書籍

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研究成果の刊行物・別刷

Title

Preoperative poor glycemic control is associated with worse outcomes after percutaneous coronary intervention compared with coronary artery bypass grafting
- Insights from the CREDO-Kyoto Registry –

Running Title

Poor glycemic control as a predictor for worse PCI outcomes

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ABSTRACT

AIMS: Glucose metabolism disorders are associated with poor outcomes after coronary revascularization. HbA1c level is a recommended marker for long-term glycemic control. The aim of the present study was to investigate the impact of preoperative glycemic control on outcomes after percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG).

METHODS AND RESULTS: Among the patients undergoing first PCI or CABG who were enrolled in the CREDO-Kyoto Registry, those with multivessel and/or left main coronary disease had preoperative HbA1c level obtained and enrolled into the present study (1975 PCI and 1175 CABG). Median follow-up was 3.5 years. Preoperative HbA1c levels were not different between patients undergoing PCI and CABG (6.4±1.5% vs. 6.4±1.5%, p=0.81). In good control patients (diabetes with preoperative HbA1c level of <7%, n=954), the incidences of propensity-matched all-cause death and composite events (cardiovascular death, stroke, or myocardial infarction) were similar between PCI and CABG (hazard ratio [95% confidence interval]: 1.14 [0.75-1.72], p=0.55 and 0.87 [0.62-1.23], p=0.44, respectively). Outcomes were similar in nondiabetic patients (n=1311). However, in poor control patients (diabetes with HbA1c level of ≥7%, n=885), the incidences of propensity-matched all-cause death and composite events were higher in the PCI compared with CABG (2.56 [1.54-4.26], p<0.01 and 1.75 [1.18-2.59], p<0.01, respectively).

CONCLUSIONS: Poor preoperative glycemic control, as measured by an elevated HbA1c level, is associated with poor outcomes after PCI compared with CABG. However, outcomes are similar in good control diabetes or nondiabetic patients. CABG may be a favorable revascularization strategy in patients with multivessel and/or left main disease, who suffer from

poor preoperative glycemic control.

Key Words: coronary artery disease, percutaneous coronary intervention, coronary artery bypass grafting (CABG), follow-up study, diabetes.

INTRODUCTION

Diabetes mellitus has been recognized as an independent risk factor for poor outcomes following coronary revascularization [1]. Several studies have compared the outcomes between diabetic and nondiabetic patients after percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) [2-5]. However, outcomes may be different between patients with good and poor control diabetes. Namely, the influence of preoperative glycemic control on outcomes has not been well elucidated. Furthermore, there are few multicenter studies that investigated the impact of preprocedural glycemic control on outcomes of each treatment modality (PCI or CABG).

Hemoglobin A1c (HbA1c), known as glycosilated hemoglobin, indicates a patient's blood glucose control during the previous 3 to 4 months. The American Diabetes Association recommended that patients with diabetes achieve HbA1c level less than 7%, which is associated with a lower risk of diabetes-associated complications [6]. Thus, HbA1c level rather than the diagnosis of diabetes may be a good indicator for preoperative glycemic control.

The CREDO-Kyoto (Coronary REvascularization Demonstrating Outcome Study in Kyoto) is a multicenter registry in Japan enrolling consecutive 9877 patients undergoing first PCI or CABG [7]. In the present study, we sought to investigate the impact of preoperative

glycemic control on outcomes after coronary revascularization by dividing the patients into following 3 groups using the preoperative HbA1c level; 1) Nondiabetes, 2) Good control diabetes (diabetes with HbA1c level of <7%), and 3) Poor control diabetes (diabetes with HbA1c level of ≥7%.

PATIENTS AND METHODS

Study Population

This study was approved by the institutional review boards or ethics committees of all participating institutions. Because the study subjects were retrospectively enrolled, written informed consent was not obtained, in concordance with the guidelines for epidemiologic studies issued by the Ministry of Health, Labor and Welfare of Japan. However, 73 patients were excluded because of their refusal to participate in the study when contacted for follow-up [7].

Between January 2000 and December 2002, 9877 patients were identified to have undergone either CABG or PCI without prior history of coronary revascularization. Among them, patients with multivessel and/or left main coronary artery disease whose preprocedural blood HbA1c level obtained were included in the present study. Patients undergoing concomitant valvular, left ventricular or major vascular operation were excluded from the current analysis.

