

ORIGINAL ARTICLE

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Influence of diabetes on >10-year outcomes after percutaneous coronary intervention

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Abstract There are few reports showing the relationship between diabetes and the long-term outcome following percutaneous coronary intervention (PCI) in Asians. As well, the association between glycosylated hemoglobin (HbA1c) level and outcome remains controversial. In this analysis, 748 Japanese patients including 298 with diabetes (DM) and 450 without diabetes (non-DM) who underwent PCI from 1984 to 1992 were evaluated over the long term. The mean follow-up was 12.0 ± 3.6 years. There were 47 (15.8%) total deaths in DM and 41 (9.1%) in non-DM [hazard ratio (HR) 1.71, 95% confidence interval (CI) 1.11–2.65, $P = 0.013$] and 28 (9.4%) cardiovascular deaths in DM and 19 (4.2%) in non-DM (HR 2.09, 95% CI 1.14–3.81, $P = 0.016$). Among DM, increased HbA1c was associated with both total (HR 1.25, 95% CI 1.03–1.53, $P = 0.024$) and cardiovascular (HR 1.30, 95% CI 1.00–1.69, $P = 0.048$) mortality. Even in Asians, DM showed an increased mortality following PCI. Among DM, increased HbA1c level was also associated with mortality.

Key words Type 2 diabetes mellitus · Percutaneous coronary intervention · Long-term outcome · Glycosylated hemoglobin · Asian

Introduction

There is a large evidence base linking diabetes and the development and progression of coronary artery disease (CAD).^{1–5} Diabetes, one of the important risk factors for progression of CAD, is also associated with a worse outcome after revascularization.^{6–8} Several clinical studies have shown

that patients with diabetes have a greater incidence of cardiovascular events following percutaneous coronary intervention (PCI), and that this might increase long-term mortality.^{9,10} In fact, many studies have shown that the presence of diabetes at the time of PCI increased long-term mortality.^{11–15} However, in most of these studies follow-up was limited to less than 10 years; in only a few studies was follow-up over 10 years. In addition, most studies were done in Western countries, while no long-term studies have been done in Asian populations to determine whether the presence of type 2 diabetes at the time of PCI affects long-term (>10 years) mortality.

Asians tend to have a lower body mass index than non-Asians and have remarkably different obesity-related characteristics. Actually, the prevalence and incidence of type 2 diabetes varies among ethnic groups, such as higher rates in Asians than in Western populations even under the condition of similar body mass index (BMI).¹⁶ Studies in Asian countries showed that the risk of having type 2 diabetes is high at leaner body mass.¹⁷ Therefore, it is of interest to determine whether Asian diabetic patients who reveal a leaner body mass have a similar risk to the Western patient population for long-term mortality after PCI.

Furthermore, although the increasing prevalence of type 2 diabetes among patients with CAD is a concern, it is controversial whether the degree of glycemic control at the time of PCI is associated with long-term outcome.^{18–22} On the other hand, it has been shown that strict glycemic control is associated with a decreased incidence of microvascular complications.^{19,23} However, the association between the degree of glycemic control and the incidence of macrovascular complications has not yet been established. Recently, several studies have shown that strict glycemic control improves outcome after acute myocardial infarction.²⁴ Given these results, the association between the degree of glycemic control and the incidence of macrovascular complications has been questioned. Furthermore, though one study showed that periprocedural glucose levels affect relatively long-term outcome following PCI, no studies have shown an association between the degree of glycemic control and long-term (>10 years) outcome.

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Therefore, we investigated the long-term (>10 years) mortality after PCI among type 2 diabetic patients with leaner body mass and analyzed whether the degree of glycemic control, as reflected by the glycosylated hemoglobin (HbA1c) level, which mirrors glycemic control levels more accurately than the glucose level, was important.

Subjects and methods

Subjects and data collection

We retrospectively analyzed 748 consecutive Japanese patients who had undergone a PCI at Juntendo University Hospital from January 1984 to December 1992. In all cases, the indications for PCI were either objective evidence of myocardial ischemia (positive stress test) or ischemic symptoms associated with significant angiographic stenosis. Demographic data, coronary risk factors, medication use, and intervention procedures were prospectively recorded in our institution's database. As well, in the diabetic cases, the HbA1c level at the time of PCI was noted. Blood samples were obtained in the early morning after an overnight fast. Blood pressures were measured at the time of admission for elective cases or a few days after admission for emergency cases. Patients were classified based on the presence or absence of diabetes at baseline using the following definitions: fasting plasma glucose level ≥ 126 mg/dl during hospitalization, or treatment with oral hypoglycemic drugs or insulin injection. Each patient was further categorized based on the presence of coronary risk factors using the following criteria. Hypertension was defined as a systolic blood pressure ≥ 140 mm Hg, or a diastolic blood pressure ≥ 90 mm Hg, or treatment with antihypertensive medications. A current smoker was defined as one who smoked at the time of PCI or had quit smoking within 1 year prior to the procedure. A patient with kidney failure was defined as one under dialysis or whose estimated creatinine clearance was < 15 ml/min. Mortality data were collected until September 2002. The medical records of patients who died in our hospital were examined. For patients who were admitted to or followed by other hospitals or clinics during the follow-up period, the institutions were asked to provide the details and cause of death. Informed consent was obtained from all patients or their families. Mortality data were categorized according to the cause of death, such as death from all causes or composite cardiovascular death. Cardiovascular death included death from coronary artery disease, cardiogenic shock, stroke, and sudden death.

