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Surgical Versus Percutaneous Coronary Revascularization in Patients With Diabetes and Acute Coronary Syndromes

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ABSTRACT

BACKGROUND Randomized trial data support the superiority of coronary artery bypass grafting (CABG) surgery over percutaneous coronary intervention (PCI) in diabetic patients with multivessel coronary artery disease (MV-CAD). However, whether this benefit is seen in a real-world population among subjects with stable ischemic heart disease (SIHD) and acute coronary syndromes (ACS) is unknown.

OBJECTIVES The main objective of this study was to assess the generalizability of the FREEDOM (Future REvascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multi-vessel Disease) trial in real-world practice among patients with diabetes mellitus and MV-CAD in residents of British Columbia, Canada. Additionally, the study evaluated the impact of mode of revascularization (CABG vs. PCI with drug-eluting stents) in diabetic patients with ACS and MV-CAD.

METHODS In a large population-based database from British Columbia, this study evaluated major cardiovascular outcomes in all diabetic patients who underwent coronary revascularization between 2007 and 2014 (n = 4,661, 2,947 patients with ACS). The primary endpoint (major adverse cardiac or cerebrovascular events [MACCE]) was a composite of all-cause death, nonfatal myocardial infarction, and nonfatal stroke. The risk of MACCE with CABG or PCI was compared using multivariable adjustment and a propensity score model.

RESULTS At 30-days post-revascularization, for ACS patients the odds ratio for MACCE favored CABG 0.49 (95% confidence interval [CI]: 0.34 to 0.71), whereas among SIHD patients MACCE was not affected by revascularization strategy (odds ratio: 1.46; 95% CI: 0.71 to 3.01; $p_{interaction} < 0.01$). With a median follow-up of 3.3 years, the late (31-day to 5-year) benefit of CABG over PCI no longer varied by acuity of presentation, with a hazard ratio for MACCE in ACS patients of 0.67 (95% CI: 0.55 to 0.81) and the hazard ratio for SIHD patients of 0.55 (95% CI: 0.40 to 0.74; $p_{interaction} = 0.28$).

CONCLUSIONS In diabetic patients with MV-CAD, CABG was associated with a lower rate of long-term MACCE relative to PCI for both ACS and SIHD. A well-powered randomized trial of CABG versus PCI in the ACS population is warranted because these patients have been largely excluded from prior trials. (J Am Coll Cardiol 2017;70:2995–3006)
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Globally, the prevalence of diabetes mellitus (DM) among adults is projected to reach 642 million by 2040 (1). Total deaths from DM are projected to rise by more than 50% in the next 10 years, thereby making DM and its complications important societal and public health concerns. Patients with DM are prone to a diffuse and rapidly progressive forms of atherosclerosis, which increases their likelihood of having multivessel coronary artery disease (MV-CAD) requiring

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ABBREVIATIONS AND ACRONYMS

ACS = acute coronary syndrome(s)

CABG = coronary artery bypass grafting

CAD = coronary artery disease

CI = confidence interval

DES = drug-eluting stent

DM = diabetes mellitus

HR = hazard ratio

IQR = interquartile range

IV = instrumental variable

LVEF = left ventricular ejection fraction

MACCE = major adverse cardiac or cerebrovascular event(s)

MACCE(r) = composite of major adverse cardiac or cerebrovascular event and repeat revascularization

MI = myocardial infarction

MV-CAD = multivessel coronary artery disease

OR = odds ratio

PCI = percutaneous coronary intervention

SIHD = stable ischemic heart disease

revascularization (2). Selecting the optimal coronary revascularization strategy for patients with DM and MV-CAD is crucial to reduce the high rate of thrombotic complications and improve quality of life.

The choice between CABG and PCI in DM remains an area of intense discussion and debate. In 2012, the results of the randomized controlled FREEDOM (Future REvascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multi-vessel Disease) trial demonstrated lower rates of major adverse cardiovascular events in patients with stable ischemic coronary disease (SIHD) who were assigned to coronary artery bypass grafting (CABG) compared with percutaneous coronary intervention (PCI) using drug-eluting stents (PCI-DES), over a median of 3.8 years of follow-up (3). The results of FREEDOM also showed a borderline reduction in all-cause mortality ($p = 0.049$) favoring CABG over PCI-DES; this effect was confirmed in a robust meta-analysis of randomized trials (4).

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Although carefully planned and conducted randomized trials provide the greatest intrinsic validity of the study question under consideration, the generalizability of these observations in the real world are often limited by the recruitment criteria. Therefore, well-conducted population-based analyses that provide complementary extrinsic validation of randomized trials remain important components of overall knowledge translation efforts and are often the sources of supplementary information for key stakeholders.

The main objective of our study was to assess the generalizability of the FREEDOM trial in real-world practice among patients with DM and MV-CAD in residents of British Columbia, Canada. Additionally, we evaluated the impact of mode of revascularization (CABG vs. PCI-DES) in diabetic patients with acute coronary syndromes (ACSs) and MV-CAD. Previous studies of CABG versus PCI in DM patients with MV-CAD consisted mostly of patients with stable ischemic heart disease (SIHD) (4). The present study allowed us to analyze the ACS subgroup that represents a large proportion of people with DM who are undergoing revascularization, and where there is guideline equipoise (5).

METHODS

DATA SOURCES. Cardiac Services British Columbia holds a province-wide registry that captures patients' demographic and clinical data for all coronary angiography and revascularization procedures in British Columbia. This registry was used to define the study cohort. Hospitalization separation data for all patients hospitalized in British Columbia, including admission and discharge date, hospital identification code, and International Classification of Disease-10th Revision diagnosis codes, were used to identify the following outcomes: myocardial infarction (MI) and stroke. The Vital Statistics Deaths registry provides all death dates in British Columbia and was used to identify all-cause mortality. There are 5 cardiac catheterization sites in British Columbia, all with PCI and CABG capabilities. All 5 sites are located in the southern and central regions of British Columbia and are reliant on a "hub and spoke" referral process and an extensive transport network. In British Columbia, approximately 80% of all PCIs are carried out as ad hoc procedures with high rates of DES use (80%). We obtained ethics approval from the University of British Columbia-Providence Health Care Research Ethics Board.

COHORT DEFINITION. This is a population-based, retrospective cohort study of all patients older than 20 years of age with DM and angiographically confirmed MV-CAD (stenosis of >70% in 2 or more major epicardial vessels, excluding the left main coronary artery) who underwent either PCI or isolated CABG between October 1, 2007 and January 31, 2014 in British Columbia. As in the FREEDOM trial, subjects with severe heart failure (New York Heart Association functional class III or IV), prior CABG or PCI within 6 months, prior valve surgery, 2 or more chronic total occlusions, ST-segment elevation MI within 72 h, and stroke within 6 months were excluded (**Figure 1**).

OUTCOME DEFINITION. The primary outcome was the first occurrence of a major adverse cardiac or cerebrovascular event (MACCE), defined as a composite of all-cause mortality, nonfatal MI (International Classification of Disease-Tenth Revision [ICD-10] codes I21, I22) and nonfatal stroke (ICD-10 codes I60 to I64, H356, H341, H342, and H348) after revascularization. Secondary outcomes included the individual components of MACCE, repeat revascularization post-discharge (RR), and a composite of MACCE and repeat revascularization (MACCE[r]). Staged PCI was defined as a nonemergency PCI that was planned and performed within 2 months of the previous PCI; these PCIs were not included in identifying repeat revascularizations post-discharge. The validity of ICD-10 codes for determination of outcomes has been well validated (6).

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