and older because increasing age is associated with having CABG or PCI and the risks for adverse outcomes after revascularization (Brooks, et al., 2000; Magee, Coombs, Peterson, & Mack, 2003; Vavlukis, Georgievska-Ismail, Bosevski, & Borozanov, 2006). This study's analyses examined three areas. In Chapters 3 and 4, I focused on procedural outcomes: in-hospital mortality, postoperative stroke and postoperative renal failure. In addition, Chapter 3, I compared the experience of patients with diabetes complications having CABG with having PCI. In Chapter 4, I compared the experience of patients with complications of diabetes and those without with off-pump and on-pump CABG. In Chapter 5, I focused on the association of comorbid diabetes complications and discharge disposition with 30-day readmissions.

Understanding the experience of individuals with diabetes complications after revascularization will help to identify the revascularization strategy that may offer better outcomes for patients with CAD and diabetes complications. Further, the results of these analyses will help to clarify the benefits of off-pump CABG in patients with diabetes, and to identify patient and contextual factors that are associated with adverse outcomes following CABG. In identifying predictors of readmissions for individuals with diabetes, this study will assess patient's characteristics at the time of an index coronary revascularization hospitalization that are associated with the likelihood of readmission. Moreover, this study's findings will add to the understanding of important factors to

consider when planning post-discharge care for individuals who have diabetes and revascularization procedures, and may help reduce readmissions in this high-risk group.

CHAPTER 3: ASSOCIATIONS BETWEEN DIABETES COMPLICATIONS AND ADVERSE HEALTH OUTCOMES AFTER CORONARY REVASCULARIZATION

Introduction

Heart disease care costs represent the largest single category of health spending in the United States, 8.3% of total health expenditures during 1997-2002 (Olin, 2005).

Coronary artery disease (CAD), characterized by blockages in the coronary artery due to atherosclerosis, accounts for a large proportion of spending for heart disease. Diabetes is often a comorbid condition with CAD, and increases the cost and health care burden of CAD (Lloyd-Jones, et al., 2010). Among the 25% of Medicare beneficiaries with the highest health care costs, 72% have CAD or diabetes (CBO, 2005). Older adults with CAD and diabetes are more likely to have worse outcomes after coronary revascularization (Berry, et al., 2007; Bravata, et al., 2007). Thus, it is useful to understand treatment options and care processes that are associated with better outcomes for individuals with CAD and diabetes. It is also useful to identify individual characteristics associated with adverse outcomes among patients with CAD and diabetes having revascularization. This information can help to reduce health care costs related to CAD and diabetes, reduce the burden of secondary illnesses, and improve quality of life for persons with CAD and diabetes.

Overview of Coronary Artery Disease and Diabetes

Coronary artery disease is also known as atherosclerotic heart disease because of the gradual build-up of cholesterol and plaque in the coronary artery, which causes the narrowing and blockage of arteries (Lloyd-Jones, et al., 2010). As the artery narrows, blood flow to the heart is restricted, or stopped if the artery is blocked. Often CAD is not diagnosed until a person suffers a heart attack (NHLBI, 2009b). CAD is a leading cause of mortality in the U.S. In 2006, CAD caused 425,425 deaths, representing a sixth of all deaths (Heron, et al., 2009). Across all age groups, CAD death rates were highest for Blacks and lowest for Asians (NHLBI, 2009a).

About 8% of adults age 20 and over in the United States have CAD (Pleis, et al., 2009). Among non-Hispanic Whites (hereafter Whites), the prevalence is higher among men (9.4%) than women (6.9%). Among non-Hispanic Blacks (hereafter Blacks) CAD rates are higher for women than men (8.8% versus 7.8%); this is also true among Mexican Americans (6.6% for women versus 5.3% for men) (Pleis, et al., 2009). CAD occurs at earlier ages among men than among women; the lifetime risk of developing CAD for men at age 45 is 11% higher than the comparable risk for women (Lloyd-Jones, et al., 1999). In a follow-up study of adults aged 45 to 64, the incidence of CAD per 1000 person-years was 12.9% for White men, 10.6% for Black men, 5.1% for Black women and 4.0% for White women. When CAD cases from revascularization procedures were excluded, CAD rates were higher for Black men than for White men (Jones, et al., 2002).

Although CAD mortality rates have been trending downward since 1968, the largest percentage decrease in the general U.S. population and for Whites occurred from

1999-2006. The decline was smaller for Blacks than for Whites (Heron, et al., 2009; NHLBI, 2009a). Using data from 1980-2000 representing adults ages 25 to 84, researchers quantified the decline in CAD rates that were attributable to medical and surgical treatments compared to CAD risk factors modifiable by changes in health behaviors (Ford et al., 2007). Ford et al. found that medical and surgical treatments accounted for 47% of the decrease, while changes in CAD risk factors accounted for 44% (Ford, et al., 2007). However, increases in the prevalence of obesity and diabetes in the U.S. (Mokdad, et al., 2003; Mokdad et al., 2000) offset some of the gains from improvements in risk factors such as reducing cholesterol, blood pressure, and smoking (Ford, et al., 2007).

Diabetes is a major risk factor for CAD, accelerates CAD progression (Resnick, et al., 2001), and is an indicator of worse outcomes after medical procedures (Vaccaro, et al., 2004; Zornitzki, et al., 2007). People with diabetes are more likely to have more coronary calcification than others (Oei, et al., 2004), which is a marker for heart attack and coronary death (Detrano, et al., 2008). Some studies suggest that people with CAD and diabetes are less likely to report chest pain, have more significant coronary stenosis, and more abnormal electric cardiographic measurements than those without diabetes (Cariou, et al., 2000; Ledru, et al., 2001). These differences may be due to greater microvascular vessel damage (Sobel, 2001). Although factors such as age, hypertension, gender, and hyperlipidemia are strong predictors of CHD severity, diabetes is also a major risk factor, especially among women (Natali, et al., 2000).

Coronary Revascularization

The two surgical treatments of choice for people with severe coronary artery

disease are coronary artery bypass grafts (CABG) and percutaneous coronary intervention (PCI). CABG was the only surgical treatment until Andreas Gruentzig introduced coronary angioplasty in 1977, as a non-surgical substitute for treating CAD (Smith, et al., 2001). More recently, technological advancements such as use of the drug eluting stent (DES) in PCI have improved the safety and effectiveness of PCI, leading some researchers to suggest that the two techniques may be equally effective (Bravata, et al., 2007; Smith, et al., 2001). Studies have suggested that certain patient populations experience better outcomes with CABG, and others with PCI (Eagle, et al., 2004; Smith, et al., 2001). However, there are subgroups for whom the optimal revascularization technique is less clear. For example, subgroup analyses in many trials including patients with diabetes lack information about the presence of diabetes complications; thus, the effectiveness of PCI and CABG in patients with diabetes complications is not well supported in the literature (Berry, et al., 2007).

A panel including cardiac surgeons, interventional cardiologists, and specialists rated common clinical scenarios for which patients would be better served with CABG than with PCI (Patel, Dehmer, Hirshfeld, Smith, & Spertus, 2009a). In general, CABG was rated as appropriate for patients with 3-vessel disease, left main stenosis, regardless of multi-vessel status or the presence of diabetes (Patel, et al., 2009a). PCI was viewed as being inappropriate for these patients. PCI was judged to be appropriate for patients with 2-vessel disease with left proximal anterior descending artery stenosis (Cantor, et al., 2002), again with or without diabetes. Overall, CABG was rated more favorably than PCI for individuals with diabetes (Patel, et al., 2009a). However, guidelines for the comparative effectiveness of CABG and PCI were developed with clinical evidence from

high-risk populations, studies with highly selective patients that may not represent the general population (Bourassa, 2000; Detre et al., 1999; Eagle, et al., 2004; King, 1999; King, Kosinski, Guyton, Lembo, & Weintraub, 2000; Kip, et al., 2002; Patel, et al., 2009a; Smith, et al., 2001). Furthermore, the review of randomized clinical trials and registry studies examining revascularization that included patients with diabetes conducted by Berry and colleagues (2007) highlighted limitations among many studies, including small samples of individuals with diabetes, and lack of information about glycemic control or complications of diabetes.

Revascularization Outcomes

Considerable research has evaluated long-term effects of revascularization. Much less research has examined short-term effects of revascularization. Common short-term outcomes include procedural adverse events, such as in-hospital mortality, postoperative stroke, and renal failure requiring hemodialysis. The rate of in-hospital mortality after CABG varies across studies, in part due to methodological differences (Bittner & Savitt, 2002; Ellis, et al., 1988; O'Connor, et al., 1991). Common risk factors for in-hospital mortality among CABG and PCI patients include being older or female, having a history of peripheral vascular disease or heart surgery, or having renal dysfunction, postoperative stroke, or diabetes (Gruberg, et al., 2001; Stamou, et al., 2001). Both CABG and PCI have been associated with greater risk of in-hospital mortality (Eagle, et al., 2004; Smith, et al., 2006), although some studies suggest no difference (Berry, et al., 2007; Bravata, et al., 2007).

The incidence of adverse neurological effects due to cerebral vascular accidents (CVA) ranges between 0.05% to 0.38% for PCI (Brown & Topol, 1993; Fuchs, et al.,

2002), and 0.40% to 0.80% for CABG (Breuer, et al., 1983; McKhann, et al., 1997). The wide ranges for these rates may be attributable in part to differences in the definition of CVA, or differences in study designs or research samples. The CVA definition may be restrictive, as in cerebral infarction detected by imaging techniques. Alternatively, CVA may be defined broadly to include transient ischemic attacks and loss of neurological function (McKhann, et al., 2006; Smith, et al., 2006). Stroke and renal dysfunction are sequelae of microvascular and macrovascular complications of diabetes and are major complications of coronary revascularization, particularly for individuals with compromised physiologic and metabolic status associated with diabetes complications, such as vessel shrinkage and reduced creatinine clearance (Beckman, et al., 2002; Fuchs, et al., 2002; Rosolova, et al., 2008; Schachner, et al., 2005; Vlassara, 1997). Despite the link between diabetes complications and poorer outcomes after CABG and PCI, this relationship has received little attention in prior research.

Revascularization Outcomes among Patients with Diabetes

Epidemiological evidence suggests that the physiologic and metabolic dysfunction associated with diabetes contributes to worse outcomes among individuals with diabetes and comorbid atherosclerotic disease (Nesto, 2004; Yan, et al., 2003). Chronic hyperglycemia, dyslipidemia, and vascular inflammation cause arterial dysfunction, severity of arterial stenosis, and more diffuse CAD (Nesto, 2004; Yan, et al., 2003). In addition, hyperglycemia causes glycosylation of protein, a precursor to diabetes microvascular complications (Vlassara, 1997). Hyperglycemia is also associated with platelet abnormalities, evident in a higher number of pro-coagulating platelets, a risk factor for thrombotic events (Creager, et al., 2003). Diabetic nephropathy, reduced

creatinine clearance, and proteinuria are indicators of long-term poor glycemic control, and are associated with poor short and long-term outcomes after coronary revascularization (Reeder, et al., 2002). In addition to metabolic dysfunction, studies have suggested coronary artery remodeling, where the vessel dimension compensates to changes in atherosclerotic plaque build-up (Barsness, et al., 2005). This compensation is less than optimal in individuals with diabetes (Jiménez-Quevedo, et al., 2009; Vavuranakis, et al., 1997). Coronary arteries of individuals with diabetes lack the tendency to compensate for changes caused by atherosclerosis, which is linked with vessel shrinkage, a major risk factor for restenosis and adverse cardiac events after PCI (Cantor, et al., 2002; Jiménez-Quevedo, et al., 2009; Mazeika, et al., 2003). Some studies have suggested the optimal control of blood glucose may reduce both mortality and illness severity. Several studies found a significant reduction in mortality due to strict perioperative glucose control among patients having CABG (Díaz, et al., 1998; Furnary, et al., 2003; Malmberg, et al., 1996). Anatomical, physiologic and metabolic dysfunctions that affect individuals with diabetes are antecedent to diabetes complications, and are risk factors for severe CAD and for adverse short-and long-term outcomes of CABG and PCI.

Study Contributions

Despite evidence that poorer revascularization outcomes are associated with metabolic changes resulting from suboptimal glycemic control, few research is focused on the response to revascularization procedures among individuals with diabetes complications. The present study addresses this gap in the literature and quantifies adverse outcomes of diabetes complications among patients having either CABG or PCI.

Understanding the experience of individuals with diabetes complications after revascularization will help to identify the revascularization strategy that may offer better outcomes for patients with CAD and diabetes complications. The purpose of this study is to examine the effect of diabetes complications using three measures of adverse outcomes – in-hospital mortality, postoperative stroke, and renal failure – among individuals with diabetes having CABG or PCI, using a large nationally representative hospital discharge dataset. This research was guided by two hypotheses:

Hypotheses

1: Among individuals with diabetes who have CABG or PCI, those with diabetes complications will be more likely to have one or more adverse short-term health outcomes. Adverse short-term outcomes examined in this study are in-hospital mortality, postoperative stroke, and renal failure. The rationale for this hypothesis is: (1) Macrovascular and microvascular complications of diabetes are sequelae of prolonged hyperglycemia, which is a factor in arteriosclerosis and more diffuse CAD, a characteristic associated with a poorer prognosis (Abdul-Ghani et al., 2006; Hanssen, 1997; Silva, Escobar, Collins, Ramee, & White, 1995; Stratton et al., 2000). (2) Metabolic changes due to prolonged hyperglycemia have been shown to reduce creatinine clearance, and increase proteinuria, vessel narrowing, and platelet abnormalities; all of these are indicators for poor outcomes of coronary revascularization (Jiménez-Quevedo, et al., 2009; Reeder, et al., 2002; Vavuranakis, et al., 1997). (3) Studies have also suggested an increased risk for mortality and morbidity in patients with uncontrolled diabetes and retinopathy who had coronary revascularization. (Ishihara et al., 2005; Malmberg, et al., 1996; Schmeltz et al., 2007).

2. Among individuals with diabetes complications, short-term adverse health outcomes will be less likely for those having CABG than for those having PCI. The rationale for this hypothesis is: (1) Although studies have suggested more favorable long-term outcomes with CABG over PCI, (Berry, et al., 2007) evidence supporting the benefit of CABG over PCI in reducing postoperative morbidity and mortality is mixed (Bravata, et al., 2007). (2) Narrowing of coronary vessels, a risk associated with the microvascular complications of diabetes has been suggested as a predisposing factor for adverse outcomes in angiography (Schunkert, Harrell, & Palacios, 1999). (3) Contrast-induced nephropathy is a complication of the PCI procedure and a risk factor for renal failure, especially in patients with vascular abnormalities (Marenzi et al., 2004; Rashid et al., 2004). Thus, these factors are likely to increase the risk of adverse outcomes among patients with diabetes, especially those with comorbid diabetes complications having PCI.

Design and Methods

Conceptual Framework

The framework for this study was adapted from the framework developed by Shroyer and colleagues in the Process, Structures and Outcomes of Care in Cardiac Surgery (PSOCS) study, a modified version of the Donabedian model (Donabedian, 1966; Shroyer et al., 1995). The PSOCS model has been used by a number of studies to evaluate the relationship between the dimensions of the model and cardiac surgery outcomes (Khuri et al., 1999; O'Brien et al., 2004; Rumsfeld et al., 1999). The PSOCS framework has a hierarchical set of interacting dimensions and sub-dimensions, and suggests that cardiac surgery outcomes are dependent on the interactions of the

process/structure dimensions with characteristics of patients. Figure 3.1 shows the model. The main dimensions of this framework are patient risk factors, structure, process, interval events, and outcomes. Patient risk factors are characteristics that predispose patients to experiencing adverse outcomes. Structure relates to the staffing, physical facilities and equipment, organizational system type, and oversight process. Process relates to the type, conduct of the revascularization procedure, and postoperative care. In this study, the type of cardiac surgery refers to CABG and PCI. Not all patients benefit equally from CABG or PCI (Berry, et al., 2007; Bravata, et al., 2007; Eagle, et al., 2004). However, good process of care in cardiac surgery includes treating patients with the optimal revascularization procedure, which should increase the likelihood for good outcomes (O'Keefe, Blackstone, Sergeant, & McCallister, 1998). This study postulated that the optimal revascularization procedure for patients with diabetes complications would increase their chances for better outcomes, controlling for the potential effects of patient and hospital structure on the process of care and outcomes.

Data Source

This is a cross-sectional analysis using data from the 2007 Nationwide Inpatient Sample (NIS), hospital discharge data maintained as part of the Healthcare Cost and Utilization Project (HCUP) by the Agency for Healthcare Research and Quality (AHRQ) (HCUP, 2007). The NIS is nationally representative administrative data representing all inpatient stays from a stratified 20% sample of United States community hospitals (HCUP, 2010). Many quality assurance procedures are performed on the NIS data to ensure consistent internal and external validity (HCUP, 2009). Five nested stratification variables based on the characteristics of hospitals from HCUP participating states were

used to create sampling strata; discharge sample weights were calculated as the probability of sampling within each stratum (HCUP, 2006). The NIS offers two major advantages: a) it provides a large volume of data that allows examination of sub-groups defined by ethnicity and other characteristics; and b) the data can be weighted for national representation. The NIS includes four data groups: a) de-identified inpatient discharge-level data with information about demographics, admission information, length of stay, payer information, procedures and diagnoses; b) hospital-level data on location, ownership, bed size, staffing ratio, hospital state, and teaching status; c) inpatient discharge-level data on measures of severity and comorbidity; and d) discharge-level information on diagnosis and procedure groups. This study was approved by the Institutional Review Board of University of North Carolina at Charlotte.

Study Sample

The study sample consists of hospital discharge data for patients age 45 and older with diabetes who had a CABG or PCI procedure in 2007 at U.S. community hospitals. The sample was restricted to patients age 45 and older because increasing age is associated with the use of PCI and CABG and the risks for adverse outcomes after revascularization (Brooks, et al., 2000; Magee, et al., 2003; Vavlukis, et al., 2006). In addition, 95% of PCI and CABG procedures were performed in patients age 45 and older, representing about 97% of all CABG discharges and 95% of all PCI discharges in 2007 (HCUPnet., 2010). Patients were included if their hospitalization had one of the following International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes: 36.10-36.19, 00.66, and 36.01, 36.02, 36.05-36.07 and any diagnosis codes indicating that they had diabetes, shown in Table 3.1. Patients with

diabetes who also had comorbid diabetes with renal, ophthalmic, and neurological manifestations; diabetes with peripheral circulatory disorders; uncontrolled diabetes; chronic kidney disease; or renal failure were considered to have diabetes complications. Of more than 8 million hospital discharges in the 2007 NIS database, 62,101 met the selection criteria. The sample was further restricted by excluding patients who had both CABG and PCI during hospitalization (535) (Figure 3.2).

Outcome Variables

There were three outcome variables: in-hospital mortality, postoperative renal failure requiring hemodialysis, and postoperative stroke. Postoperative renal failure was defined as acute renal failure requiring hemodialysis. Patients with renal dysfunction were identified by the presence of any of these diagnoses for acute renal failure: 584, 5840, 5845-5849 and procedure code 3995 for hemodialysis. Patients who had postoperative stroke were identified by the presence of any of the following diagnosis codes as a secondary diagnosis: 43881-43882, 43889, 4389, 4380, 43850-43853, 43830-43832, 43840-43842, 43820-43822, 43810-43812, 43819, 99702 (Chu et al., 2009).

Predictor variables

The main predictor variable of interest was diabetes complications during hospitalization. Patients with diabetes complications were identified using ICD-9-CM diagnosis codes shown in Table 3.1. Other explanatory variables included demographic characteristics, comorbidities, and hospital factors.

Patient Characteristics

Patient characteristics were categorized into demographic and clinical characteristics. Demographic characteristics were age, sex, race, median household

income, and health insurance. Table 3.2 shows the definition and coding for each variable. Clinical characteristics included admission type, comorbidities, and measures of patients' illness severity. Except for the variable for illness severity, all patient characteristic variables were coded as dichotomous variables. The referent group was the group with the lowest risk if there was evidence of relative risk from the literature; otherwise the referent group was selected to be the group with the most observations. For age, sex, admission type, and comorbidity variables the referent category was the group with the lowest risk. As listed in Table 3.2, age was categorized into the following groups: 45-54 (referent), 55-64, 65-74, and 75 and over. Elective admission was the referent group for admission type. All clinical and comorbidity variables were coded "1" if the condition was present, and '0' otherwise. Whites were the referent group for race; men for gender; those residing in Zip code areas with median household income of \$45,000 or more were the referent group for income. A disease-staging variable was computed using an algorithm based on patient's diagnoses, the stage of the principal diagnosis and the predictive scale for death, length of stay and resource use and included in the NIS database as a measure of illness severity (HCUP, 2005). This measure was analyzed as a continuous variable.