Data Collection and Definitions

Demographic, angiographic, and procedural data were collected from hospital charts or

databases in each center by independent clinical research coordinators according to prespecified definitions. Follow-up data were obtained from hospital charts or by contacting patients or referring physicians.

Elevated HbA1c was defined as that of 7% or greater, which is associated with a higher risk of diabetes-associated complications [6]. Elderly patients were defined as those patients 75 ≥ years of age. Left ventricular ejection fraction (LVEF) was measured either by contrast left ventriculography or echocardiography. Patients with LVEF of less than 40% were regarded as having left ventricular dysfunction. Chronic kidney disease was regarded as present when creatinine clearance estimated by Cockcloft-Gould formula was less than 60 mL/min. Anemia was defined as blood hemoglobin level less than 12 g/dL as previously described [7].

Study groups

Patients were divided into three groups according to their degree of glycemic control using preoperative HbA1c level: 1) poor control group (diabetic patients with HbA1c level of ≥7%), 2) good controlled group (diabetic patients with HbA1c level of <7%), 3) normal group (nondiabetic patients with HbA1c level of <7%). Subsequently, outcomes after PCI or CABG in each group were compared.

Endpoints

An independent clinical events committee adjudicated events. Death was regarded as cardiovascular in origin unless obvious noncardiovascular causes could be identified. (Any death during the index hospitalization was regarded as cardiovascular death.) Myocardial infarction was adjudicated according to the definition in the Arterial Revascularization Therapy Study [8]. Within 1 week of the index procedure, only Q-wave myocardial infarction was

adjudicated as myocardial infarction. Stroke at follow-up was defined as symptomatic stroke.

Primary endpoint was death from any cause. Secondary endpoints were cardiovascular death, stroke, myocardial infarction, and composite cardiovascular event (cardiovascular death, stroke, and myocardial infarction), during the follow-up period.

Statistical Analyses

After the descriptive statistical analysis, we used Kaplan-Meier estimates to plot survival curves in each group. The log-rank test was used to identify significant differences in unadjusted survival curves. The multivariable Cox proportional hazard models were used for adjustment for confounding factors; we included in the model the following risk factors for mortality confirmed previously [7]: age $\geq$ 75 years, chronic kidney disease, hemodialysis, history of heart failure, chronic obstructive lung disease, malignancy, anemia, peripheral vascular disease, stroke, left ventricular dysfunction, body mass index $\geq$ 25.0, diabetes with insulin, absence of statin use, and use of angiotensin converting enzyme inhibitors. Multivariate-adjusted hazard ratios and 95% confidence intervals are reported in this analysis. All analyses were conducted by a statistician with the use of SAS software version 9.2 (SAS Institute Inc) and S-Plus version 7.0 (Insightful Corp) and all reported p values were 2-sided. The authors had full access to the data and take responsibility for its integrity. All authors have read and agreed to the manuscript as written.

RESULTS

Baseline Characteristics

Among the 3150 patients with multivessel and/or left main disease, 1975 patients (63%) in the PCI and 1175 (37%) in the CABG group obtained preoperative HbA1c level. Baseline characteristics of the patients in the two groups are shown in Table 1. The PCI group included more elderly patients (≥ 75 years). The CABG group generally included more high-risk patients, such as those with left ventricular dysfunction, heart failure, prior myocardial infarction, chronic kidney disease, stroke, and anemia. Patient with diabetes, diabetes with any therapy, or diabetes with insulin therapy was more common in the CABG group. Preoperative HbA1c level and a ratio of patients with HbA1c of 7% or greater were not different between the groups (6.4 ± 1.5 vs. 6.4 ± 1.5, p=0.81 and 28% vs. 27%, p=0.56, respectively).

Regarding the complexity of coronary artery anatomy, the CABG group included more complex patients, such as those with triple-vessel disease, left main disease, involvement of proximal LAD, and total occlusion. In the PCI group, bare-metal stents were used in 83% of patients. None of the patients received drug-eluting stents. In the CABG group, internal mammary artery graft was used in 93% of patients. Thirty-four percent of CABG operations were performed without cardiopulmonary bypass.

Medications such as statins, thienopyridines, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, beta blockers, and nitrates were more frequently used in the PCI group than the CABG group.

Overall outcomes

Clinical follow-up were completed in 99% at 1 year, and 95% at 2 years in the PCI group and 97% and 94% in the CABG group. The median follow-up period was 1291 days in the PCI group (interquartile range, 957 to 1583) and 1245 days in the CABG group (interquartile range, 930 to 1563).