Comorbidities

Patient comorbidities were defined based on the approach used to construct the Elixhauser Comorbidity Index. The Elixhauser Comorbidity index includes 30 comorbidities and has been validated for use with administrative data (Elixhauser, Steiner, Harris, & Coffey, 1998; Friedman, Jiang, Elixhauser, & Segal, 2006; Stukenborg, Wagner, & Connors, 2001; Yan, Birman-Deych, Radford, Nilasena, & Gage,

2005). The algorithm differentiates between comorbidities and complications due to the care process by conservatively considering only secondary diagnosis unrelated to the patient assigned diagnosis-related group (DRG). A secondary diagnosis related to the DRG was considered to be a contributor to illness severity rather than a comorbid condition. For example, a patient with valve disorder with a cardiac DRG was not coded as having a valve disorder comorbidity, although it is likely that the valve disorder would contribute to her or his illness severity. For this study, separate variables for secondary diagnoses related to the DRG were created to indicate markers of illness severity. Thus, in addition to the 30 Elixhauser comorbidities, variables for illness severity were created for secondary diagnoses of congestive heart failure, valve disorder, and pulmonary disorder. Each comorbid condition was included in the analyses as a dichotomous variable, “Yes/No.” In addition, the total number of comorbid conditions for each patient was included in the multivariate analyses to adjust for potential association between increasing number of comorbidities and the outcomes.

Process Factors

The process factors included revascularization techniques, and myocardial preservation strategies are shown in Figure 3.1 (Shroyer, et al., 1995). The process variables included in the models used to determine the risk of adverse outcomes were volume of CABG procedures, volume of PCI procedures, use of DES in PCI procedure, and use of mammary artery graft in CABG procedure. According to the recommended minimum CABG and PCI volume by the Leapfrog Group, hospitals having less than 450 annual CABG cases were categorized as low-volume; those having 450 and above were categorized as high-volume. For PCI volume groups, hospitals having less than 400

annual PCI cases were categorized as low-volume; those having 400 and above were categorized as high-volume (Birkmeyer & Dimick, 2004).

Structure Factors

The measures for the structure dimension include staffing ratio, facility size, and hospital organization, which are shown in Figure 3.1 (Shroyer, et al., 1995). The variables included in the analyses were the hospital's teaching status, its location, whether it is urban or rural, the size of the hospital measured by bed size, and measures of nurse staffing. For the latter, as shown in Table 3.2, the ratio of registered nurses was defined as the percentage of registered nurses among all licensed nurses. For licensed practical nurses (LPNs), the workload ratio was defined as the LPN full time equivalents (FTEs) per 1000 adjusted inpatient days. All of these variables were coded as dummy variables except variables for staffing ratio. The variable for bed size was defined by the AHRQ, which categorized hospitals as small, medium, or large, taking into consideration the region in which the hospital was located as well the hospital's urban or rural location and its teaching status (HCUP, 2010), large hospitals were the referent category. The referent group for teaching status was teaching hospital and urban hospitals were the reference group for hospital location.

Statistical Analysis

For each subgroup, differences in characteristics for CABG and PCI patients were presented and compared using the t-test for continuous variables and chi-square statistic for categorical variables. To evaluate whether diabetes complications were associated with CABG and PCI outcomes, the proportions of outcomes were compared between individuals with diabetes who also had diabetes complications and those without diabetes

complications. Multivariate logistic regression models examined factors associated with the risks of poor health outcomes adjusting for confounders. In a two-step multivariate analysis, the propensity score approach was used to adjust for potential confounders and computed propensity-adjusted risk of adverse CABG and PCI outcomes.

The propensity score statistical approach has been widely used in studies with observational data to assess differences in outcomes of treatment options (Curtis, Hammill, Eisenstein, Kramer, & Anstrom, 2007; Li, Zhang, Liu, & Ren, 2009; Rubin, 1997). This approach is used to minimize selection bias that may have affected the assignment of patients to treatment options. For this study, patients' demographic and clinical characteristics, hospital factors, and interaction terms for age and number of comorbidities were used to build the propensity score model. The model assessed the probability of receiving CABG instead of PCI. In building the propensity score model, the goal is to include many covariates and proxies for variables that best estimate treatment assignment (D'Agostino, 2007; Rubin, 1997). Hospital state (location), CABG and PCI volume for the hospitals, hospital bed size, ratio of registered nurses to all nurses, and teaching status were included in the propensity model to adjust for hospital level effects and differences in state policy such as certificate of need (CON) that may influence CABG and PCI volume (Ho, Ross, Nallamotheu, & Krumholz, 2007). Using the inverse probability of treatment weight (IPTW) approach, a propensity score weight for CABG patients was computed as the inverse of the propensity score ($1/PS$), and for PCI patients as the inverse of 1 minus the propensity score ($1/(1-PS)$) (Curtis, et al., 2007; Hirano K, 2001; Rosenbaum PR, 1987).

All multivariate logistic regression models included the propensity score weights

and a subset of patient related covariates that included age, race gender, illness severity and the comorbidities significant in bivariate analysis (D'Agostino, 2007). Patients with end-stage renal failure were excluded from the analyses for postoperative renal failure due to their dependence on hemodialysis. All analyses included necessary adjustments for the complex survey design used to select hospitals for the NIS database, and were weighted for national representativeness. The survey procedures in SAS version 9.2 were used to estimate, means, frequencies and odds ratios (SAS Institute, Cary, NC). Model discrimination and goodness of fit were determined using c statistics and Hosmer–Lemeshow statistics, respectively. Differences and effects with $p < 0.05$ were considered to be statistically significant.

Results

Patient Characteristics

The weighted frequencies of the study sample are reported in Table 3.3. Overall, in-hospital mortality rate was 1.60%; postoperative stroke was 1.24%; renal failure was 0.55%. Of the 61,566 hospitalizations for patients with diabetes who had CABG or PCI, 12,979 had diabetes complications, 21.2% of the weighted sample; 48,587 did not have diabetes complications, 78.8% of the weighted sample. PCI was the most common revascularization procedure, 71.7% of the weighted sample. Men were 63.2% of the weighted sample. Those between age 55 and 74 represented about 62.4% of the total population. Patients who were Whites represented 55.3%, Blacks 7.5%, Hispanics 7.5%, and Asians/Pacific Islanders 2.1%.

Unadjusted Results for Patient Characteristics

Unadjusted results of differences in patient characteristics for those with and

without diabetes complications are reported in the data columns at the left of Table 3.4. The table also shows differences between the characteristics of CABG patients compared to those of PCI patients. Compared to those without diabetes complications, those who had diabetes complications were more likely to have indicators of illness severity: significantly, higher mean stage of illness (4.6 compared with 4.4, $p < .0001$) and more severe cardiac related comorbidities (all $p < .0001$). The proportion of patients with diabetes complications was highest for those 75 and older than those in other race groups. Although Whites represented more than half of the study sample, individuals in minority ethnic groups were more likely to have diabetes complications.

Turning to differences in results associated with revascularization strategies, compared to PCI patients, CABG patients were more likely to have higher mean stage of illness and more than two comorbidities. Men were more likely to have CABG, whereas women were more likely to have PCI. Patients having PCI were substantially more likely to have had a previous CABG (9.0% vs. 1.3%, $p < .0001$) and previous PCI (18.6% vs. 10.3%, $p < .000$) than patients having CABG. They were also more likely to have emergency admissions (34.8% vs. 21.7, $p < .0001$). Health insurance and ethnicity did not differ significantly for patients selected for CABG compared to PCI. Only Blacks had substantially higher proportions of patients having PCI compared to CABG (8.2% vs. 5.8%).

Unadjusted Results for In-Hospital Mortality, Renal Failure, and Stroke

Table 3.5 shows descriptive results for the three adverse outcome measures for patients with and without diabetes complications and for patients having CABG or PCI. Unadjusted percentages of patients affected by all three adverse outcomes were

significantly higher for patients with diabetes complications than for those without complications: for in-hospital mortality 2.20 versus 0.98 ($p < .0001$); for post-operative stroke 2.44 versus 1.38 ($p < .0001$); for post-operative renal failure 1.18 versus 0.12 ($p < .0001$). Similarly, unadjusted rates for all three adverse outcomes were higher for patients having CABG compared with those having PCI: in-hospital mortality 1.66 versus 1.07 ($p < .0001$), post-operative stroke 2.66 versus 1.18 ($p < .0001$); post-operative renal failure 0.55 versus 0.10 ($p < .0001$).

Patient Characteristics Associated with Adverse Health Outcomes

The adjusted results of factors associated with the odds of adverse outcomes are presented in Table 3.6. For each result, the table shows the odds ratio (OR), 95% confidence interval (CI), and p-value. The propensity-adjusted results for factors associated with adverse outcomes for patients with diabetes showed that for in-hospital mortality, women had 25% greater odds of in-hospital death (OR 1.25, CI 1.06-1.47). Patients with diabetes complications had 62% greater odds of in-hospital death than those without complications (OR 1.62, CI 1.37-1.91). The odds of in-hospital mortality increased with age. Compared to those ages 45 to 54, those who were 74 years and older had 186% higher odds of in-hospital death (OR 2.86, CI 2.08-3.93); those in the 65-74 age group had 66% higher odds (OR 1.66, CI 1.20-2.29). Congestive heart failure ($p < .0001$), coagulopathy ($p < .0001$), and electrolyte disorder ($p < .0001$), were all significant predictors of in-hospital mortality. Compared to hospitals with high PCI volume, the odds of in-hospital mortality were 37% higher for patients in hospitals with low PCI volume (OR 1.37, CI 1.13-1.67). Compared to PCI, CABG was associated with substantially lower odds of in-hospital death (OR 0.42, CI 0.34-0.57).

Factors predictive of postoperative stroke risk included a CABG procedure (OR 1.58, CI 1.33-1.89), and increasing age. Each additional increase in the number of comorbidities increased the odds of postoperative stroke by 60% (OR 1.60, CI 1.49-1.72). Compared with Whites, individuals in the three ethnic minority groups had higher odds of having a stroke: Blacks (OR 1.61, CI 1.28-2.03), Hispanics (OR 1.55, CI 1.20-1.99), and Asians/Pacific Islanders (OR 1.87, CI 1.16-2.99). Having diabetes complications was not associated with a greater likelihood of postoperative stroke.

Diabetes complications were significantly associated with renal dysfunction (OR 3.03, CI 1.71-5.39). This was also the case with comorbid coagulopathy (OR 1.89, CI 1.10-3.25) and electrolyte disorder (OR 2.58, CI 1.48-4.52). Demographic factors were not significant predictors.

Adjusted Results for Effects of Diabetes Complications on CABG and PCI Outcomes

The adjusted results for the likelihood of adverse outcomes for patients with diabetes complications having PCI or CABG are shown in Table 3.7. Patients with diabetes complications had significantly higher odds of in-hospital mortality than those without complications with either CABG (OR 1.60, CI 1.22-2.10) or PCI (OR 1.59, CI 1.27-1.99). Although patients with diabetes complications also had significantly higher odds of renal failure with PCI and CABG, their risk with PCI (OR 4.27, CI 1.60-11.42) was much higher. Diabetes complications were not associated with postoperative stroke for either CABG or PCI.

Discussion

Given the large volume of revascularization procedures in the United States, it is useful to identify patient demographic and clinical characteristics associated with adverse

outcomes. Doing so may help identify patients who may be best served with CABG or PCI (Patel, et al., 2009b). Although both CABG and PCI are effective for treating coronary artery disease, not all patients have equal experience with CABG and PCI (Berry, et al., 2007; Bravata, et al., 2007). To better clarify the relative effectiveness of CABG and PCI, more research is needed on patient subgroups. However, this has been a challenge in most randomized control trials, which are often limited by inadequate statistical power and strict criteria for selecting patients. Using a large administrative dataset from United States community hospitals and focusing on patients with diabetes, this study examined how outcomes differ for patients with diabetes complications after coronary revascularizations. Further, using the PSOCs conceptual framework to guide the analyses, risk adjustment included patient characteristics, and factors for the process and structure of care. Adjusting for process and hospital factors that may influence outcomes minimized the potential for “lack of robustness of risk-adjustment,” a limitation often associated with the use of administrative data (DesHarnais, McMahon, Wroblewski, & Hogan, 1990; Iezzoni, Shwartz, Ash, Mackiernan, & Hotchkin, 1994).

This study tested two hypotheses. The first hypothesis was that patients with diabetes complications would have a higher likelihood of in-hospital mortality, postoperative stroke and renal failure than those without diabetes complications. The adjusted results provided partial support for this expectation: patients with diabetes complications had a higher likelihood of in-hospital mortality and renal failure (Jones, et al., 2008; Kim et al., 2002; Ono et al., 2002). However, for postoperative stroke, those with diabetes complications did not experience significantly worse outcomes than those without such complications. In contrast with prior studies that compared differences

between patients with diabetes and those without diabetes, this study focused on those with diabetes, comparing outcomes for those with and without diabetes complications. As a result, those having CABG or PCI in this study may have been similar in some characteristics that influenced the outcome for postoperative stroke. For example, they may have had similar hyperglycemia thresholds, which were not evaluated in this study (Puskas et al., 2007; Voll & Auer, 1991).

There was partial support for the second hypothesis, that individuals with diabetes complications would have better outcomes with CABG than with PCI. Among patients with diabetes complications, those having PCI were substantially more likely to have renal failure than those having CABG. Diabetes complications were associated with 60% higher odds of in-hospital mortality with CABG and 59% with PCI, suggesting a similar experience with both revascularization procedures. The risk of postoperative stroke did not differ between CABG and PCI.

Although there is little guidance from randomized trials on the experience of patients with diabetes complications with CABG compared to PCI, consistent with the expectation of this study, observational studies have suggested an advantage for CABG over PCI for patients with retinopathy and strong indications for renal dysfunctions after PCI (Marenzi, et al., 2004; Ohno et al., 2006). In addition, observational studies examining effects of diabetes complications such as hyperglycemia and retinopathy on revascularization outcomes have found associations between both complications and in-hospital mortality, which are consistent with the results of the present study (Jones, et al., 2008; Ono, et al., 2006).

Overall, the findings of this study suggest that patients with diabetes

complications may be more susceptible to adverse outcomes after coronary revascularization, particularly in-hospital death and renal failure. The results also suggest that their likelihood of having renal failure is higher with PCI than with CABG. Thus, more attention should be given to patients who have diabetes complications during hospitalizations involving PCI or CABG. To better clarify the benefits of CABG and PCI for patients with diabetes complications, future randomized controlled trials examining the comparative effectiveness of CABG and PCI in patients with diabetes should also focus on patients with diabetes complications. Nevertheless, the finding in this study of a higher risk for renal failure for PCI than for CABG is useful, particularly because the patients who had renal failure following PCI or CABG were not identified as having comorbid renal failure prior to the procedure.

The main strength of this study comes from using a large nationally representative hospital discharge database, which allowed the evaluation of adverse post-operative outcomes that occur with relatively low frequency. The large dataset allowed us to compare the experiences of patients with and without diabetes complications. The database also included measures of illness severity and comorbidities, which permitted risk adjustment. Randomized controlled trials often adopt restrictive selection criteria, rely on registry data, or include a small number of hospitals. In contrast, this study used a representative sample of United States community hospitals. The NIS is weighted to represent all hospitalizations in the United States. Thus, the results can be generalized.

Several study limitations are acknowledged. The study relied on administrative data that have limited clinical details. For example, the effect of ejection fraction, left main disease status and other clinical measures could not be evaluated. However,

information about several secondary diagnoses was available for assessing the likelihood of poor outcomes. Outcomes and predictor variables were determined from diagnosis codes. If there is systematic error in coding and reporting, the results of the study may be biased. The NIS database has been extensively validated by AHRQ; further, potential coding errors are likely to affect both groups equally (Chu, et al., 2009). In addition, data on physician experience and practice preferences were not available; such factors may introduce unmeasured selection bias. To minimize this potential bias, the propensity score representing each patient's probability of receiving CABG instead of PCI was computed, using patient clinical and demographic characteristics and hospital factors; all adjusted models included the propensity score to adjust for potential selection bias.

Implications for Policy and Practice

This study highlights the potential risks associated with diabetes complications in coronary revascularization. Specifically, for in-hospital mortality and renal dysfunction, having diabetes complications increased the risk of these outcomes. In making routine clinical decisions for coronary revascularization, patients and clinicians should consider the added risk of diabetes complications. While this study did not consistently show a beneficial advantage of CABG over PCI for patients with diabetes complications, findings suggest that PCI may be associated with renal dysfunction. Adverse renal outcomes should be considered when making decisions about revascularization options, particularly for patients with diabetes who may have diabetes complications other than chronic renal failure. Although results did not show clear benefits of CABG compared with PCI with regard to in-hospital mortality and postoperative stroke, findings suggest that regardless of the revascularization strategy, patients with diabetes complications may

have higher risks of in-hospital death. Additional research is needed to determine why patients with diabetes complications were more likely to have renal failure with PCI. As studies have indicated, contrast-induced nephropathy is a risk factor for adverse outcomes for patients with chronic renal failure. More research is needed to assess whether contrast-induced nephropathy explains the likelihood of renal failure in those having diabetes complications other than chronic renal failure.

Table 3.1: Criteria Used to Define Outcomes and Explanatory Variables

Diagnosis and Procedure	ICD-9-CM Codes ^a
Post operative stroke	4380, 43810, 43811, 43812, 43819, 43820, 43821, 43822, 43830, 43831, 43832, 43840, 43841, 43842, 43850, 43851, 43852, 43853, 43881, 43882, 43889, 4389, 99702
Post operative renal failure ^b	3995
Coronary artery bypass graft	3610, 3611, 3612, 3613, 3614, 3615, 3616, 3617, 3618, 3619
Percutaneous coronary intervention	0066, 3601, 3602, 3605, 3606, 3607
Diabetes	25000-25033, 64800-64804
Diabetes complications	25040 - 25093, 5853, 5854, 5855, 5856, 5859, 586,
Drug Eluting stent	3607
Mammary artery graft	3615, 3616
CABG history	V4581
PCI history	V4582

^aICD-9-CM _ International Classification of Diseases, 9th Revision, Clinical Modification. ^bPostoperative renal failure requiring hemodialysis; CABG= Coronary artery bypass graft; PCI= Percutaneous coronary intervention

Table 3.2: Definition of Variable and Coding^a

Variable	Definition
Gender	Men Women
Race	Non-Hispanic White Black Hispanic Asian/Pacific Islander Native American/others
Primary payer	Medicare Medicaid Private insurance Self-pay Other
Median household income ^b	\$45,000 or more \$25,000-34,999 \$35,000-44,999 \$1-24,999
Admission type	Elective Emergency Urgent
Age	45-54 55-64 65-74 74 and over
Comorbidities	Conditions diagnosed as secondary to the primary diagnosis and unrelated to the patient assigned diagnosis-related group
Disease staging measure	Determined based on illness category, the stage of principal diagnosis and the predictive scale for death and disease progression
Hospital bed size ^c	Large Medium Small
Teaching status of	Teaching Nonteaching
Hospital location ^d	Urban Rural
PCI volume ≥400 <400	All PCI procedures per hospital High volume Low volume

CABG volume	All CABG procedures per hospital
≥450	High volume
<450	Low volume
<i>Staffing</i>	
Registered nurse	Percentage of registered nurses among all licensed nurse
Licensed <i>practitioner</i> nurse	LPN FTEs per 1000 adjusted inpatient days

^aSource: Nationwide Inpatient Sample, 2007; ^bThe median household income of the patient's ZIP Code of residence; ^c See Appendix A for definition; ^dHospitals residing in counties with a CBSA type of metropolitan were considered urban, while hospitals with a CBSA type of micropolitan or non-core were classified as rural; CABG= Coronary artery bypass graft; PCI= Percutaneous coronary intervention

Table 3.3: Characteristics of Patients with Diabetes Having Revascularization Procedures in 2007^a

	n=61566	N=304480	%	95% Confidence	
				LB	UB
<i>Adverse Outcomes</i>					
Postoperative stroke	985	4869	1.6	1.44	1.76
In-hospital mortality	760	3776	1.2	1.12	1.36
Postoperative renal failure	340	1689	0.6	0.24	0.68
<i>Diabetes complications</i>					
Yes	12979	64093	21.2	21.05	21.93
No	48587	240387	78.8	78.06	79.84
<i>Admission type^b</i>					
Elective	21448	105940	34.8	31.43	38.15
Urgent	14511	73516	24.1	20.38	27.91
Emergency	18733	94663	31.1	28.37	33.81
<i>Revascularization Procedure</i>					
CABG	17442	86232	28.3	26.79	29.85
PCI	44124	218248	71.7	70.15	73.21
<i>Prior revascularization</i>					
CABG history	4226	20798	6.8	6.31	7.35
PCI history	10008	49465	16.3	15.12	17.37
<u>Demographic Characteristics</u>					
<i>Gender</i>					
Men	38932	192501	63.2	62.54	63.92
Women	22626	111943	36.8	36.08	37.46
<i>Age group</i>					
45-54	9602	47557	15.6	15.16	16.08
55-64	18668	92098	30.3	29.61	30.88
65-74	19827	97996	32.2	31.65	32.72
75 and older	13469	66830	22.0	21.24	22.66
<i>Race^b</i>					
White	33817	168347	55.3	50.53	60.05
Black	4702	22856	7.5	5.90	9.11
Hispanic	4729	22708	7.5	5.36	9.55
Asians/Pacific Islanders	1383	6488	2.1	2.00	3.59
Others	2332	11328	3.7	2.24	3.87
<i>Health Insurance</i>					
Medicare	34048	168537	55.4	53.85	56.86
Medicaid	3280	16266	5.3	4.60	6.09
Self	1954	9558	3.1	2.72	3.55
Private	20056	99253	32.6	30.98	34.22
<i>Median household income</i>					
\$1-24,999	17141	84282	27.7	24.34	31.02
\$25,000-34,999	15512	76333	25.1	22.70	27.44
\$35,000-44,999	14085	69901	23.0	20.95	24.96

Table 3.3 (Cont'd)

\$45,000 or more	13056	65218	21.4	17.22	25.62
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^aData source: 2007 Nationwide Inpatient Sample (NIS), weighted results for national representativeness. ^bPercentages may not total 100 because of missing data. CABG=Coronary artery bypass graft, PCI=Percutaneous coronary intervention. LB=lower bound, UB=upper bound. The percentages of some categories may not add to 100% due to missing data.

Table 3.4: Stratified Demographic and Clinical Characteristics of Patients With Diabetes—With and Without Diabetes Complications, and With Coronary Artery Bypass Graft (CABG) or Percutaneous Coronary Intervention (PCI), 2007^a

Variables	<u>Diabetes Complications</u>		P-value	<u>Revascularization Procedure</u>		P-value
	Yes %	No %		CABG %	PCI %	
<u>Clinical Characteristics</u>						
Mean level of illness stage ^b (SD)	4.6(0.48)	4.4(0.49)	<.0001	4.9(0.16)	4.2 (0.43)	<.0001
Illness severity						
Valve disorder	10.1	6.7	<.0001	10.6	6.2	<.0001
Severe CHF	25.0	11.7	<.0001	18.9	12.7	<.0001
Pulmonary hypertension ^c	3.0	1.6	<.0001	2.6	1.6	<.0001
Emergency admission	34.8	30.1	<.0001	21.7	34.8	<.0001
CABG history	6.7	6.9	0.6583	1.3	9.0	<.0001
PCI history	13.4	17.0	<.0001	10.3	18.6	<.0001
Number of Comorbidities						
1-2	13.3	47.8		29.4	44.9	
3-5	74.5	50.3		64.5	51.9	
6 and over	12.1	1.9		6.1	3.3	
<u>Demographic Characteristics</u>						
Gender			0.0115			<.0001
Men	62.1	63.5		68.9	61.0	
Women	37.9	36.5		31.1	39.0	
Age			<.0001			<.0001
45-54	12.9	16.3		13.4	16.5	
55-64	28.2	30.8		30.7	30.1	
65-74	32.4	32.1		34.6	31.3	
75 and older	26.5	20.7		21.4	22.2	
Race			<.0001			<.0001
White	53.2	55.9		55.9	55.0	
Black	9.9	6.9		5.8	8.2	
Hispanic	8.2	7.3		7.8	7.3	
Asians/Pacific Islanders	2.5	2.2		2.3	2.1	
Other	3.6	3.8		3.8	3.7	
Health Insurance			<.0001			<.0001
Medicare	64.7	52.9		54.7	55.8	
Medicaid	5.8	5.2		5.3	5.4	
Private Insurance	24.7	34.7		33.5	32.3	
Self pay	1.9	3.5		2.9	3.3	
Median household income			0.7814			0.0988
\$1-24,999	28.4	28.7		26.8	29.2	
\$25,000-34,999	25.8	26.0		26.6	25.5	
\$35,000-44,999	23.6	23.8		24.5	23.3	
\$45,000 or more	22.2	21.4		22.1	22.0	

Table 3.4 (Cont'd)

^aData source: 2007 Nationwide Inpatient Sample (NIS); SD=standard deviation; CABG=Coronary artery bypass graft; PCI=Percutaneous coronary intervention; CHF=Congestive heart failure; ^bMean and standard deviation; ^cIncludes those with pulmonary embolism.

Table 3.5: Description of Poor Health Outcomes for Patients with Diabetes after Coronary Revascularization in 2007^a

Outcomes	Diabetes Complications			Revascularization Strategy		
	Yes %	No %	P-value	CABG %	PCI %	P-value
In-hospital mortality	2.20	0.98	<.0001	1.66	1.07	<.0001
Post operative stroke	2.44	1.38	<.0001	2.66	1.18	<.0001
Post operative renal failure	1.18	0.12	<.0001	0.55	0.10	<.0001

^a Data source: 2007 Nationwide Inpatient Sample (NIS). CABG= Coronary artery bypass graft, PCI= Percutanenous coronary intervention.

Table 3.6: Propensity Adjusted Risks for Poor Health Outcomes for Patients with Diabetes, 2007^a

Risk Factors	In-hospital mortality			Postoperative Stroke			Postoperative renal failure		
	OR	95% CI	P-value	OR	95% CI	P-value	OR	95% CI	P-value
<i>Gender</i>									
Women	1.25	1.06-1.47	**	0.96	0.84-1.10		0.75	0.45-1.23	
<i>Revascularization Strategy</i>									
CABG	0.42	0.34-0.57	***	1.59	1.29-1.90	***	1.73	0.98-3.064	
<i>Diabetes complications</i>									
Yes	1.62	1.37-1.91	***	0.99	0.85-1.16		3.03	1.71-5.39	***
<i>Age group</i>									
55-64	1.17	0.83-1.66		1.31	1.02-1.66	*	0.78	0.45-1.23	
65-74	1.66	1.20-2.29	***	1.58	1.23-2.04	***	0.78	0.41-1.50	
>74	2.86	2.08-3.93	***	1.68	1.30-2.17	***	1.00	0.52-1.94	
<i>Race</i>									
Black	0.83	0.60-1.16		1.61	1.28-2.03	***	1.77	0.84-3.77	
Hispanic	0.96	0.74-1.24		1.55	1.20-1.99	***	2.35	1.23-4.46	**
Asians/Pacific Islanders	1.00	0.57-1.57		1.87	1.16-2.99	*	1.56	0.32-7.73	
Others	0.93	0.63-1.38		1.46	1.01-2.11	*	1.49	0.52-4.28	
<i>CABG Volume</i>									
< 450 (Low)	1.11	0.83-1.48		0.83	0.61-1.11		0.94	0.52-1.69	
<i>PCI Volume</i>									
< 400 (Low)	1.37	1.13-1.67	***	1.05	0.87-1.27		1.06	0.61-1.84	
Number of comorbidities	0.90	0.82-0.98	*	1.60	1.49-1.73	***	0.95	0.74-1.21	
Congestive heart Failure	2.14	1.81-2.53	***	1.17	0.97-1.41		1.93	1.12-2.88	
Coagulopathy	2.08	1.55-2.78	***	0.49	0.36-0.68	***	1.89	1.10-3.25	***
Electrolyte disorder	3.28	2.68-4.02	***	0.59	0.47-0.73	***	2.58	1.48-4.52	***

Table 3.6 (Cont' d)

^a Data source: 2007 Nationwide Inpatient Sample (NIS). Reference categories: men, PCI, without diabetes complications, ages 45-54, Whites, high volume (\geq 450 CABG cases), high volume (\geq 400 PCI cases), CABG= Coronary artery bypass graft, PCI= Percutaneous coronary intervention. * $p<.05$, ** $p<.01$, *** $p<.001$.

Table 3.7: Comparison of Risks for Poor Outcomes Associated with Diabetes Complications for CABG and PCI, 2007^a

<u>Outcomes</u>	<u>Revascularization strategy</u>	<u>Odds Ratio^b</u>	<u>95% CI</u>	<u>P-value</u>
In-hospital mortality	CABG	1.60	1.22-2.10	<.0001
	PCI	1.59	1.27-1.99	<.0001
Postoperative Stroke	CABG	0.96	0.77-1.21	0.7223
	PCI	0.98	0.80-1.22	0.8836
Post operative renal failure	CABG	2.25	1.10-4.69	0.0311
	PCI	4.27	1.60-11.42	0.0038

^a Data source: 2007 Nationwide Inpatient Sample (NIS).

^b Models for each outcome included adjustment for illness severity, age, race, propensity score, use of drug eluting stent in PCI and the use of mammary artery graft in CABG. CABG=Coronary artery bypass graft, PCI= Percutaneous coronary intervention; CI=Confidence Interval.

Figure 3.1: Graphical Representation of Conceptual Model: from Shroyer et al., 1995

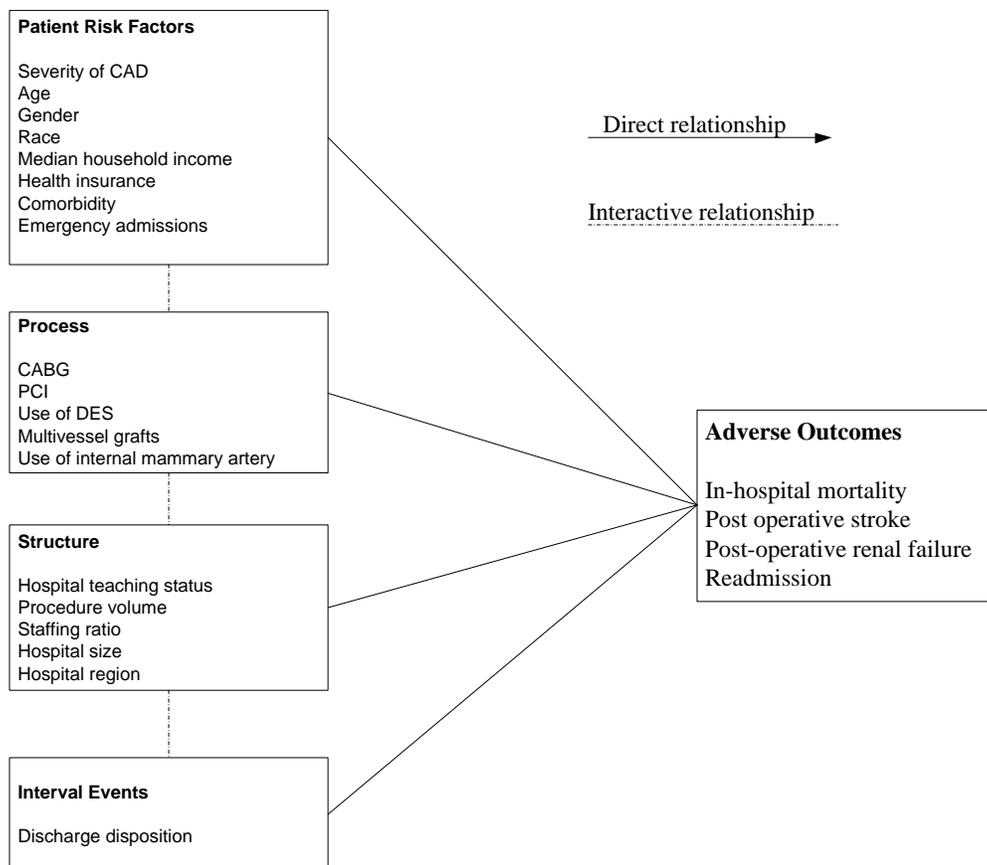
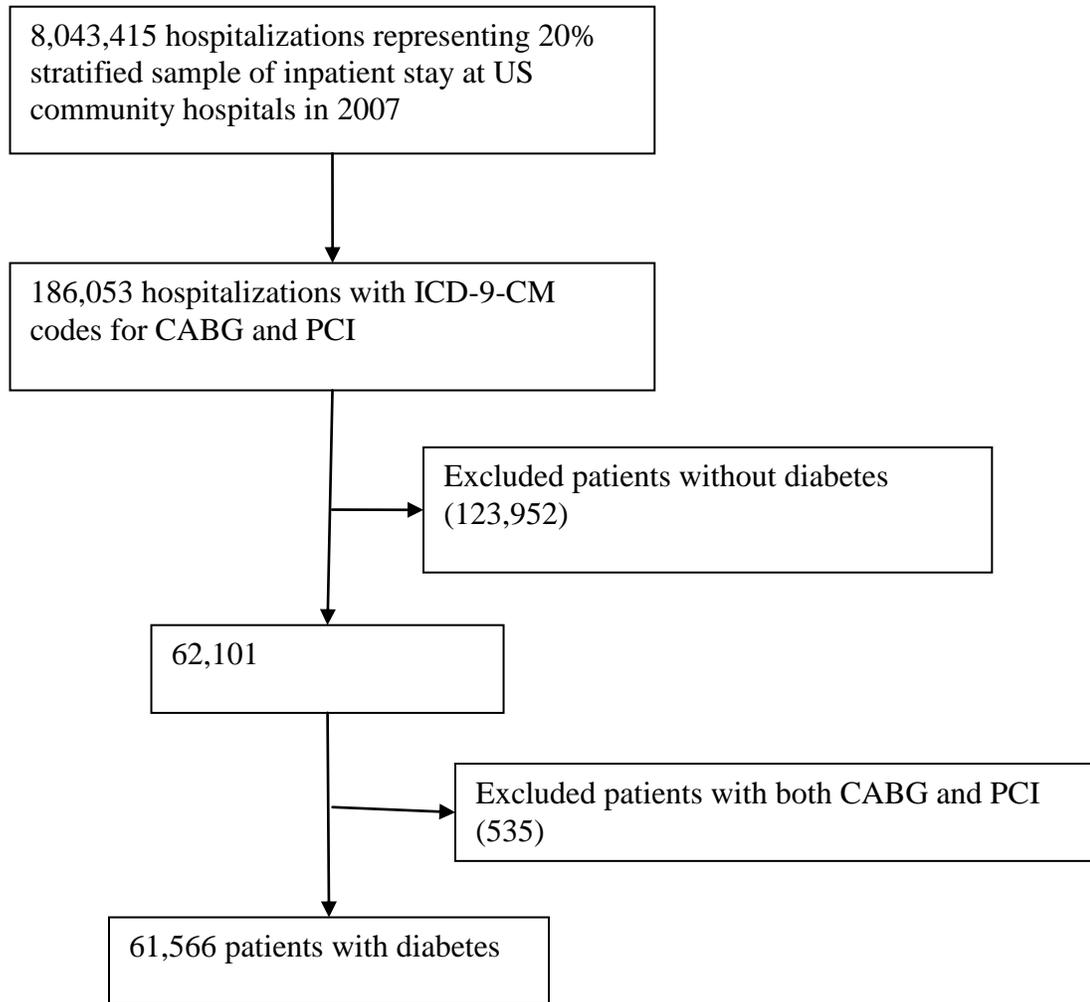


Figure 3.2: Sample Selection of Patients with Diabetes Having Coronary Revascularization in 2007



CHAPTER 4: OFF-PUMP CORONARY ARTERY BYPASS OUTCOMES IN PATIENTS WITH DIABETES AND DIABETES COMPLICATIONS

Introduction

Historically, on-pump coronary artery bypass graft (CABG) was the established treatment for atherosclerotic heart disease. Its beneficial effect on survival and overall quality of life, especially in patients with severe coronary artery disease (CAD), is well documented (Eagle, et al., 2004; Hunt, et al., 2000; Sjoland, et al., 1997). Nevertheless, some complications associated with the on-pump CABG procedure remain a concern. As a result, the use of off-pump CABG as an alternative to on-pump CABG attracted much interest because of its potential to minimize the complications and morbidity risks associated with the on-pump CABG technique (Cleveland, Shroyer, Chen, Peterson, & Grover, 2001; Plomondon et al., 2001). In general, studies show a trend toward off-pump CABG benefits over on-pump CABG in high-risk patients who are older and have multiple comorbidities (Chamberlain, Ascione, Reeves, & Angelini, 2002; Meharwal et al., 2002). However, the enthusiasm for off-pump CABG is tempered by inconsistent evidence of its advantages over on-pump CABG in reducing perioperative complications, ensuring patency of graft in the long-term, and reducing mortality (Parolari et al., 2003; Parolari et al., 2005; Patel, Patel, Loulmet, McCabe, & Subramanian, 2004).

CAD in persons with diabetes progresses rapidly, and is often more severe and diffuse. Outcomes after coronary revascularization are often worse among individuals with diabetes compared to those without diabetes (Flaherty & Davidson, 2005; Nesto, 2004). Despite the fact that individuals with diabetes are in a high-risk group, studies have not shown differences for people in this group for off-pump compared with on-pump CABG (Magee, et al., 2001; Srinivasan, et al., 2004). Diabetes complications are indicative of vascular abnormalities caused by metabolic changes due to hyperglycemia (Beckman, et al., 2002). Individuals with comorbid diabetes complications may benefit from off-pump CABG because of their elevated risk. However, the relative efficacy of off-pump CABG compared to on-pump CABG in individuals with diabetes complications has not been evaluated. Using a large, nationally representative sample of patients with diabetes, the goal of this study is to compare the relative effectiveness of off-pump and on-pump CABG strategies among individuals with and without diabetes complications. The findings can help to inform clinical decision making about CABG strategies that may be better for individuals with diabetes.

Overview of Coronary Artery Bypass Graft

The development of CABG fundamentally changed the treatment of atherosclerotic heart disease. It is the established technique for coronary revascularization in patients with severe coronary artery disease (Eagle, et al., 2004; Patel, et al., 2009b). The conventional CABG technique entails stopping the heart and using the cardiopulmonary machine to supply blood to the rest of the body during surgery (Shekar, 2006). Studies suggested that the use of cardiopulmonary bypass creates an inflammatory response as the blood circulates through the bypass circuit, which increases

the risks of perioperative and postoperative complications in on-pump CABG surgery (Day & Taylor, 2005). To reduce these risks, off-pump CABG avoids using cardiopulmonary bypass by performing the procedure on a beating heart. While off-pump CABG eliminates the risks associated with cardiopulmonary bypass, without cardioplegia the constant motion of the heart can jeopardize graft patency. In addition, there is concern for higher risks of adverse outcomes for patients who begin off-pump CABG, but who must be converted to the on-pump procedure (Li et al., 2008). Clearly, both CABG techniques have associated risks. Recommendations from the International Society for Minimally Invasive Cardiothoracic Surgery indicate equivalent perioperative morbidity and mortality for on-pump and off-pump CABG; however, the recommendations suggest a preference for off-pump CABG for high-risk patients, including patients with diabetes (Puskas, et al., 2005). The review conducted by the International Society for Minimally Invasive Cardiothoracic Surgery suggests lower morbidity for off-pump compared with on-pump CABG among patients with diabetes (Puskas, et al., 2005).

On-pump and Off-pump CABG outcomes

Although research has not quantified the proportion of adverse outcomes attributable to use of the cardiopulmonary machine, there is evidence that patients having the on-pump procedure may be more likely to have complications, including postoperative stroke, renal failure, and mortality (Chen-Scarabelli, 2002). The in-hospital mortality rate after on-pump CABG in patients aged 45 and older is between 3.5% to 4.3%, a risk that is influenced by comorbidities, and perioperative and postoperative morbidities (Holmes, et al., 2007). For example, the mortality risk was twenty times

greater for CABG patients who had acute renal failure that required hemodialysis compared to those without acute renal failure (Conlon, et al., 1999). Similarly, stroke following on-pump CABG surgery is a serious complication associated with mortality (McKhann, et al., 2002; Stamou, et al., 2001). Further, hemodynamic changes due to cardiopulmonary bypass make the kidney susceptible to embolic damage and renal failure (Baker, et al., 2001).

CABG Strategies and Diabetes

Diabetes is an independent risk factor for CAD. It accelerates the progression of CAD, and coronary artery stenosis, often making patients with diabetes candidates for coronary revascularization (Barsness, et al., 2005). The interest in off-pump CABG has grown because of its potential to minimize the risks associated with the bypass process. The majority of CABG procedures are performed using the on-pump technique because there is still a debate on the superiority of off-pump over on-pump CABG, although some studies have suggested that patients with certain risk factors are likely to have better outcomes with off-pump CABG (Ascione, et al., 2002; D'Ancona, et al., 2003; Newman, et al., 1996). These risk factors include advanced age, comorbid diabetes, and left ventricular dysfunction (Puskas, et al., 2005). Patients with diabetes are considered high-risk because CAD in patients with diabetes is more diffuse, involves multiple vessels, and often results in more severely occluded vessels with more rupture prone plaques (Cariou, et al., 2000; Ledru, et al., 2001; Moreno, et al., 2000). In addition, metabolic and hematologic abnormalities, such as platelet aggregation and poor creatinine clearance, elevate the risks for complications and adverse events (Reeder, et al., 2002).

Considering these risk factors, patients with diabetes may benefit from the off-

pump CABG strategy compared to on-pump CABG (Puskas, et al., 2005). However, results from a small number of studies that have examined the efficacy of off-pump CABG for individuals with diabetes are mixed and inconclusive (Magee, et al., 2001; Srinivasan, et al., 2004). In a prospective study using the Society of Thoracic Surgeons (STS) database, including 2,891 patients with diabetes who had CABG, the off-pump procedure was not associated with lower mortality among those with diabetes; patients without diabetes did have lower mortality with off-pump CABG than those with diabetes (Magee, et al., 2001). Similarly, in a recent study examining outcomes of off-pump and on-pump CABG in patients with diabetes, there was no reduction in mortality for those undergoing the off-pump procedure; however, those with the off-pump procedure had significantly shorter length of stay, fewer blood transfusions, and less postoperative stroke (Srinivasan, et al., 2004). Srinivasan and colleagues suggested that the lack of a significant association between the CABG procedure used and mortality may have been due to inadequate statistical power. They also suggested that unmeasured factors, such as staffing issues and hospital characteristics, may have contributed to the results. In addition, effects of comorbid complications of diabetes such as uncontrolled diabetes, retinopathy and nephropathy were not assessed, although studies have suggested these complications as risk factors for morbidity and mortality after coronary revascularization (Jones, et al., 2008; Ono, et al., 2006). Patients with diabetes complications are a high-risk group that may benefit from off-pump CABG (Abraham, et al., 2001; Magee, et al., 2001).

Research Objectives

The objective of this study is to compare three outcomes for patients with diabetes

who underwent off-pump or on-pump CABG: in-hospital mortality, postoperative stroke, and postoperative renal failure. A related study objective is to determine patient and hospital characteristics associated with off-pump CABG outcomes, and to examine contextual factors that may be associated with outcomes for patients with comorbid diabetes complications. The results of these analyses will help to further clarify the benefits of off-pump CABG in patients with diabetes, and to identify patient and hospital characteristics that are associated with adverse outcomes following CABG. The literature supports three hypotheses.

Hypotheses

1. Compared with on-pump CABG, the off-pump procedure will be associated with lower in-hospital mortality, postoperative stroke, and postoperative renal failure.

The use of off-pump CABG is based on its potential reduction of adverse outcomes, especially in high risk patients (Bucerius et al., 2004; Puskas, et al., 2005; Puskas et al., 2009). Although evidence supporting these beneficial effects in high risk patients is mixed, and varies with the sample studied (Racz et al., 2004; Shroyer, et al., 2009; Yokoyama et al., 2000), some studies support a trend for improved outcomes with off-pump CABG in patients with diabetes (Abraham, et al., 2001; Magee, et al., 2001; Srinivasan, et al., 2004). Thus, my expectation is that among patients with diabetes having CABG, those with the off-pump procedure will have fewer adverse outcomes than those with the on-pump procedure.

2. Teaching hospitals will have fewer poor CABG outcomes.

Research on quality of care suggests teaching hospitals provide care of better quality and have more favorable outcomes, perhaps because the level of expertise, adequacy of

staffing and volume of surgical procedures are all higher in teaching hospitals than in non-teaching hospitals (Allison et al., 2000; Ayanian, Weissman, Chasan-Taber, & Epstein, 1998; Taylor, Whellan, & Sloan, 1999). Although evidence on the comparative benefit of teaching hospitals to non-teaching hospitals on outcomes is mixed (Kuhn, Hartz, Krakauer, Bailey, & Rimm, 1994; Simunovic et al., 2000), large volume hospitals for CABG are often teaching hospitals (Ross et al., 2010); adherence to standard care processes such as aspirin, ACE inhibitors and β blockers at discharge, is higher in teaching hospitals (Allison, et al., 2000). Teaching hospitals may better manage complications, which may result in fewer adverse outcomes (Polanczyk et al., 2002; Silber et al., 2009).

3. Patients with diabetes complications who had off-pump CABG will have lower risks of postoperative stroke, postoperative renal failure, and in-hospital mortality than those with on-pump CABG. Patients with diabetes who also have comorbid diabetes complications, such as uncontrolled diabetes, renal, ophthalmic, and neurological manifestations, may have higher risk of adverse outcomes following coronary revascularization (Ishihara, et al., 2005; Marenzi, et al., 2004; Ono, et al., 2006). Off-pump CABG may minimize risks for high-risk patients. Thus, patients with comorbid diabetes complications may have better outcomes with off-pump CABG than with on-pump CABG.

Design and Methods

Conceptual Framework

The framework for this study is based on the framework developed by Shroyer and colleagues in the Process, Structures and Outcomes of Care in Cardiac Surgery (PSOCS) study, a modified version of the Donabedian model (Donabedian, 1966;

Shroyer, et al., 1995). The PSOCS extends the Donabedian model and added patient factors, representing individual patient risks that also directly influence outcomes. The structure refers to the hospital setting, location, staffing structure, resources and organizational structure. A good hospital structure encourages an appropriate and quality process of care that can potentially minimize patients' risks, resulting in better outcomes.

As shown in Figure 4.1, cardiac surgery outcomes can be influenced by the hierarchical relationship between the dimensions of the PSOCS model. For example, teaching status affords hospitals access to more resources. Teaching hospitals often have higher nursing staffing levels and overall higher staffing quality (Clark et al., 2004). Higher staffing levels are associated with lower risks of adverse outcomes (Bloom, Alexander, & Nuchols, 1997; Silber, et al., 2009). In addition, the characteristics of patients served by a hospital are related to the hospital location, which consequently may influence the hospital's case mix (Popescu, Nallamotheu, Vaughan-Sarrazin, & Cram, 2010). Procedure volume is a structure variable extensively studied for its influence on quality of care. Although the use of CABG volume as a predictor of mortality and a proxy for quality of care is not conclusive (Peterson, et al., 2004; Welke, Barnett, Sarrazin, & Rosenthal, 2005), studies have suggested that CABG outcomes are better in hospitals with high CABG volume compared to low-volume hospitals because high-volume hospitals are more experienced (Konety, Rosenthal, & Vaughan-Sarrazin, 2009; Peterson, et al., 2004).

Process variables describe the procedures and care patients received. The CABG procedures are off-pump and on-pump techniques; these techniques do not benefit all patient groups equally (Bainbridge, Martin, & Cheng, 2005). Patient characteristics

associated with benefiting from off-pump CABG include older patients, those at high-risk, and those with multiple comorbidities (Ricci & Salerno, 2006; Stamou et al., 2002). Patient characteristics include severity of coronary artery disease, comorbidities, and demographic and socioeconomic factors. Patient risk factors may play an important role in the choice of the on-pump or off-pump CABG technique. Some patient characteristics associated with being selected for off-pump CABG include: the need for fewer grafts, whether there is stenosis in the left main artery, older age, comorbid diabetes, chronic lung disease, and renal failure (Magee, et al., 2003; Magee, et al., 2001).

Data Source

This is a cross-sectional analysis using data from the 2007 Nationwide Inpatient Sample (NIS), hospital discharge data maintained as part of the Healthcare Cost and Utilization Project (HCUP) by the Agency for Healthcare Research and Quality (AHRQ) (HCUP, 2007). The NIS is nationally representative administrative data representing all inpatient stays from a stratified 20% sample of United States community hospitals (HCUP, 2010). Many quality assurance procedures are performed on the NIS data to ensure consistent internal and external validity (HCUP, 2009). The 2007 database includes about 8 million of discharge records sampled from approximately 90% of all hospital discharges in 40 states, weighted to provide national estimates. Five nested stratification variables based on the characteristics of hospitals from HCUP participating states were used to create sampling strata; discharge sample weights were calculated as the probability of sampling within each stratum (HCUP, 2006). The NIS includes four data groups: a) de-identified inpatient discharge-level data with information about demographics, admission information, length of stay, payer information, procedures and

diagnoses; b) hospital-level data on location, ownership, bed size, staffing ratio, hospital state, and teaching status; c) inpatient discharge-level data on measures of severity and comorbidity; and d) discharge-level information on diagnosis and procedure groups. Information on hospital characteristics, location, size, staffing, and resources included in the NIS database were derived from the American Hospital Association's Annual Survey Database (Steiner, Elixhauser, & Schnaier, 2002). This study was approved by the Institutional Review Board of University of North Carolina at Charlotte.

Study Population

The study analysis was restricted to patients age 45 and older who had coronary artery bypass graft (CABG) procedures, defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes: 36.01, 36.02, and 36.05-36.07. The sample was restricted to patients age 45 and older because increasing age is associated with both having a CABG procedure and the risks for adverse outcomes after revascularization (Brooks, et al., 2000; Magee, et al., 2003; Vavlukis, et al., 2006). About 97% of 2007 discharges involving CABG were for patients age 45 and older (HCUPnet., 2010). There were 49,324 hospitalizations with a procedure code for CABG. Of these, 17,977 (36%) had a diagnosis code indicating diabetes (Table 4.1). Of all patients with diabetes, 14,398 (80%) were identified as having had on-pump CABG; i.e., their records included ICD-9-CM procedure codes 3961 and 3966. Twenty percent (3,579) had off-pump CABG procedures; these patients were identified by the lack of procedure codes 3961 and 3966 (Chu, et al., 2009). Of those with diabetes, 4,494 (25%) had renal, ophthalmic, neurological, diabetes with peripheral circulatory disorders, uncontrolled diabetes, or chronic kidney disease; patients who had

one or more of these conditions were considered to have comorbid diabetes complications.

Outcomes

The outcomes assessed in the study were postoperative stroke, postoperative renal failure, and in-hospital mortality. The outcomes were assessed independently, and also collectively as a composite of all the outcomes. In-hospital mortality was defined as death during a hospital admission where CABG was performed. Postoperative stroke was determined using a combination of primary and secondary ICD-9-CM diagnosis codes. The diagnosis codes are shown in Table 4.1. The codes for postoperative stroke indicate late effects of stroke and postoperative neurological complications. Postoperative renal failure was defined as having acute renal failure with concurrent use of hemodialysis during hospitalization, specified by the presence of these procedure codes: 3995, 584, 5840, 5845, 5846, 5847, 5848, and 5849. All the outcomes were dummy coded as “1” if found in the patient’s record, “0” otherwise.

Independent Variables

The independent variables were selected based on the conceptual model that guided this study, and grouped as patient characteristics, process variables, and structure variables (Shroyer, et al., 1995).

Patient Characteristics

These include demographic variables, medical history, comorbidities, and clinical characteristics. Age was represented in the model as a continuous variable centered at 45 and measured in decades. For sex, men are the referent group. For race and ethnicity, the groups are African American or Black (hereafter Black), non-Hispanic white

(hereafter White), Hispanic, Asian (includes Pacific Islander) and others (includes Native American and mixed race) (Trivedi, Sequist, & Ayanian, 2006). Dummy variables for each race and ethnicity group were included in the models, with an additional dummy variable representing those with missing race data. White was the referent group for race and ethnicity. Health insurance categories were Medicare (referent), Medicaid, self-pay, private insurance and other payment source (uninsured and other government program). The admission type has three categories, elective (referent), emergency, and urgent. Dummy variables for categories of health insurance, admission type and median household income were used in the analysis. Patient's use of prophylactic aspirin, anticoagulants, anti-inflammatory drugs, and antiplatelets and antithrombotics were determined from ICD-9-DM codes. These variables were included in the analysis because of their potential effect on CABG outcomes (Hongo, Ley, Dick, & Yee, 2002; Kowey, Taylor, Rials, & Marinchak, 1992). The variable for length of stay was log transformed because of skewed distribution, and included in the model as a continuous variable.

Patient comorbidities were defined based on the approach used to construct the Elixhauser Comorbidity Index. The Elixhauser Comorbidity index, which includes 30 comorbidities, has been validated for use with administrative data (Elixhauser, et al., 1998; Friedman, et al., 2006; Stukenborg, et al., 2001; Yan, et al., 2005). The algorithm differentiates between comorbidities and complications due to the care process, by conservatively considering only secondary diagnosis unrelated to diagnosis-related group (DRG) assigned to the discharge record. A secondary diagnosis related to the DRG was considered to be a contributor to illness severity rather than a comorbid condition. In

addition to assessing the effect of each comorbid condition, a variable representing the sum of comorbidities was created to assess the cumulative effect of comorbidities.

Clinical characteristics were determined based of diagnosis codes. Variables for insulin dependency and atherosclerotic ascending aorta were dummy coded and included in the model because of their potential to influence postoperative stroke and postoperative renal failure (Davila-Roman, Kouchoukos, Schechtman, & Barzilai, 1999; Nurozler, Kutlu, & Kucuk, 2007; Varga et al., 2004).

Process Variables

Process variables represented in the analysis included the CABG strategy performed, categorized as off-pump or on-pump (referent). The internal mammary artery graft is a dummy variable, coded 1 if these ICD-9 codes (3615, 3616) were present on the record, 0 otherwise. Procedure volume for off-pump, on-pump and overall CABG procedures were computed as the sum of the procedure for each hospital. Due to the skewed nature of these variables, the variables were log transformed and included in the model as continuous variables.

Structure Variables

The measures for the structure dimension include staffing ratio, and facility size, which are shown in Figure 4.1 (Shroyer, et al., 1995). The variables included in the analyses were the hospital's teaching status; its location in an urban or rural area; its bed size; and measures of nurse staffing. For the latter, the ratio of registered nurses was defined as the percentage of registered nurses among all licensed nurses. For licensed practical nurses (LPNs), the workload ratio was defined as the LPN full time equivalents (FTEs) per 1000 adjusted inpatient days. All of these variables were coded as dummy

variables except variables for staffing ratio. The variable for bed size was defined by the AHRQ, which categorized hospitals as small, medium, or large, taking into consideration the region in which the hospital was located as well the hospital's urban or rural location and its teaching status (HCUP, 2010); large hospitals were the referent category.

Detailed description of the definition of hospital bed size categories is in Appendix A.

The referent group for teaching status was teaching hospital. Urban hospitals were the reference group for hospital location.

Statistical Analysis

Descriptive analyses included weighted frequencies of the dependent and independent variables. Characteristics were compared between patients with and without off-pump use, and between patients who received care at teaching and non-teaching hospitals, using the chi-square test for categorical variables and t-test for continuous variables. Using the SAS GLIMMIX procedure for binary dependent variables, multilevel analyses was used to identify factors associated with the outcome variables. Multilevel modeling is widely used in research estimating adjusted effects with contextual variables. Multilevel analysis accounted for the clustering of patients within hospitals, and allowed for accurate calculation of standard errors. Model fit was determined using the ratio of the generalized chi-square statistic and its degrees of freedom. Ratios close to 1 indicate a model with little residual (Schabenberger, 2005). Separate models were fit to assess in-hospital mortality, postoperative stroke, postoperative renal failure, and the additional outcome indicating that one or more of these were present. The sample was grouped by off-pump and on-pump CABG, and models were fit to assess each outcome for off-pump CABG and on-pump CABG

patients separately. All analyses were conducted using SAS 9.2 (SAS Institute, Cary, North Carolina) and were weighted for national representativeness.

Results

Sample Characteristics

Table 4.2 shows the sample size (n), the weighted population size (N), the weighted percent and the confidence interval for the weighted estimate for adverse outcomes and selected characteristics for patients with diabetes who had coronary artery bypass graft. Those who died in the hospital represented 1.7% of the weighted sample, 2.6% had postoperative stroke; and 1% had postoperative renal failure. Patients with diabetes complications represented 25% of those having CABG. About 80% of patients had on-pump CABG. The remaining 20% had off-pump CABG. About 55% of patients were age 65 or older, White, or Medicare beneficiaries.

Bivariate Results

Adverse Outcomes

Table 4.3 reports the percentage of adverse outcomes by CABG strategies, diabetes complications status, and hospital teaching status. For all outcomes, patients with diabetes complications had significantly higher rates of adverse outcomes than those without diabetes complications: in-hospital mortality (2.7% vs. 1.4%); postoperative stroke (3.3% vs. 2.5%); postoperative renal failure (3.5% vs. 0.3%); and the composite outcome (8.7% vs. 4.0%). The proportion of patients who had off-pump CABG and had adverse outcomes was not significantly different from those who had on-pump CABG. There was no significant difference in the percentage of adverse outcomes among patients who had CABG at teaching hospitals compared to those who received care at

non-teaching hospitals.

CABG Strategies

The results of statistical tests that separately compared characteristics of off-pump patients to those having on-pump CABG are presented in Tables 4.4. The average age (65.6 vs. 65.9 $p=0.0749$), and length of hospital stay (LOS) (9.7 vs. 9.6, $p=0.5350$) were not significantly different between patients in the off-pump or on-pump groups.

However a higher percentage of patients with the off-pump procedure were women, had low median house household income and had an emergency admission.

Diabetes Complications

Differences between patients with diabetes complications and those without diabetes complications are shown in Table 4.5. A number of characteristics differed among patients with diabetes who had diabetes complications and those that did not have diabetes complications. On average, patients with diabetes complications stayed longer in the hospital (11.9 days versus 8.9 days, $p<.0001$), were slightly older (66.5 versus 65.7, $p<.0001$) and had higher average number of comorbidities (4.0 versus 3.1, $p<.0001$). In addition, compared with those without complications, patients with diabetes complications were more likely to have had a blood transfusion (5.1% vs. 3.7%, $p<.0001$), to have used insulin (12.4% vs. 8.0%, $p<.0001$), and to be Blacks (8.0% vs. 5.1%, $p<.0001$).

Teaching and Non-teaching Hospitals

The results of statistical tests that separately compared characteristics of teaching hospitals with those of non-teaching hospitals are presented in Table 4.6. Although measures of staffing between the hospitals were not significantly different, teaching

hospitals performed more CABG procedures than non-teaching hospitals. The average volume of all CABG procedures (247.9 vs. 167.4, $p < .0001$), and the respective average volume of total off-pump and on-pump CABG procedures was higher in teaching hospitals. The average length of stay for patients treated at teaching hospitals was significantly higher than that for patients in non-teaching hospitals (9.9 vs. 9.3, $p = < .0001$).

Multivariate Results

The multilevel analyses focused on associations between the adverse outcomes and patients' characteristics, exploring the association of process factors and hospital characteristics. The adjusted results of factors associated with in-hospital mortality, postoperative stroke, postoperative renal failure, and the composite outcome (either in-hospital mortality, or postoperative stroke, or postoperative renal failure), with their estimated odds ratios (ORs) and 95% confidence intervals (CIs) are presented in tables 4.7 and 4.8.

Patient Risk Factors

Patient risk factors that were associated with the composite outcome included longer hospital stay (OR 1.16, CI 1.01-1.33); increasing age (OR 1.17, CI 1.09-1.26); wound complications (OR 1.90, CI 1.07-3.36) and the degree of renal dysfunction. Further, those with advanced renal dysfunction had greater risk of having one of the adverse outcomes represented in the composite variable than those without renal dysfunction (OR 2.59, CI 1.55-4.32). Other risk factors were post surgical hemorrhage (OR 1.61, CI 1.18-2.18); congestive heart failure (OR 1.34, CI 1.15-1.57); and a greater number of comorbidities (OR 1.18, CI 1.11-1.25). Compared with Whites, the odds of

having one of the composite outcomes were 39% greater for Blacks (OR 1.39, CI 1.06-1.83) and 42% greater for Hispanics (OR 1.42, CI 1.10-1.84).

Most patient factors that were associated with higher odds of having a composite outcome were also associated with in-hospital mortality. An exception was female gender. Compared with men, women had 67% greater odds of death during the hospital stay (OR 1.66, CI 1.29-2.17).

Patient characteristics that were significantly associated with the risk of postoperative renal failure were limited, which may be due to the small number of postoperative renal failure cases. Longer hospital stay (OR 5.07, CI 3.90-6.60), comorbid diabetes complications (OR 2.01, CI 1.11-3.63) and coagulopathy (OR 1.64, CI 1.07-2.50), were associated with postoperative renal failure. The degree of renal function was an important predictor of postoperative failure: patients with poorer renal function were particularly at risk (OR 19.68, CI 9.49-41.00).

Consistent with the other outcomes, postoperative stroke was associated with longer hospital stay. A greater number of comorbidities and Hispanic ethnicity were associated with greater postoperative stroke risk. Compared to Medicare beneficiaries, patients with private insurance were much less likely to have postoperative stroke (OR 0.58, CI 0.44-0.77).

Hospital Factors

Increasing volume of CABG procedure was associated with lower odds of a composite outcome (OR 0.86, CI 0.75-0.99) and in-hospital mortality (OR 0.66, CI 0.53-0.82). A larger number of LPN FTEs per 1000 adjusted inpatient days was associated with substantially lower odds of in-hospital mortality (OR 0.16, CI 0.03-0.92). There

was no difference in outcomes between patients who had a CABG procedure at teaching or non-teaching hospitals.

Process Factors

The risk for patients who had off-pump compared to those who had on-pump CABG is reported in Table 4.9. Compared to patients without comorbid diabetes complications, those with comorbid diabetes complications who had off-pump CABG did not experience significantly lower risks for in-hospital mortality, postoperative stroke, or postoperative renal failure. For patients undergoing on-pump CABG, however, those with comorbid diabetes complications had 69% higher odds of post-operative stroke (OR 1.69, CI 1.10-2.60) and 67% higher odds for the composite outcome (OR 1.67, CI 1.20-2.32).

Discussion

Off-pump CABG is a relatively safe and effective alternative to on-pump CABG (Bainbridge, et al., 2005; Puskas, et al., 2005). Evidence from research that points to benefits of off-pump techniques, especially for patients in high-risk groups, has sparked interest in research comparing outcomes among patients undergoing off-pump and on-pump CABG. Interest in this area of research is supported by the expectation that off-pump processes should provide benefits for patients for whom the use of cardiopulmonary bypass is potentially harmful during coronary grafting (Bainbridge, et al., 2005). With advancement in adjunct therapies and coronary grafting techniques, patients with higher risk profiles are increasingly candidates for the less invasive off-pump CABG technique. Patients with diabetes are a large and growing group of high-risk patients with underlying pathophysiological factors associated with diabetes

that predispose them to poorer outcomes following revascularization (Beckman, et al., 2002; Flaherty & Davidson, 2005). Some studies have assessed the effect of off-pump CABG in patients with diabetes, and have had with mixed results (Abraham, et al., 2001; Magee, et al., 2001; Srinivasan, et al., 2004). However, no previous studies have focused on patients with diabetes who have comorbid diabetes complications as a high-risk subgroup that may benefit from off-pump CABG. Diabetes complications indicate harmful effects of prolonged hyperglycemia, which is also associated with physiologic and metabolic changes that may increase the risk for adverse outcomes with the use of cardiopulmonary bypass (Knapik et al., 2009; Marren, 1994). This study addressed this research gap by examining effects of off-pump CABG for patients with diabetes, with a focus on outcomes of off-pump versus on-pump techniques among patients with comorbid diabetes complications. As differences among hospitals may affect outcomes, the association of structural factors was also examined.

Three hypotheses guided this research. The first hypothesis was that compared with on-pump CABG; the off-pump CABG process use would be associated with lower risk of in-hospital mortality, postoperative stroke, and postoperative renal failure. The results did not support this hypothesis. Previous study among patients with diabetes that suggested protective effects of off-pump on stroke and renal failure were restricted to hospitals participating in a cardiac surgery registry (Magee, et al., 2001), or one cardiac center (Srinivasan, et al., 2004). In contrast, the present study used data from hospitals representative of hospitals across the U.S., and is more representative of clinical experience, which may explain the differing findings. In support of this view, studies that compared off-pump and on-pump CABG using administrative data, as in the present

study, did not find a protective association between off-pump CABG with postoperative stroke and postoperative renal failure, which is consistent with this current study's results (Chu, et al., 2009; Chukwuemeka et al., 2005). Systematic differences in contextual factors between hospitals, such as surgeon's experience and preference, CABG volume, and staffing ratios, may also explain some of the differences in outcomes of this study and previous studies.

This study's analyses included adjustment for the nested nature of the data and potential differences between hospitals that might affect outcomes. Further, patients with diabetes are not a homogeneous group. The pathophysiologic mechanisms in the development of coronary artery disease may be distinct for Type 1 and Type 2 patients with insulin-resistance playing an important role in Type 1 diabetes (Orchard et al., 2003) with associated risks and the likelihood for poorer outcomes (Luciani et al., 2003). While the analyses in this study adjusted for insulin use, information on insulin use was obtained from diagnosis codes and may not reflect an accurate count of all patients who were insulin-dependent.

The second hypothesis was that patients who had CABG in teaching hospitals would have better outcomes than those in non-teaching hospitals. There were no differences in outcomes between teaching and non-teaching hospitals; thus, this expectation was not supported. Although, no specific study has assessed differences in outcomes of CABG strategies in teaching and non-teaching hospitals, studies have suggested that processes of care such as adjunct therapy like the use of angiotensin-converting enzyme inhibitors, aspirin and β -blockers in the management of myocardial infarction, a risk factor for mortality and morbidity after CABG is higher at

teaching hospitals (Allison, et al., 2000; Rosenthal, Harper, Quinn, & Cooper, 1997). A higher volume of CABG procedures, a measure of quality, is associated with better surgical outcomes and is often higher at teaching hospitals than non-teaching hospitals (Urbach & Baxter, 2004). As shown in this study's results, the volume of overall CABG procedures and respective volume of off-pump and on-pump CABG procedures were higher for teaching hospitals. Despite these results, patients in teaching hospitals did not have lower risk of adverse outcomes. Patients with high illness severity are more likely to receive care at teaching than non-teaching hospitals (Iezzoni et al., 1990). The lack of significant benefit associated with teaching hospitals observed in this study's results may be due to unmeasured illness acuity that reduced potential benefits of better care processes in teaching hospitals.

The third hypothesis was that patients with diabetes complications who had off-pump CABG would have lower risks of in-hospital mortality, postoperative stroke, and postoperative renal failure than those who had on-pump CABG. The results suggested that patients with diabetes complications who had off-pump CABG did not have significantly lower risk of these adverse outcomes. Thus, the third hypothesis was not supported. Prior studies that suggested a protective effect of off-pump CABG on postoperative adverse complications did not assess outcomes in patients with diabetes (Al-Ruzzeh, Ambler, et al., 2003; Al-Ruzzeh, Nakamura, et al., 2003; Bucerius, et al., 2004; Stamou, et al., 2002). In contrast, patients selected for this study were restricted to those who had diabetes; these patients are likely to have different risks for coronary atherosclerosis from the general CABG population (Flaherty & Davidson, 2005; Zornitzki, et al., 2007); their experience with off-pump CABG may be different from that

of general CABG patients. The finding for in-hospital mortality in the present study was similar to results from previous research in patients with diabetes (Magee, et al., 2001; Srinivasan, et al., 2004). Additionally, differences in methods and unmeasured differences in adjuvant care therapy may further explain some of the variations. Other factors other than CABG strategies have also been suggested as more important in predicting postoperative stroke and postoperative renal failure (Marasco, Sharwood, & Abramson, 2008; Selnes et al., 2005). The findings of the present study indicate that the degree of renal function was a strong predictor of postoperative renal failure. Further, Hispanic ethnicity, a greater number of comorbidities, and regional location were some of the few factors associated with greater risks of postoperative stroke.

Although the present study suggests that off-pump CABG and teaching status had no significant protective effect on in-hospital mortality, postoperative stroke, and postoperative renal failure, the results suggested that patient risks factors may be better predictors of these outcomes than process and structure factors. Patient risk factors that were associated with in-hospital mortality and the composite outcome included greater age, being female, post surgical hemorrhage, wound complications, congestive heart failure, a greater number of comorbidities, and advanced stages of renal impairment. Further, structural factors such as increasing volume of CABG procedures and a greater number of licensed practical nurse full-time equivalents (LPN FTEs) per 1000 adjusted inpatient days reduced the risk of in-hospital mortality and the composite outcome.

The main strength of this study came from using a large nationally representative hospital discharge database, which allowed the evaluation of adverse post-operative outcomes that occur with relatively low frequency. The large dataset allowed us to

compare the experiences of patients with and without diabetes complications. The database also included measures of illness severity and comorbidities, which permitted risk adjustment. Randomized controlled trials often adopt restrictive selection criteria, rely on registry data, and include a small number of hospitals. In contrast, this study used a representative sample of United States community hospitals. The NIS is weighted to represent all hospitalizations in the United States. Thus, the results can be generalized.

Several study limitations are acknowledged. The study relied on administrative data that have limited clinical details. For instance, the effect of ejection fraction left main disease status and other clinical measures could not be evaluated. However, information about several secondary diagnoses was available for assessing the likelihood of poor outcomes. Outcomes and predictor variables were determined from diagnosis codes. If there is systematic error in coding and reporting, the results of the study may be biased. The NIS database was extensively validated by the Agency for Healthcare Research and Quality; potential coding errors are likely to affect both groups equally (Chu, et al., 2009). Further, data on physician's practice preferences was not available; such factors may introduce unmeasured selection bias. As this analysis was restricted to events occurring during hospitalization, we did not account for potential adverse outcomes related to the surgical procedure that occurred after discharge. This study was a retrospective analysis of cross-sectional data, which precludes establishing causal relationships. The lack of adjustment for conversion from off-pump to on-pump is also a limitation. Surgical experience and preference in selecting patients for either CABG strategy have been suggested to play a role in surgical outcomes (Mitka, 2004). This information was not available in the data, and was not evaluated. However, conducting

multilevel analyses, which accounted for differences in hospital characteristics, should have reduced the potential effect of this limitation. In addition, there were a small number of cases with renal failure, especially among patients who had off-pump CABG. The analysis may not be adequately powered to detect a significant association between off-pump CABG and outcomes in off-pump CABG patients.

Implications for Policy and Research

Patients with diabetes complications were significantly different from those without complications. Some indicators of adverse outcomes were more common among patients with diabetes complications, such as receiving blood transfusion, having wound complications, having atrial fibrillation, or having comorbid valve disorder. Considering these risks, it may be useful to give more attention to patients with comorbid diabetes complications during and after CABG procedures, to minimize the potential effect of these risk factors.

Although process and structure variables are important in measuring outcomes, the results suggest that patient risk factors were stronger in determining outcomes in patients with diabetes having CABG. Thus, it is useful for health care providers to assess these risks in patients before and while in the hospital. For example, post surgical hemorrhage was associated with higher odds of having a composite outcome. Assessing for surgical hemorrhage post CABG and providing prompt intervention may mitigate detrimental effects. While this study did not show a support for a benefit of off-pump CABG in reducing short-term poor outcomes in patients with diabetes, it supports other published research that suggested equivalent effect for both CABG strategies with regards to short-term outcomes. Both CABG strategies should be considered in selecting

patients with diabetes for coronary bypass grafting. However, more emphasis should be on patient risk factors as they may be more predictive of poor outcomes.

High volume of CABG procedures had a protective effect on the likelihood of having the study's outcomes. This supports existing evidence on the protective effect of procedure volume and further provided support in a high-risk group. Although not assessed in this study, surgeon's specialization in off-pump CABG may be important in deriving a benefit with off-pump CABG in patients with diabetes because they are often complex patients with multiple comorbidities. Further, women were at higher risk for in-hospital mortality than men, and were more likely to have off-pump than on-pump CABG. Some studies have suggested that the off-pump procedure may benefit women; future research should assess this potential benefit for women with diabetes.

Table 4.1: Criteria Used to Define Outcomes and Explanatory Variables

<u>Diagnosis and Procedure</u>	<u>ICD-9-CM Codes^a</u>
Post operative stroke	4380, 43810, 43811, 43812, 43819, 43820, 43821, 43822, 43830, 43831, 43832, 43840, 43841, 43842, 43850, 43851, 43852, 43853, 43881, 43882, 43889, 4389, 99702
Hemodialysis	3995
Postoperative renal failure	Hemodialysis and ARF codes
Coronary artery bypass graft	3610, 3611, 3612, 3613, 3614, 3615, 3616, 3617, 3618, 3619
Percutaneous coronary intervention	0066, 3601, 3602, 3605, 3606, 3607
Diabetes	25000-25033, 64800-64804
Diabetes complications	25040 - 25093, 7751, 5853, 5854, 5855, 5856, 5859, 586, V420, V451
Drug Eluting stent	3607
Mammary artery graft	3615, 3616
CABG history	V4581
PCI history	V4582
Long-term /use of antiplatelets/antithrombotics	V5863
Long-term / use of nonsteroidal anti-inflammatories	V5864
Long-term / use of insulin	V5867
Long-term /current use of aspirin	V5866
Long-term / use of anticoagulants	V5861
Atherosclerotic ascending aorta	4400
Acute renal failure (ARF)	584,5840, 5845,5846, 5847,5848, 5849

^aICD-9-CM _ International Classification of Diseases, 9th Revision, Clinical Modification. ^bPostoperative renal failure requiring hemodialysis.

Table 4.2: Characteristics of Patients with Diabetes Having Coronary Artery Bypass Graft Procedure in 2007^a

<u>Parameters</u>	n=17975	N=88848	%	95% Confidence	
				LB	UB
<i>Adverse Outcomes</i>					
Postoperative stroke	466	2337	2.6	2.29	2.96
In-hospital mortality	303	3776	1.7	1.47	1.95
Postoperative renal failure	193	980	1.0	0.88	1.32
<i>Diabetes complications</i>					
Yes	4494	22217	25.0	23.65	26.35
No	13483	66631	75.0	73.64	76.34
<i>Admission type^b</i>					
Elective	7759	38593	43.4	39.97	46.9
Urgent	4033	20457	23.0	19.37	26.67
Emergency	3934	19817	22.3	19.84	24.76
<i>CABG Strategy</i>					
On-pump	14346	71201	80.1	76.58	83.69
Off- pump	3631	17647	19.9	16.31	23.41
<u>Demographic Characteristics</u>					
<i>Gender</i>					
Men	12389	61161	68.8	68.01	69.67
Women	5587	27683	31.2	30.32	31.99
<i>Age group</i>					
45-54	2459	12112	13.6	13.01	14.26
55-64	5526	61590	30.7	29.72	31.64
65-74	6212	30636	34.5	33.64	35.36
75 and older	3780	18842	21.2	20.12	22.29
<i>Race^b</i>					
White	9969	49767	56.0	50.63	61.39
Black	1062	5127	5.8	4.34	7.19
Hispanic	1448	6935	7.8	4.99	10.61
Asian	441	2050	2.3	1.56	3.05
Others	673	3297	3.2	2.67	4.75
<i>Health Insurance</i>					
Medicare	9780	48337	54.4	52.83	55.98
Medicaid	945	4669	5.3	4.31	6.2
Self	542	2614	2.9	2.46	3.43
Private	5978	29665	33.4	31.79	34.99
<i>Median household income</i>					
\$1-24,999	4716	23083	26.0	22.41	29.55
\$25,000-34,999	4693	22949	25.8	23.16	28.49
\$35,000-44,999	4256	21108	23.8	21.48	26.04
\$45,000 or more	3772	19056	21.5	17.18	25.71

Table 4.2 (Cont'd)

^a Data source: 2007 Nationwide Inpatient Sample (NIS), weighted results for national representativeness. ^b Percentages may not total 100 because of missing data. CABG=Coronary artery bypass graft, PCI=Percutaneous coronary intervention. LB=lower bound, UB=upper bound.

Table 4.3: Description of Adverse Outcomes for Patients with Diabetes after Coronary Artery Bypass Graft (CABG), 2007^a

<u>Outcomes</u>	<u>CABG Strategies</u>		<u>Diabetes Complications</u>			<u>Teaching Status</u>			
	Off-pump	On-pump	P-value	Yes %	No%	P-value	Yes %	No%	P-value
In-hospital mortality	1.8	1.7	0.7195	2.7	1.4	<.0001	1.8	1.6	0.2592
Post operative stroke	2.6	2.7	0.7796	3.2	2.5	0.0111	2.8	2.4	0.1704
Post operative renal failure	0.9	1.2	0.1897	3.5	0.3	<.0001	1.2	1.0	0.5567
Composite endpoint	4.8	5.3	0.3814	8.7	4.0	<.0001	5.4	4.7	0.1139

^a Data source: 2007 Nationwide Inpatient Sample (NIS). CABG= Coronary artery bypass graft,

Table 4.4: Stratified Demographic and Clinical Characteristics of Patients With Diabetes—With Off-pump and With On-pump Coronary Artery Bypass Graft (CABG), 2007^a

<u>Risk factors</u>	<u>CABG Strategies</u>		P-value
	Off-pump	On-pump	
Age	65.6±9.8	65.9±9.5	0.0749
Length of stay ^b	9.7± 8.5	9.6 ± 6.8	0.5350
Number of comorbidities	3.3 ± 1.3	3.3 ± 1.3	0.4995
Hypertension	76.7	79.2	0.0451
Valve disorder	11.2	14.3	0.0058
CHF	24.9	24.4	0.7512
Coagulopathy	7.3	9.4	0.0182
COPD	21.8	20.3	0.1611
Diabetes complications	25.6	24.9	0.5404
Peripheral vascular disease	16.3	14.6	0.0589
Emergency admission	34.8	30.1	<.0001
Women	33.2	30.7	0.0090
Income \$1-24,999	30.0	25.0	0.0356

^aData source: 2007 Nationwide Inpatient Sample (NIS); SD=standard deviation; CABG=Coronary artery bypass graft; COPD=Chronic obstructive pulmonary disorder; CHF=Congestive heart failure;

^bMean and standard deviation.

Table 4.5: Stratified Demographic and Clinical Characteristics of Patients With Diabetes—With Diabetes Complications and Without Complications who had Coronary Artery Bypass Graft (CABG) ^a, 2007^b

Risk factors	Diabetes Complications		p-Value
	Yes %	No %	
Length of stay ^c	11.9 ± 10.2	8.9 ± 5.6	<.0001
Age ^c	66.5 ± 9.8	65.7 ± 9.8	<.0001
Number of comorbidities ^c	4.0 ± 1.4	3.1 ± 1.2	<.0001
Blood Transfusion	5.1	3.7	0.0035
Hypertension	76.7	79.4	0.0105
Wound complications	0.9	0.6	0.0164
Atrial fibrillation	28.4	26.1	0.0033
Valve disorder	16.0	12.9	<.0001
Had off-pump CABG	20.0	19.4	0.5404
Coagulopathy	11.3	8.2	<.0001
History of insulin use	12.4	8.0	<.0001
Electrolyte disorder	26.1	17.1	<.0001
CHF	35.8	20.7	<.0001
COPD	22.3	20.0	0.0025
Peripheral vascular disease	18.7	13.7	<.0001
Emergency admission	24.6	21.5	0.0017
Women	32.3	30.8	0.0990
Private insurance	27.3	35.4	<.0001
Self Pay	2.0	3.3	<.0001
Medicare	61.2	52.1	<.0001
Black	8.0	5.1	<.0001

^a Table reports only factors that were significantly different. ^b Data source: 2007 Nationwide Inpatient Sample (NIS); ^c Mean and standard deviation. CABG=Coronary artery bypass graft; COPD=Chronic obstructive pulmonary disorder; CHF=Congestive heart failure;

Table 4.6: The Differences in Hospital Characteristics by Hospital Teaching Status 2007^a

<u>Parameters</u>	<u>Teaching</u>	<u>Non-teaching</u>	<u>P-value</u>
Length of stay ^b	9.9 ± 7.6	9.3 ± 6.4	<.0001
Age	65.7 ± 9.6	66.2 ± 9.6	<.0001
LPN FTE ^c	0.34 ± 0.4	0.4 ± 0.4	0.1423
RN FTE ^d	4.3 ± 1.4	4.1 ± 1.23	0.1349
% of RN ^e	92.6 ± 7.4	90.8 ± 6.43	0.0631
CABG volume	247.9 ± 191.4	167.4 ± 131.2	0.0002
Off-pump CABG volume	50.9 ± 74.4	38.5 ± 54.0	0.1441
On-pump CABG	197 ± 162.7	128.9 ± 119.1	0.0003
Urban location	95.3	92.2	0.2641
<i>Hospital Bed-size</i>			
Small	10.6	5.2	<.0001
Medium	30.8	21.2	<.0001
Large	58.6	73.7	<.0001
<i>Region</i>			
North East	22.2	7.2	<.0001
Mid-West	34	29.9	0.0155
South	29.6	36.8	<.0001
West	14.2	26.2	<.0001

^aData source: 2007 Nationwide Inpatient Sample (NIS); SD=standard deviation; CABG=Coronary artery bypass graft; CHF=Congestive heart failure; ^bMean and standard deviation; ^bThe number of licensed practical nurse full-time equivalents (LPN FTEs) per 1000 adjusted inpatient days; ^cThe number of licensed practical nurse full-time equivalents (RN FTEs) per 1000 adjusted; ^dThe percentage of registered nurses among all licensed nurses (RN & LPN).

Table 4.7: The Risk for Adverse Outcomes Following Coronary Artery Bypass Graft (CABG) in Patients with Diabetes, Multilevel Models, 2007^a

Parameters	Composite endpoint			In-hospital mortality				
	OR ^a	LB	UB	P-value	OR ^a	LB	UB	P-value
Log of length of stay	1.16	1.01	1.33	*	0.16	0.13	0.21	***
Age – 45 (decades)	1.17	1.09	1.26	***	1.65	1.39	1.95	***
Women	1.16	1.00	1.34		1.67	1.29	2.17	***
Off-pump CABG	0.94	0.78	1.14		1.19	0.87	1.64	
Hyper lipid	0.59	0.51	0.69	***	0.32	0.25	0.43	***
Diabetes Complications	1.24	0.98	1.57		1.00	0.63	1.59	
Use of mammary artery graft	0.58	0.49	0.69	***	0.32	0.25	0.43	***
Wound complications	1.90	1.07	3.36	*	4.55	1.77	11.71	**
Stage 1-3 renal dysfunction	1.13	0.76	1.70		1.51	0.73	3.10	
Stage IV and V renal dysfunction	2.59	1.55	4.32	***	2.52	0.89	7.19	
End state renal dysfunction	1.40	1.07	1.83	*	2.21	1.30	3.76	**
Post-surgical hemorrhage	1.61	1.18	2.18	**	2.21	1.38	3.54	***
Hypertension	0.74	0.62	0.88	***	0.53	0.39	0.72	***
CHF	1.34	1.15	1.57	***	2.51	1.91	3.30	***
Number of Comorbidities	1.18	1.12	1.25	***	0.99	0.88	1.13	
Teaching hospital	1.10	0.91	1.33		1.32	0.96	1.83	
Log of CABG volume	0.86	0.75	0.99	*	0.69	0.55	0.85	***
LPN FTEs ^b	0.67	0.26	1.70		0.16	0.03	0.92	*
Percentage of registered nurses	1.02	0.92	1.14		1.19	0.99	1.43	
Black	1.39	1.06	1.82	**	1.00	0.58	1.73	
Hispanic	1.42	1.10	1.84	**	0.89	0.53	1.50	
Asian	1.03	0.65	1.63		0.51	0.17	1.50	
Other	0.99	0.68	1.44		1.00	0.58	1.73	

Table 4.7 (Cont'd)

Missing	0.77	0.61	0.96	0.64	0.43	0.94
Pulmonary Disorder				2.90	1.25	6.73

^aData source: Nationwide Inpatient Sample 2007. OR^a indicates odds ratio. UB: Upper bound of the 95% confidence interval; LB: Lower bound of the same interval. Length of length of stay was log-transformed and modeled in continuous form. Age was centered at 45 and its effect measured in decades. Results included adjustment for payment source, hospital location and region; comorbidities (included coagulopathy, electrolyte disorders, peripheral vascular disease, and chronic lung disease). Medical history, (long-term insulin, aspirin and anticoagulant use). Reference categories: category is non-Hispanic white and elective admission. CABG=Coronary artery bypass graft; CHF=Congestive heart failure^b. The number of licensed practical nurse full-time equivalents (LPN FTEs) per 1000 adjusted inpatient days. *p < .05, **p < .01, ***p < .001.

Table 4.8: Predictors of Adverse Outcomes Following Coronary Artery Bypass Graft (CABG) in Patients with Diabetes, Multilevel Models, 2007^a

Parameters	Postoperative renal failure			Postoperative Stroke			
	OR	LB	UB	OR	LB	UB	P-value
Log length of stay	5.07	3.90	6.60	2.23	1.84	2.71	***
Age – 45 (decades)	1.02	0.87	1.19	0.96	0.85	1.09	
Women	0.86	0.62	1.19	0.93	0.76	1.15	
Off-pump CABG	0.77	0.50	1.19	0.94	0.73	1.21	
Hyper lipid	0.69	0.50	0.97	0.84	0.68	1.03	
Diabetes Complications	2.01	1.11	3.63	1.23	0.92	1.66	
Stage 1-3 renal dysfunction	3.74	1.81	7.72	0.50	0.26	0.96	*
Stage 4-5 renal dysfunction	19.73	9.49	41.00	0.25	0.06	1.04	
End stage renal failure	4.65	2.61	8.28	0.51	0.35	0.75	***
Coagulopathy	1.64	1.07	2.50	0.55	0.38	0.80	**
Electrolyte Disorder	1.39	0.98	1.98	0.54	0.41	0.71	***
Number of Comorbidities	0.88	0.77	1.01	1.41	1.30	1.53	***
Teaching hospital	0.87	0.58	1.30	1.10	0.85	1.42	
CABG volume	1.03	0.77	1.38	0.92	0.76	1.12	
Black	1.57	0.96	2.58	1.45	0.99	2.11	
Hispanic	1.50	0.89	2.54	1.64	1.15	2.33	**
Asian	0.51	0.15	1.79	1.59	0.91	2.76	
Other	0.64	0.25	1.61	1.24	0.78	1.97	
Missing	0.63	0.37	1.06	0.93	0.66	1.30	
Private insurance				0.58	0.44	0.77	***
<i>Hospital region</i>							
Northeast				0.81	0.42	1.57	
Midwest				0.48	0.26	0.88	**
South				0.62	0.34	1.13	

Table 4.8 (Cont'd)

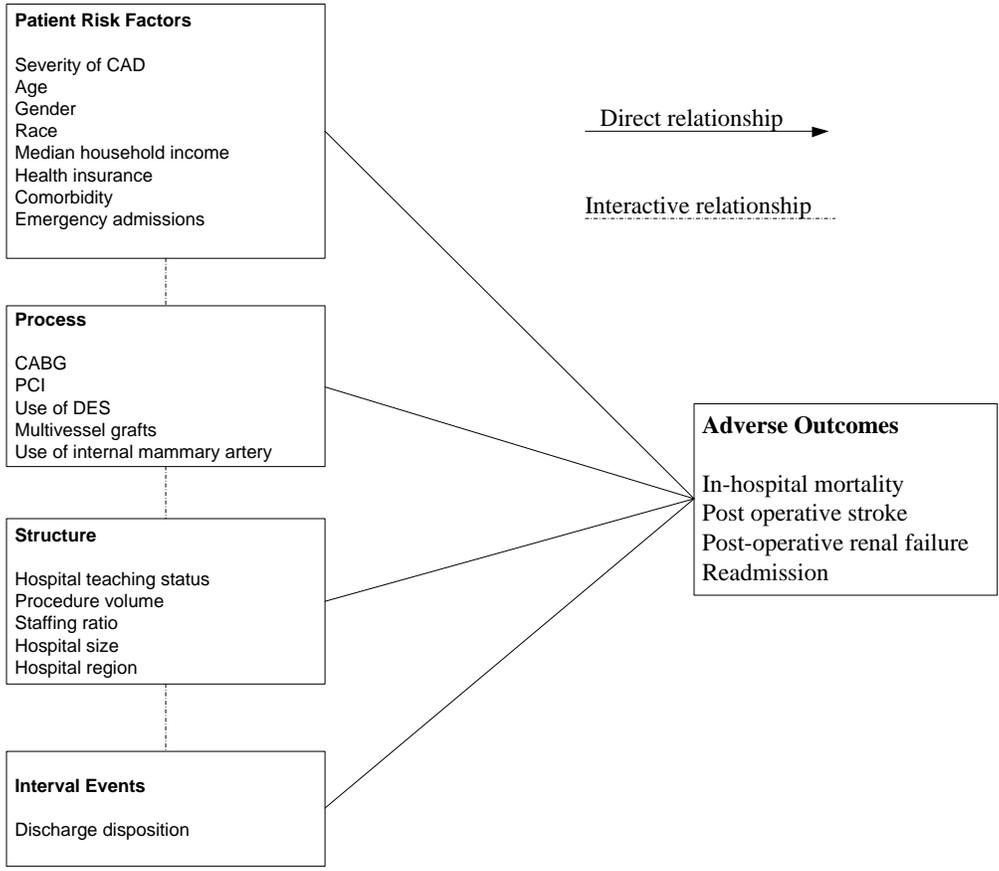
^aData source: Nationwide Inpatient Sample 2007. UB: Upper bound of the 95% confidence interval; LB: Lower bound of the same interval. OR^a indicates odds ratio. Length of stay was log-transformed and modeled in continuous form. Age was centered at 45 and its effect measured in decades. Results included adjustment for payment source, hospital location and region, comorbidities (included coagulopathy, electrolyte disorders, peripheral vascular disease, chronic lung disease). Medical history, (long-term insulin, aspirin and anticoagulant use). Reference categories: category is non-Hispanic white and elective admission, no renal dysfunction and the West region. CABG=Coronary artery bypass graft; CHF=Congestive heart failure; ^bThe number of licensed practical nurse full-time equivalents (LPN FTEs) per 1000 adjusted inpatient days. *p < .05, **p < .01, ***p < .001.

Table 4.9: The Risk for Patients with Diabetes Complications, Comparing Off-pump and On-pump Coronary Artery Bypass Graft (CABG), 2007^a

<u>Outcomes</u>	<u>Off-pump CABG</u>				<u>On-pump CABG</u>			
	OR	LB	UB	P-value	OR	LB	UB	P-value
In-hospital mortality	0.82	0.33	2.02	0.6638	1.41	0.71	2.81	0.3205
Post operative stroke	0.73	0.37	1.44	0.3647	1.69	1.10	2.60	0.0167
Post operative renal failure	2.71	0.69	10.58	0.1521	2.32	0.97	5.53	0.0572
Composite endpoint	0.81	0.46	1.43	0.4673	1.67	1.20	2.32	0.0023

^a Data source: 2007 Nationwide Inpatient Sample (NIS). CABG= Coronary artery bypass graft.

Figure 4.1: Graphical Representation of Conceptual Model: from Shroyer et al., 1995



CHAPTER 5: READMISSIONS FOLLOWING CORONARY REVASCULARIZATION AMONG PATIENTS WITH DIABETES: EFFECTS OF DISCHARGE DISPOSITION

Introduction

Health care expenditures in the United States continue to grow, accounting for over 16% of the national gross domestic product (GDP) in 2008 (Kaiser, 2011). Hospital readmissions have been proposed as one of the reasons health care costs in the U.S. are growing. Reducing readmission rates gained prominence during the discussions of the recent health care policy reform (U.S.Senate, 2009). Among patients insured by Medicare in 2005, readmission rates ranged between 6.2% for early readmissions, those occurring within 7 days of discharge, and 17.6% for 30-day readmissions (MEDPAC, 2007), those occurring between 8 and 30 days of discharge. In 2009, the estimated rate of readmissions within 30 days of discharge was 19.6% (Jencks, Williams, & Coleman, 2009). The potential savings from reducing readmissions among Medicare beneficiaries over a 10-year period has been estimated at more than \$8 billion (Manchikanti & Hirsch, 2009). The Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program added reporting of readmission rates in 2009 (CMS, 2009). This inclusion provides an incentive for hospitals to improve hospital efficiency, enhance care and discharge planning, and reduce complications of care—all of which may contribute to controlling readmission rates (QualityNet, 2011).

This study focuses on readmissions for patients who have had coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI). CABG and PCI differ in complexity, but it is known that patients having these procedures are at risk for readmission (Curtis et al., 2009; Stewart et al., 2000; Takahashi et al., 2001). CABG is a more invasive procedure than PCI, but 30-day readmission rates for these procedures are similar, about 15% for PCI (Curtis, et al., 2009) and about 16% for CABG (Hannan et al., 2003; Stewart, et al., 2000). Comorbid conditions are generally associated with readmission rates, with multiple comorbidities predicting higher readmission rates (Friedman, Jiang, & Elixhauser, 2008). Congestive heart failure, diabetes or diabetes complications, and complications from bypass grafts are among the top illnesses identified during the index admission that may increase the probability of readmission (Friedman, et al., 2008; Krumholz et al., 2000). Improved follow-up care after hospital discharge can also reduce readmission (Harrison, Hara, Pope, Young, & Rula, 2010; Manning, 2011). Post discharge care includes informal care received at home, formal home-care services, and care received at a transitional care facility (TCF). Research has suggested an association between these sources of post-discharge care and lower readmission rates. The purpose of this study was to examine early (≤ 10 days) and late (> 10 days) readmissions that occurred within 30-day of discharge in patients with diabetes who had coronary revascularization. Understanding patient characteristics and other factors present during the index hospitalization that are associated with readmission after revascularization can help to identify factors to be addressed by effective follow-up care, thus reducing readmissions.

Overview of Readmissions

There is lack of consensus on a definition of a readmission (Minott, 2009). The terms “readmission” and “rehospitalization” are used interchangeably. Both terms refer to a repeat hospital admission following a discharge. Readmissions may be categorized as unavoidable or avoidable, where the latter are due to adverse events that occurred during the index admission, care during the index admission that did not adequately prepare the patient for discharge, poor discharge planning, or poor follow-up care (CRS, 2010; Lin, Chung, Casey, & Snow, 2007; Minott, 2009). It is often difficult to link subsequent admissions to the index hospitalization because of potential effects of intervening variables (Clarke, 1990). In practice, readmissions are typically defined as acute care hospitalizations following prior acute care admissions within a specified time interval (Goldfield et al., 2008).

Although there is a lack of consensus on the definition of a readmission, there is consensus about the negative impact of readmissions. In addition to their costs, readmitted patients are at greater risk for nosocomial infection and other iatrogenic problems, falls or other accidents, and death (Boyce, 1998; Curtis, et al., 2009; Hannan, et al., 2003; Jarvis et al., 1991). Thus, there is considerable interest and research on how to predict and reduce readmissions. This need is particularly great for patients having surgical treatment for coronary artery disease, who have a higher readmission risk.

Coronary Revascularization and Readmissions

Outcomes of coronary revascularization have been widely studied due in part to the complexity of the procedures, the volume, costs, and the characteristics of patients who are often candidates for revascularization. Revascularization outcomes are

evaluated to identify risks, to minimize adverse events, and to improve quality of care. While considerable efforts have been devoted to outcomes such as mortality, morbidity, and the need for repeat revascularization, research on readmission is limited. Most prior research on readmissions related to coronary revascularization has focused on patients having CABG. Very few studies have examined readmissions following PCI, although the number of PCIs in the U.S. is growing (Smith et al., 2006).

Readmission rates vary by time interval, with readmission risk increasing with time following the index hospitalization. The rate of 30-day readmission after discharge following CABG has been estimated to be 16%; the corresponding 60-day readmission estimate is 18% (Cowper et al., 1997; Stewart, et al., 2000). In contrast, the estimated readmission rate for PCI patients was 14.6% within 30 days of discharge, and 48% within one year (Curtis, et al., 2009; Halon, Rennert, Flugelman, Jaffe, & Lewis, 2002).

Although readmission rates vary due to the heterogeneity of patients and their measured and unmeasured risk profiles, studies have suggested some factors that are consistently associated with readmissions. These factors include older age, multiple comorbidities, diabetes, illness severity, being female, being African American, and having surgical complications (Beggs, Birkemeyer, Nugent, Dacey, & O'Connor, 1996; Ferraris, Ferraris, Harmon, & Evans, 2001; Hannan, et al., 2003; Slamowicz, Erbas, Sundararajan, & Dharmage, 2008; Stewart, et al., 2000). In a follow-up study of patients who had isolated primary CABG, the risk of readmission was 22% greater for those with diabetes and only 12% for others (Stewart, et al., 2000). Further, among low-risk CABG patients, 28% of those with diabetes were readmitted, compared to 21% of others (Sun et al., 2008). The association of diabetes with readmissions has also been found for PCI

patients (Curtis, et al., 2009), especially those with sub-optimal glycemic control (Corpus et al., 2004; Moss, Klein, & Klein, 1999).

Post-discharge care may also influence readmission. Increasingly, patients are discharged to transitional care facilities to reduce inpatient care costs. Facilities providing transitional care include special units within the hospital, post-acute skilled nursing facilities, intermediate care facilities and rehabilitation facilities (AGS, 2007; Naylor & Keating, 2008; Naylor, 2006). From 1990-1998 CABG discharge from a medical center to transitional care increased by 40%, discharges with home care services increased by 32%, and discharge to home without home care decreased by 42% (Lazar et al., 2001). Understanding whether discharge disposition affects readmission may help to improve discharge planning.

Measures of Readmissions

Most studies of readmissions after revascularization procedures limit their analyses to 30-day or within 1-year readmission window (Curtis, et al., 2009; Slamowicz, et al., 2008; Stewart, et al., 2000; Sun, et al., 2008). While some studies have evaluated readmissions for a longer duration after the index admission (Herlitz et al., 1997), there is concern that surgical related readmission more than 30 days after discharge has less to do with the care received during the index hospitalization and more with other factors (CMS, 2011). Some research has suggested that studying late readmissions may help to identify readmissions preventable through ambulatory care (Benbassat & Taragin, 2000).

However, shorter duration is preferable for assessing quality of care during the index hospitalization, and for comparing effects of surgical care on readmissions (CMS, 2011; Sibbritt, 1995).

Reducing Readmission

Although some risk factors such as race, gender and socioeconomic status are not modifiable, understanding whether such risk factors are independently associated with readmissions would help to identify characteristics of patients who are at higher readmission risk. Some preventive measures at the point of care include focused monitoring of at-risk patients, better care transition from inpatient to outpatient care, and better coordination of care between inpatient and primary care providers (Greenwald & Jack, 2009). Further, whether the patient is discharged to home without provision for home care services, to home with home care services, or to transitional care, may influence the risk for readmission (Bohmer, Newell, & Torchiana, 2002). Little research has examined effects of discharge disposition on readmission risk for patients having PCI or CABG.

Research Objectives

The objective of this study was to assess 30-day readmissions, categorized into early (≤ 10 days) and late (11 to 30 days) readmission for patients with diabetes who had coronary revascularization. Focusing the analysis on patients with diabetes is useful as studies have consistently found that diabetes predicts readmissions (Ferraris, et al., 2001; Jiang, Andrews, Stryer, & Friedman, 2005; Stewart, et al., 2000; Sun, et al., 2008; Whang & Bigger, 2000). In addition, diabetes is associated with nosocomial infection (Jarvis, et al., 1991; Yamashita et al., 2000), particularly among patients with poor glucose control (Pomposelli et al., 1998). The analysis examined factors associated with early readmissions for patients having CABG or PCI, and also determined the effect of diabetes complications on readmissions. The analysis also examined the association of

discharge disposition with readmission. Three discharge statuses were examined: discharge to home; discharge to home with home health care service (HHC); and discharge to a transitional care facility. In identifying predictors of readmissions for individuals with diabetes, this study will assess how comorbid diabetes complications at the time of an index coronary revascularization hospitalization affect the likelihood of readmission. The findings will add to our understanding of important factors to consider when planning post-discharge care for individuals with diabetes who have revascularization procedures, and may help reduce readmissions in this high-risk group. Moreover, it will help to identify modifiable factors to target for interventions. The literature supports the following two hypotheses.

Hypotheses

1. Comorbid diabetes complications identified during the index hospitalization will be associated with a higher risk of hospital readmission among patients with diabetes having coronary revascularization, either CABG or PCI.

Research on readmissions for patients with congestive heart failure and for CABG patients has identified diabetes as a predictor of readmission. This association is consistent for 30-day readmission and for longer readmission durations (Krumholz, et al., 2000; Stewart, et al., 2000). Although there is little research on factors explaining readmission risk for patients with diabetes, studies have suggested complications of diabetes are independently associated with readmissions in the general population of patients with diabetes, and particularly among surgical patients with renal complications (Jiang, Stryer, Friedman, & Andrews, 2003; Molina-Corona & Zonana-Nacach, 2010; Moss, et al., 1999). Studies have also shown that patients with poor control of diabetes

and poor self-management behaviors are more likely to miss primary care appointments; lack of primary care post discharge may increase the need for emergent care that may result in a readmission (Booth & Hux, 2003).

2. Readmissions will be lower for patients discharged to home than for those discharged to transitional care, or to home with home care service.

One aim of using transitional care is to improve care transition for patients with complex needs who are vulnerable to poor care if discharged to home (Anderson, Tyler, Helms, Hanson, & Sparbel, 2005; Coleman, 2003). Patients discharged to home often have informal support that can provide necessary post-discharge care. Additional home health care service is provided for those who lack informal support or need additional formal support (Anderson, Petersen, Kistner, Soltero, & Willson, 2006; Parsons & Gifford, 2002). Ranking these discharge disposition types helps to identify patients at risk for poor health outcomes such as readmissions, and to provide services appropriate for their needs. Among these potential discharge dispositions, discharge to transitional care for cardiac-related hospitalizations has increased substantially due to the need to save costs associated with cardiac surgery, increased adoption of fast track protocols, early extubation, and early discharge (Bueno et al., 2010; Lazar, et al., 2001; Rashid, Sattar, Dar, & Khan, 2008). Patients having cardiac surgery, and particularly those with multiple comorbidities, are more likely to be discharged to transitional care (Anderson, et al., 2006). While studies have suggested that readmission rates from transitional care are high (Bini et al., 2010; Nasraway, Button, Rand, Hudson-Jinks, & Gustafson, 2000), few studies have assessed whether discharge to these facilities is associated with readmissions for patients undergoing revascularization procedures.

Design and Methods

Conceptual Framework

The framework used in this study is based on the Process, Structures and Outcomes of Care in Cardiac Surgery (PSOCS) model developed by Shroyer and colleagues (Shroyer et al., 1995). The PSOCS extends the Donabedian model (Donabedian, 1966) by adding patient factors, which represent individual patient risks and interval events, representing events that occurred post discharge that may affect the outcome of care. As shown in Figure 5.1, the structure, process of care, patient risk and interval events are related to patient outcomes. Patient characteristics represent illness severity, comorbidities, demographic characteristics, and socioeconomic factors. The structure refers to the hospital setting, resources, and structure that may influence hospital practices and care delivery, and consequently patient outcomes. The process of care represents the procedures and the care that the patient received during hospitalization. Differences in care process can affect care quality and outcomes. For example, the CABG procedure is more complex than PCI in operative time and length of hospital stay, which are predictors of readmission (Bohmer, et al., 2002; Lahey et al., 1998; Smith, et al., 2006). The interval events refer to events that occurred after discharge and may be associated with short or long-term outcomes. These events include factors such as health behaviors, care after discharge, use of primary care services, and experiences unrelated to the cardiac surgery.

Data Source

This analysis uses discharge information from the State Inpatient Database (SID) files from the Healthcare Cost and Utilization Project (HCUP) program at the Agency for

Quality and Research (AHRQ). The SID databases represent all inpatient discharges from participating states, standardized as part of the HCUP program (HCUP, 2011b). For this study, the SID databases for Arizona, California, and Florida were used because these states have a large representation of older adults and minority and ethnic groups, and a large number of revascularization discharges. In addition, these states have a high percentage of verifiable patient identifiers needed to link hospital visits and to assess readmissions (HCUP, 2011a). Discharges from Arizona were 20% of the sample data; those from California were 43%; those from Florida were 45%. Variables assessing potential differences among the states were included in the analysis. The core data elements in the SID databases include de-identified inpatient discharge-level data with information about demographic characteristics, patient disposition, length of stay, payer information, comorbidities, procedures, and diagnoses. Hospital characteristics were not assessed due to a lack of data on hospital characteristics.

Study Population

The study sample consists of patients age 45 and older who had CABG or PCI at Arizona, California, or Florida community hospitals in 2007. The sample was restricted to patients age 45 and older because increasing age is associated with having a CABG procedure and the risks for adverse outcomes after revascularization (Brooks et al., 2000; Magee, Coombs, Peterson, & Mack, 2003; Vavlukis, Georgievska-Ismail, Bosevski, & Borozanov, 2006). About 95% of CABGs and PCIs were for patients age 45 and older in 2007 (HCUPnet., 2010). Patients were included if their discharge record had one of the following International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes: 36.10-36.19, 00.66, and 36.01, 36.02,

36.05-36.07, discharged alive and having any diagnosis codes indicating that they had diabetes, shown in Table 5.1. Patients were considered to have a comorbid diabetes complication if they had diabetes and any of the following conditions: renal, ophthalmic, and neurological manifestations; peripheral circulatory disorders; uncontrolled diabetes; chronic kidney disease; or renal failure. Of the 141,568 hospitalizations when a CABG or PCI procedure was performed, 42,396 discharges met the selection criteria. Those discharged to other hospitals or with missing discharge disposition were excluded (n=618).

Outcomes

The outcome of interest in this study was early (≤ 10 days) and late (11 to 30 days) readmission after discharge. Readmission was defined as the first admission for any cause after a hospitalization with CABG or PCI. The top 10 primary diagnoses on first readmission were also identified. The number of days between the date of discharge and subsequent admission measured the time to readmission.

Explanatory Variables of Key Interest

The key explanatory variables of interest were discharge disposition and comorbid diabetes complications on index admission. For discharge disposition, the categories were: discharged to home without home health care service (referent); discharged to home with home health care service; and discharged to transitional care.

Covariates

Other covariates included clinical characteristics, comorbidities, diagnoses and procedures identified or performed during the index admission, type of health insurance, medical history, and demographic factors. Categories of patient disposition on discharge,

age, race/ethnicity, health insurance, and admission type were dummy coded, with the group having the most observations as the referent group. In some cases, such as age, the referent group was the group with the lowest risk if there was evidence of relative risk from the literature. The categories of health insurance were Medicare (referent), Medicaid, private, and self-pay. Age was categorized as: 45-54 (referent), 55-64, 65-74, and 75 and older. For race and ethnicity, the groups were African American (hereafter Black), non-Hispanic white (hereafter White) (referent), Hispanic, Asian or Pacific Islander, and Native American or other (mixed race) (Trivedi, Sequist, & Ayanian, 2006), as shown in Table 5.2. Native Americans were included in the “other” race group due to their small number in the analytic dataset. Dummy variables representing the states were included in the analysis. The referent state was Florida because it had the most observations.

Comorbidities

The Elixhauser comorbidity list used in this analysis, which includes 30 comorbidities, has been validated for use with administrative data (Elixhauser, Steiner, Harris, & Coffey, 1998; Friedman, Jiang, Elixhauser, & Segal, 2006; Stukenborg, Wagner, & Connors, 2001; Yan, Birman-Deych, Radford, Nilasena, & Gage, 2005). The algorithm differentiates between comorbidities and complications due to the care process by conservatively considering only secondary diagnoses unrelated to the diagnosis-related group (DRG) assigned to the discharge. A secondary diagnosis related to the DRG was considered a contributor to illness severity rather than a comorbid condition. For example, a patient with valve disorder with a cardiac DRG was not coded as having a valve disorder comorbidity, although it is likely that the valve disorder would

contribute to her or his illness severity. For this study, separate variables for secondary diagnoses related to the DRG were created to indicate markers of illness severity. Thus, in addition to the 30 Elixhauser comorbidities, variables for illness severity were created for secondary diagnoses of congestive heart failure, valve disorder, and pulmonary disorder. Each comorbid condition was included in the analyses as a dichotomous variable, “Yes/No.” In addition, the total number of comorbid conditions for each patient was included in the multivariate analyses, to adjust for potential associations between an increasing number of comorbidities and the outcomes.

Statistical analysis

Differences in characteristics for patients readmitted and those not readmitted were compared using the t-test for continuous variables and the chi-square statistic for categorical variables. To evaluate whether diabetes complications and discharge disposition were associated with readmission, Kaplan-Meier analyses were conducted using the log-rank test, with censoring at 30 days. Cox proportional hazards models assessed the association between characteristics of patients and their care during the index hospitalization, with particular focus on discharge disposition and comorbid diabetes complications, and the hazard of readmission. The hazard function curve in Figure 5.2 shows multiple peaks, an indication of multiple changes in direction, and thus supports using the Cox hazard model (Allison, 2010). Adherence to the proportional hazards assumption was verified using log-cumulative hazard plots, time-dependent covariates, and Schoenfeld residuals (Allison, 2010; Fisher & Lin, 1999). Separate multivariate models were fit for readmissions that occurred within 10 days after discharge, categorized as early readmission, and 11 to 30 days after discharge,

categorized as late readmission. The point used to stratify readmission was based on the point where the hazard function rate changed. As shown in Appendix B, the log-cumulative hazard plot for diabetes complications diverged at day 5, suggesting the relationship of diabetes complications and readmission may vary with time. Thus, a time-dependent covariate was created to assess the effect of comorbid diabetes complications within 5 days of discharge. This time-dependent variable was not significant and was not included in the final models.

All models included adjustments for age, sex, race/ethnicity, health insurance, household income, and comorbidities. Patients with unknown discharge disposition and those discharged to other acute care hospitals were excluded from the analyses. The fit of the models was checked using log-likelihood statistics and covariates were manually eliminated from the models based on their p-values. Hazard ratios (HRs) and their 95% Confidence Intervals (CIs) were estimated. P-values <0.05 were considered to be statistically significant. All analyses were conducted using SAS (Version 9.2 SAS institute) and JMP ® Software (Version 8 SAS institute).

Results

Sample Characteristics

The crude survival rate for readmission within 30 days of discharge and the descriptive characteristics of the study population are shown in Figure 5.4 and presented in Table 5.3. Figure 5.4 shows that by day 5 only 2% had been readmitted. By day 10, the cumulative number of readmissions had doubled, with 4% of the patients having been readmitted. Of the 41,778 patients included in the study, 13.5% were readmitted. Table 5.3 shows that men were 65.4% of the analytic sample; 11.9% of the sample had

comorbid diabetes complications. Most were discharged to home without HHC (75.3%), followed by those discharged to home with HHC (16.7%); 8% were discharged to transitional care. The most common primary diagnoses and procedures at first readmission are presented in Table 5.4. Cardiac-related diagnoses accounted for five out of the ten top primary diagnoses, postoperative infection and complications of graft were among the top 10. The most common procedure during readmissions was angioplasty, accounting for 14.1% of all readmission procedures.

Bivariate Analyses

Descriptive differences between patients readmitted and those who were not readmitted are presented in Table 5.5. Compared to those who were not readmitted, those readmitted were more likely to be 75 years and older (32.1% vs. 24.4%, $p<.0001$), women (38.7% vs. 33.9%, $p<.0001$), Blacks (6.8% vs. 5.8%, $p=.0016$), Hispanics (16.5% vs. 15.4%, $p=.0295$) and to have public health insurance. In addition, those readmitted were more likely to have been discharged to home with home health care service (18.6% vs. 16.4%, $p<.0001$) and to transitional care (17.6.7% vs. 6.5%, $p<.0001$). Other factors that were different included clinical characteristics such as atrial fibrillation, acute myocardial infarction and comorbidities. Most of these characteristics were more common among readmitted patients.

Multivariate Analyses

Tables 5.6 and 5.7 present the hazard ratios (HRs) and their confidence intervals (CIs) for the hazard of readmission. Table 5.6 presents the hazard ratios associated with early readmission. Table 5.7 presents the hazard ratios associated with late readmission. Diabetes complications were associated with 24% greater risk of early readmission (HR

1.24, CI 1.08-1.42). In Appendix B, Figure 5.5 shows the crude lognormal plot of diabetes complications during early readmissions. In the first five days after discharge, the risk of readmission between those with diabetes complications and those without complications was similar. However, this changed after day 5, as the risk increased for those with diabetes complications. There was no significant difference in early readmission between those discharged to home with or without home health care (HR 1.18, CI 0.98-1.42). However, the relative risk of readmission for those discharged to transitional care was quite high (HR 4.16, CI 3.53-4.91). Other factors associated with a higher likelihood of early readmission were comorbid cancer, arthritis, chronic obstructive pulmonary disease (COPD), drug abuse, and peripheral vascular disorders (PVD). There were differences in readmission risks between the states. Compared to Florida, those in Arizona (HR 1.36, CI 1.17-1.58) and California (HR 1.29, CI 1.08-1.55) had greater readmission risk. Some factors were protective against early readmissions. These included having low median household income, private insurance or self-paid care.

For late readmissions (Table 5.7), having comorbid diabetes complications (HR 1.27, CI 1.17-1.39) was a risk factor. Race/ethnicity was associated with late readmissions, with Blacks (HR 1.17, CI 1.03 -1.34) and Hispanics (HR 1.10, CI 1.00-1.20) at significantly higher risk than Whites. Discharge both to home with home care service (HR 1.24, CI 1.12-1.36) and to transitional care facility (HR 1.88, CI 1.69-2.10) were associated with a higher risk of late readmission compared to discharge to home without home care service. Other risk factors for late readmission included depression (HR 1.16, CI 1.02-1.33), psychoses (HR 1.33, CI 1.08-1.64) and being female, atrial fibrillation, comorbid cancer, anemia, COPD, and PVD. Older age was associated

with lower readmission. Compared to those in the 45-54 age group, older patients were significantly less likely to have late readmission. Other factors associated with lower readmission risk included having lower median household income, private health insurance, self-paying for care, and being uninsured. The hazard ratios for late readmissions did not differ among the states.

Discussion

While it is still debated whether readmission is an effective measure of quality (Luthi, Burnand, McClellan, Pitts, & Flanders, 2004; Powell, Davies, & Thomson, 2003), evidence highlighting the cost implications and increased risks of morbidity and mortality associated with readmission is consistent (Ashton, Kuykendall, Johnson, Wray, & Wu, 1995; Curtis, et al., 2009). Outcomes of CABG and PCI have been widely studied due to the volume of these procedures performed annually in the U.S., risk for adverse outcomes, and the need to improve care quality and reduce associated costs (Eagle et al., 2004; Smith, et al., 2006). Although readmission can be influenced by the care process, patient risk factors are also important predictors of the likelihood of readmission (Curtis, et al., 2009; Hannan, et al., 2003; Sun, et al., 2008). Understanding these risk factors can help enhance effective management of patient care, both inpatient and outpatient, to reduce readmissions. Among CABG and PCI patients, diabetes has been suggested as a predictor of readmissions (Curtis, et al., 2009; Hannan, et al., 2003; Stewart, et al., 2000; Sun, et al., 2008). Previous studies have focused on the general CABG and PCI population or the general population of patients with diabetes (Jiang, et al., 2005; Jiang, et al., 2003; Moss, et al., 1999). Little research has evaluated characteristics associated with readmission risk after coronary revascularization for patients with diabetes. This

study addressed that research gap. Further, the analysis examined associations between discharge disposition and readmission for this patient population.

This research assessed two hypotheses. The first hypothesis was that comorbid diabetes complications present during an index hospitalization for patients having coronary revascularization would be associated with higher risk of readmission. The study results support this hypothesis. Patients with comorbid diabetes complications had higher risks of both early and late readmission. Although there is limited research on readmissions among patients with diabetes complications after CABG or PCI, the finding of the present study is consistent with previous research (Jiang, et al., 2003; Moss, et al., 1999; Tomlin, Tilyard, Dovey, & Dawson, 2006), in which diabetes complications were associated with multiple hospitalizations (Jiang, et al., 2003) whereas uncontrolled glucose and nephropathy were associated with readmissions (Molina-Corona & Zonana-Nacach, 2010; Moss, et al., 1999). The current study further clarifies this association by quantifying this risk in patient with diabetes having CABG and PCI. One suggestion in the results was that the risk associated with diabetes complications may vary over time, with perhaps no associated risk in the first few days after discharge.

During the 5 days after discharge, those with and without diabetes complications had similar readmission risks. However, this risk increased after day 5. During hospitalization, management of diabetes and tight control of blood glucose is often maintained (Braithwaite et al., 2008; Yalla & Reynolds, 2009). The late effect of the tight control of blood glucose during hospitalization may explain this observation. If the diabetes was not adequately managed after discharge, the risk for readmission could increase over time.

The second hypothesis was that readmission risk would be lower for patients discharged to home without home health care than for those discharged to transitional care or to home with home health care. The results support this hypothesis. Compared to those discharged to home without home health care, the risks of early and late readmission were higher for those discharged to transitional care, and late readmission was higher for those discharged to home with home health care. This result is consistent with findings from previous research on 30-day readmission for CABG patients that assessed discharge disposition and found patients discharged to home with services, or to transitional care, had significantly more readmissions (Bohmer, et al., 2002). The current study also highlighted potential variations in the effect of discharge with HHC on readmission over time. For readmission occurring within 10 days after discharge, discharge with HHC service was not significantly different from discharge to home. However, this changed for readmissions that occurred after 10 days following discharge. This difference in the risk of readmission for patients discharged to home with HHC over time may be due to changes in formal and informal post-discharge support (McCall, Petersons, Moore, & Korb, 2003). Further, increased readmissions among patients discharged with HHC service after 10 days may be due to termination of the HHC service, a factor that was not analyzed in this study.

There was strong evidence for the effect of neurological dysfunction on readmission, with depression and psychoses associated with 16% and 33% higher risk of late readmissions. Changes in environment and social isolation, especially for patients discharged to transitional care, may explain the association between neurological dysfunction and readmission (Anderson, et al., 2005). In another area, previous research

has indicated varying readmission risks for men and women and for several race/ethnic minority groups (Jiang, et al., 2005; Steuer et al., 2002). This was confirmed in the current study, with women, Blacks and Hispanics more likely to have late readmission.

Most of the primary diagnoses from readmissions were cardiac-related; the most common primary procedure was angiography. Preliminary analysis of patients who had angiography during the first readmission, in relation to having had PCI during the index hospitalization, suggests that repeat PCI may be high for these patients. Future research should focus on assessing the link between PCI during the index hospitalization and repeat PCI during a readmission.

A strength of this study was that it provided information about factors that may increase readmission risk for patients with diabetes. The large study sample permitted sub-group analyses and evaluation of readmissions at different intervals. Stratifying the study analyses into early and late, based on changes in the hazard function, provided additional knowledge about readmission for patients with comorbid diabetes complications immediately after discharge and later. Having data on patients' discharge disposition also allowed assessing its association with readmission.

Despite the study's strengths, there are some limitations. Although the sample represented the universe of CABG and PCI performed in the states studied, the findings may not be generalizable to the U.S. population. The analyses were limited to discharges in 2007, and thus could not consider readmissions that occurred after this period. Eliminating discharges that occurred in December 2007 would have corrected this limitation; however, the month of discharge was not available for many patients. The data did not provide information about the level or quality of care received at home with

or without HHC services, or at transitional care facilities; this level and quality may affect readmission. Further, the data lack information on hospital characteristics, and the analysis could not control for the potential effects of hospital factors. Other unmeasured factors that may affect readmission include the discharge process, and use of adjuvant therapy on discharge such as aspirin and β -blockers. Adjusting readmission risks with relevant covariates, such as insurance status and income, may mitigate the effect of some unmeasured factors.

Implications for Policy and Practice

This study highlighted readmission risks following revascularization associated with comorbid diabetes complications. Patients with comorbid diabetes complications were more likely to be readmitted. While this risk was not observed in the days immediately following discharge, it steadily increased after 5 days following discharge. As poor management of diabetes is an important factor in the incidence of acute diabetes complications such as hyperglycemia, hypoglycemia, and ketoacidosis, the lack of adequate diabetes management may explain the higher risk of readmission for these patients. Further research is necessary to identify vulnerabilities that may affect these patients, and perhaps to extend the analysis to the level of diabetes management they received during inpatient and outpatient care.

Similarly, readmission risk in the first days following discharge did not differ between those discharged to home with or without home health care services. The lognormal plot actually suggested a fewer readmissions in patients discharged to home with home health care than those discharge to home during this period. However, this risk of readmission increased over time among patients discharged with home health

care. Further research should seek to explain this variation and assess the potential effect of termination of the HHC services as possibly explaining increased late readmissions for patients using HHC services after discharge. This should be evaluated, however, with consideration for potential scheduled readmissions or higher readmission risk unrelated to quality of care during the index hospitalization, associated with higher illness acuity or lack of informal care that may trigger arrangements for HHC services. As more patients who have coronary revascularization are discharged to transitional care facilities, further focus on these patients would be useful to explain their greater risk of rehospitalization.

Although using transitional care to extend care may be beneficial for some patients, it may not be cost-effective and beneficial for patients with diabetes, as more of them who have transitional care return to the hospital shortly after discharge. Providing extended diabetes management and follow-up care after discharge may help reduce readmission risk for these patients.

Table 5.1: Criteria Used to Define Outcomes and Explanatory Variables

Diagnosis and Procedure	ICD-9-CM Codes ^a
Coronary artery bypass graft	3610, 3611, 3612, 3613, 3614, 3615, 3616, 3617, 3618, 3619
Percutaneous coronary intervention	0066, 3601, 3602, 3605, 3606, 3607
Diabetes	25000-25033, 64800-64804
Diabetes complications	25040 - 25093, 5853, 5854, 5855, 5856, 5859, 586,
CABG history	V4581
PCI history	V4582

^aICD-9-CM=International Classification of Diseases, 9th Revision, Clinical Modification; CABG=Coronary artery bypass graft; PCI=Percutaneous coronary intervention.

Table 5.2: Definition of Variable and Coding^a

Variable	Definition
Gender	Men Women
Race	Non-Hispanic White Black Hispanic Asian/Pacific Islander Native American/others
Primary payer	Medicare Medicaid Private insurance Self-pay Other
Median household income ^b	\$45,000 or more \$25,000-34,999 \$35,000-44,999 \$1-24,999
Discharge disposition	Home without home health care services Home with home health care services Transitional care facility ^c
Age	45-54 55-64 65-74 74 and over
Comorbidities	Conditions diagnosed as secondary to the primary diagnosis and unrelated to the patient assigned diagnosis-related group

^aSource: Nationwide Inpatient Sample, 2007.

^bThe median household income of the patient's ZIP Code of residence.

^cIncluded: Skilled nursing facility, Intermediate care facility and rehabilitation facility.

Table 5.3: Descriptive Characteristics of Patients with Diabetes Having Coronary Revascularization (N=41,778), 2007^a

	n	%
Readmission		
No	36143	86.5
Yes	5635	13.5
Gender		
Men	27320	65.4
Women	14458	34.6
Age		
45-54	5508	13.2
55-64	11905	28.5
65-74	13778	33.0
75 and older	10587	25.3
Discharge disposition		
Home	31443	75.3
Home with home health care (HHC)	6978	16.7
Transitional care facility (TCF)	3357	8.0
Comorbid diabetes complications		
No	36788	88.1
Yes	4990	11.9
Race/Ethnicity		
White	28219	67.6
Black	2463	5.9
Hispanic	6487	15.5
Asian	2084	5.0
Other	1423	3.4
Missing	1102	2.6
Had PCI	29689	71.1
Had CABG	12487	29.9

Data source: 2007 Arizona, California, and Florida State Inpatient Databases (SIDs); CABG=Coronary artery bypass graft; PCI= Percutaneous coronary intervention

Table 5.4: Most Common Primary Diagnoses and Procedures at First Readmission, 2007^a

<i>Diagnosis</i>	%	n
Acute myocardial infarction	15.8	932
Congestive heart failure	8.4	495
Rehabilitation	4.9	289
Chest pain	4.9	287
Postoperative infection	3.9	233
Endocardia infarction	2.9	174
Atrial fibrillation	1.8	106
Pneumonia	1.67	99
Unspecified chest pain	1.54	91
Complications of graft or implant	1.47	87
<i>Procedure</i>		
PCTA ^a	14.1	835
Cardiac Catheterization	4.4	259
Pleural tap	3.2	189
Transfusion of packed cell	3.0	180
Surgical occlusion of vessels	2.5	145
Hemodialysis	3.6	126
Physical therapy	2.7	94
Diagnostic ultrasound	2.4	82
Diagnostic endoscopic	2.0	69
Defibrillator implant	1.8	61

Data source: 2007 Arizona, California, and Florida State Inpatient Databases (SIDs); ^aPCTA: Percutaneous coronary transluminal angioplasty.

Table 5.5: Baseline Characteristics of Patients According to Readmission Status Within 30 days of Discharge (N=41,778), 2007^a

<i>Demographics</i>	Readmission Status		P-value
	Yes (%)	No (%)	
<i>Age</i>			
45-54	12.0	13.4	0.0023
55-64	24.4	29.1	<.0001
65-74	32.1	33.1	0.1176
75 and older	32.1	24.4	<.0001
<i>Median household income</i>			
\$1-24,999	17.5	18.7	0.0301
\$25,000-34,999	17.0	17.8	0.1216
\$35,000-44,999	11.9	12.8	0.0526
\$50,000 and over	6.6	6.9	0.3270
<i>Race/Ethnicity</i>			
White	66.5	67.7	0.0803
Black	6.8	5.8	0.0016
Hispanic	16.5	15.4	0.0295
Asian	4.9	5.0	0.6687
Other	3.3	3.4	0.7561
Women	38.7	33.9	<.0001
<i>Health insurance</i>			
Medicare	65.0	56.7	<.0001
Medicaid	7.5	6.5	0.0065
Self-Pay	1.6	2.5	<.0001
Private insurance	22.2	29.7	<.0001
<i>Clinical characteristics</i>			
Had PCI	67.1	71.7	<.0001
Had CABG	34.3	29.2	<.0001
History of PCI	16.0	17.3	0.0148
Atrial fibrillation	21.1	14.9	<.0001
Acute myocardial infarction	4.7	3.9	0.0051
Postoperative stroke	3.2	1.7	<.0001
<i>Discharge disposition</i>			
Home	63.7	77.1	<.0001
Home with home health care	18.6	16.4	<.0001
Transitional care facility	17.6	6.5	<.0001
<i>Comorbidities</i>			
Diabetes complication	17.6	11.1	<.0001
Peripheral vascular disorders	16.7	12.9	<.0001

COPD	23.1	16.9	0.0005
Arthritis	2.0	1.4	0.0008
Neurological disorders	3.9	2.4	<.0001
Anemia deficiency	22.1	15.1	<.0001
Electrolyte disorder	14.9	10.9	<.0001
Depression	6.0	4.4	<.0001
Psychoses	2.2	1.2	<.0001
Cancer	2.2	1.4	<.0001

^aData source: 2007 Arizona, California, and Florida State Inpatient Databases (SIDs); CABG=Coronary artery bypass graft; PCI=Percutaneous coronary intervention; COPD=chronic obstructive pulmonary disorder.

Table 5.6: The Adjusted Hazard Ratio for Readmission at ≤ 10 days After Discharge, 2007^a

<u>Parameters</u>	<u>Estimate</u>	<u>HR^a</u>	<u>LB^b</u>	<u>UB^c</u>	<u>P-value</u>
Diabetes Complications	0.212	1.24	1.08	1.42	0.0022
Log of length of stay	-0.254	0.78	0.72	0.83	<.0001
Women	0.107	1.11	1.01	1.23	0.0307
Home Healthcare	0.166	1.18	0.98	1.42	0.0746
Transitional care facility	1.426	4.16	3.53	4.91	<.0001
Arizona state	0.309	1.36	1.17	1.58	<.0001
California state	0.256	1.29	1.08	1.55	0.0052
55-64	-0.033	0.97	0.82	1.14	0.6882
65-74	-0.213	0.81	0.67	0.97	0.0234
75 and older	0.022	1.02	0.85	1.24	0.8221
\$1-24,999	-0.220	0.80	0.66	0.97	0.0265
\$25,000-34,999	-0.167	0.85	0.70	1.03	0.0942
\$35,000-44,999	-0.143	0.87	0.70	1.07	0.1806
Cancer	0.416	1.52	1.11	2.07	0.0088
Medicaid	-0.111	0.9	0.72	1.11	0.3058
Self	-0.483	0.62	0.41	0.92	0.0191
Private	-0.156	0.86	0.74	0.99	0.0330
Arthritis	0.391	1.48	1.09	2.01	0.0128
CHF	-1.133	0.32	0.16	0.65	0.0016
COPD	0.223	1.25	1.11	1.41	0.0003
Drug Abuse	0.696	2.01	1.30	3.08	0.0015
Hypertension	0.145	1.16	1.03	1.30	0.0175
Peripheral vascular disorders	0.174	1.19	1.05	1.35	0.0079

^aData source: 2007 Arizona, California, and Florida State Inpatient Databases (SIDs); CABG=Coronary artery bypass graft; PCI= Percutaneous coronary intervention; CHF=congestive heart failure; COPD=chronic obstructive pulmonary disorder; Reference categories: Men, discharge to home without home health care services, Florida, age group 45-55, \$50,000+ median household income, and Medicare. ^bHR: Hazard ratio. ^cLB: Lower bound of

Table 5.7: The Adjusted Hazard Ratio of Readmission at >10 days Post-discharge, 2007^a

<u>Parameters</u>	<u>Estimate</u>	<u>HR^a</u>	<u>LB^b</u>	<u>UB^c</u>	<u>P-value</u>
Diabetes complications	0.241	1.27	1.17	1.39	<.0001
Length of stay	0.319	1.38	1.31	1.45	<.0001
Black	0.160	1.17	1.03	1.34	0.0152
Hispanic	0.095	1.10	1.00	1.20	0.0390
Asian	-0.015	0.99	0.85	1.15	0.8474
Other	0.076	1.08	0.90	1.29	0.4017
Missing	-0.315	0.73	0.58	0.92	0.0080
Atrial Fibrillation	0.163	1.18	1.08	1.28	<.0001
Women	0.090	1.09	1.02	1.17	0.0088
Home Healthcare	0.211	1.24	1.12	1.36	<.0001
Transitional care facility	0.633	1.88	1.69	2.10	<.0001
Arizona State	0.076	1.08	0.96	1.21	0.1961
California State	0.092	1.10	0.96	1.25	0.1582
55-64	-0.166	0.85	0.76	0.95	0.0046
65-74	-0.202	0.82	0.72	0.93	0.0019
75 and older	-0.165	0.85	0.74	0.97	0.0161
\$1-24,999	-0.102	0.90	0.79	1.03	0.1410
\$25,000-34,999	-0.014	0.99	0.86	1.13	0.8440
\$35,000-44,999	-0.046	0.96	0.83	1.10	0.5378
Cancer	0.271	1.31	1.05	1.63	0.0150
Medicaid	0.008	1.01	0.88	1.15	0.9129
Self	-0.457	0.63	0.49	0.82	0.0006
Private	-0.297	0.74	0.67	0.82	<.0001
Uninsured	-0.214	0.81	0.67	0.97	0.0221
Nutritional deficiency	-0.422	0.66	0.50	0.86	0.0026
Anemia deficiency	0.112	1.12	1.03	1.21	0.0062
COPD	0.168	1.18	1.10	1.28	<.0001
Depression	0.151	1.16	1.02	1.33	0.0276
Peripheral vascular disorders	0.091	1.10	1.00	1.19	0.0387
Psychoses	0.286	1.33	1.08	1.64	0.0070

^aData source: 2007 Arizona, California, and Florida State Inpatient Databases (SIDs); CABG=Coronary artery bypass graft; PCI= Percutaneous coronary intervention; CHF=congestive heart failure; COPD=chronic obstructive pulmonary disorder; Reference categories: Men, discharge to home without home health care services, Florida, age group 45-55, \$50,000+ median household income, and Medicare. ^aHR: Hazard ratio. ^bLB: Lower bound of 95% confidence interval. ^cUB: Upper bound of 95% confidence interval.

Figure 5.1: Graphical Representation of Conceptual Model: from Shroyer et al., 1995

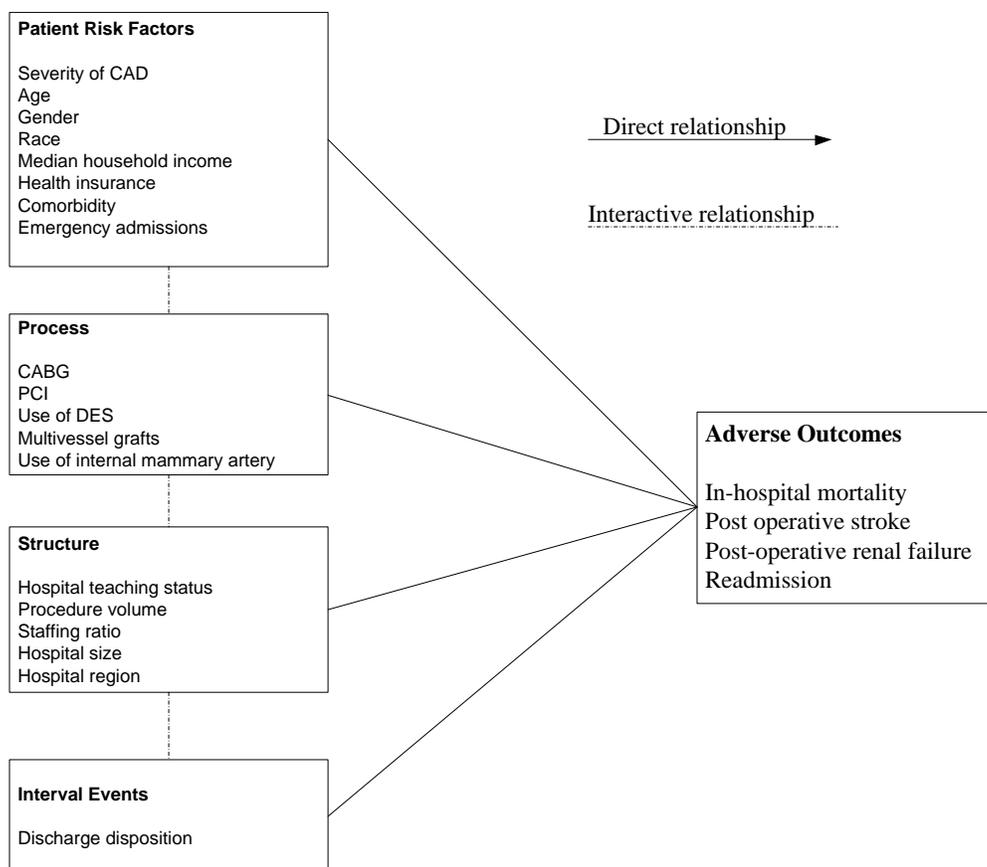


Figure 5.2: Cumulative Hazard Function for 30-day Readmissions

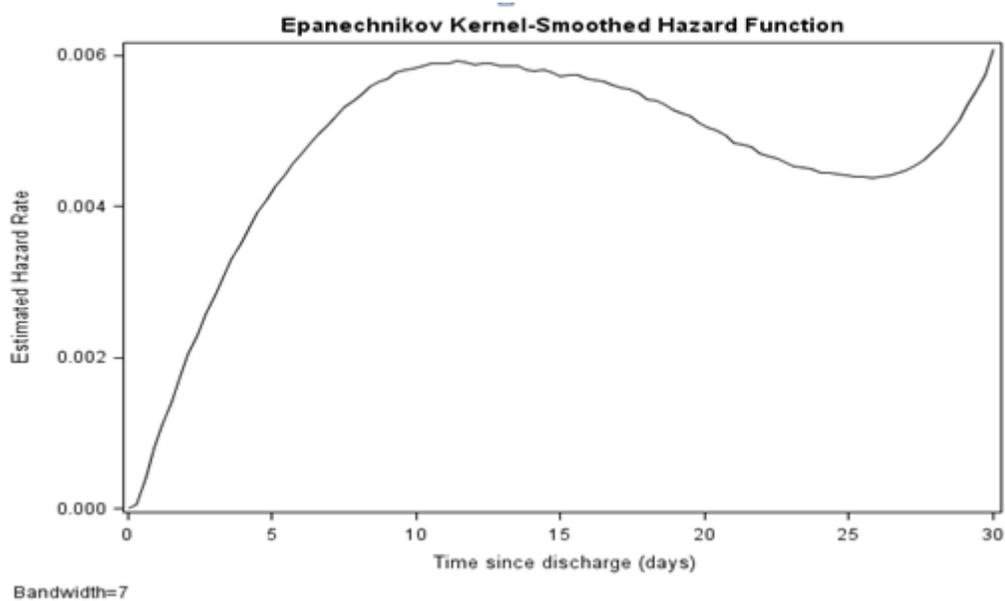


Figure 5.3: The LogNormal Cumulative Plot for Diabetes Complications and 10-day Readmissions

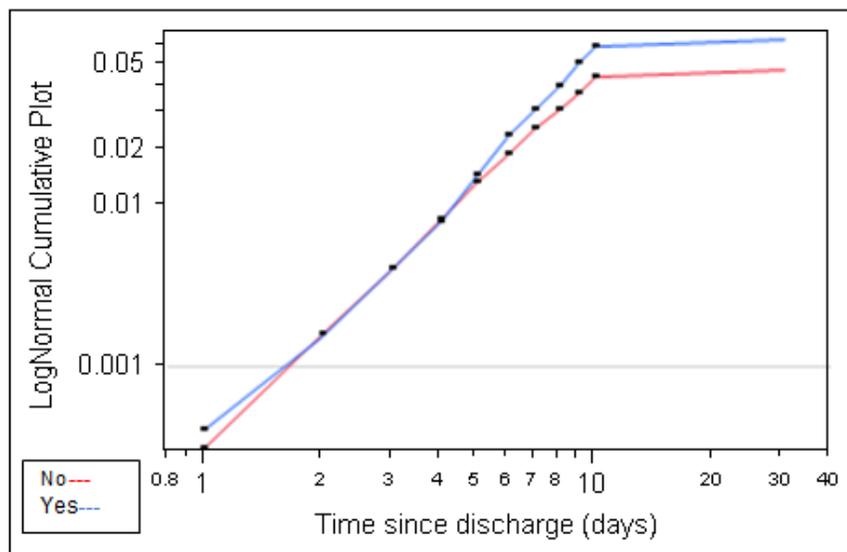
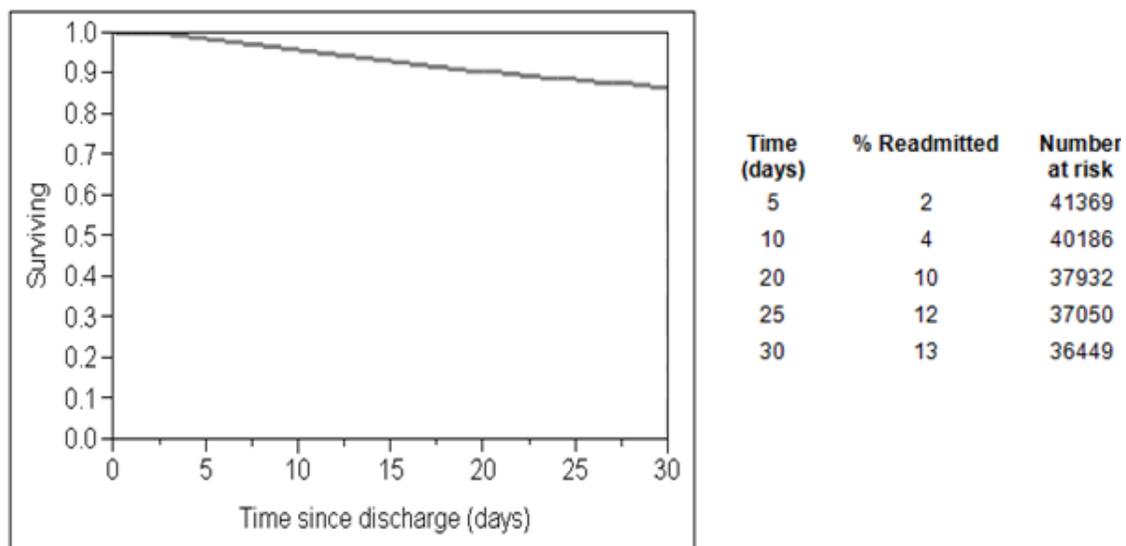


Figure 5.4: Survival Plot and Table Showing the Percentage Readmitted by Specific Days



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APPENDIX A: THE DESCRIPTION AND CODING FOR BED SIZE
BED SIZE CATEGORIES

<u>Location and Teaching Status</u>	<u>Hospital Bed Size</u>		
	<u>Small</u>	<u>Medium</u>	<u>Large</u>
NORTHEAST REGION			
Rural	1-49	50-99	100+
Urban, nonteaching	1-124	125-199	200+
Urban, teaching	1-249	250-424	425+
MIDWEST REGION			
Rural	1-29	30-49	50+
Urban, nonteaching	1-74	75-174	175+
Urban, teaching	1-249	250-374	375+
SOUTHERN REGION			
Rural	1-39	40-74	75+
Urban, nonteaching	1-99	100-199	200+
Urban, teaching	1-249	250-449	450+
WESTERN REGION			
Rural	1-24	25-44	45+
Urban, nonteaching	1-99	100-174	175+
Urban, teaching	1-199	200-324	325+

Source: Nationwide Inpatient Sample Documentation

APPENDIX B: THE UNADJUSTED CUMULATIVE PLOT OF READMISSIONS BY DIABETES COMPLICATIONS