Statistical analysis

Continuous variables are expressed as mean \pm standard deviation and were compared using Student's *t*-test or the Mann-Whitney *U*-test. Categorical data are tabulated as frequencies and percentages, and they were compared using the χ^2 test or Fisher's exact test. Kaplan-Meier estimation with the log-rank test was used for the unadjusted survival

analysis. Multivariate Cox proportional-hazards regression was also done to examine the adjusted risks for total death and cardiovascular death in the diabetic patients compared to nondiabetic patients. In the adjusted analysis, several covariates, which included age, gender, BMI, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol level, triglyceride level, presence or absence of hypertension, smoking history, presence or absence of kidney failure, prior history of myocardial infarction, undergoing prior coronary artery bypass graft, presentation of acute coronary syndrome, left ventricular ejection fraction measured by echocardiogram, vessel disease, and procedural success (defined as a residual stenosis $< 50\%$ after PCI) were used and entered into the analysis along with the presence or absence of diabetes. Further analysis of the diabetic patients was done using multivariate Cox proportional hazards regression to determine the independent predictors for long-term prognosis following PCI among diabetic patients with CAD. In this analysis, instead of the presence or absence of diabetes, the HbA1c level was entered along with the other covariates. A *P* value of less than 0.05 was considered statistically significant. All data were analyzed with Dr. SPSS II for Windows (SPSS, Chicago, IL, USA).

Results

Baseline characteristics

The baseline and clinical event data were fully documented during the follow-up period (mean follow-up, 12.0 ± 3.6 years) for all patients. Hence, all 748 patients were enrolled. Of these, 298 patients (39.8%) had diabetes at the time of PCI (diabetic group) and 450 patients (60.2%) did not have diabetes (nondiabetic group). There were no patients with type 1 diabetes. The baseline characteristics of the two groups are shown in Table 1. Most patients in both groups were middle-aged, nonobese males with single vessel disease and normal left ventricular contraction. However, the diabetic patients were significantly older and had more severely impaired left ventricular contraction than non-diabetic patients. There were no significant differences between the two groups with respect to other characteristics. As well, all patients underwent PCI using only balloon angioplasty; no stent implants were performed.

Among the diabetic group, 6.4% of patients were treated with insulin injection, 23.2% of patients were treated with sulfonylurea and others were diet treated. The mean HbA1c level of diabetic group was $7.4\% \pm 1.3\%$.

Unadjusted and adjusted analysis for total and cardiovascular mortality

Overall, 88 patients died from all causes (including 47 patients with cardiovascular death) during follow-up. Using Kaplan-Meier estimation, the presence of diabetes at the time of PCI was associated with increased long-term total

Table 1. Baseline characteristics

	Diabetic group (n = 298)	Nondiabetic group (n = 450)	P
Age, years	60.9 ± 9.2	58.2 ± 10.3	<0.0001
Male (%)	255 (85.6)	396 (88.0)	0.33
Body mass index, kg/m ²	23.9 ± 2.7	23.3 ± 2.8	0.002
Risk factors			
Fasting plasma glucose, mg/dl	117.7 ± 42.7	90.0 ± 10.5	<0.0001
Hypertension (%)	202 (67.8)	283 (62.9)	0.17
LDL cholesterol, mg/dl	134.1 ± 46.2	137.9 ± 39.8	0.23
HDL cholesterol, mg/dl	43.3 ± 13.0	41.7 ± 12.2	0.097
Triglyceride, mg/dl	162.6 ± 92.2	146.7 ± 84.5	0.015
Current smoker (%)	231 (77.5)	348 (77.3)	0.95
Family history of CAD (%)	110 (36.9)	149 (33.1)	0.29
Kidney failure (%)	10 (3.4)	10 (2.2)	0.36
Prior myocardial infarction (%)	57 (19.1)	109 (24.2)	0.10
Medications			
Nitrates (%)	270 (90.6)	402 (89.3)	0.57
Nicorandil (%)	51 (17.1)	89 (19.8)	0.36
ACE inhibitors (%)	26 (8.7)	32 (7.1)	0.42
Beta blockers (%)	69 (23.2)	117 (26.0)	0.38
Calcium channel blockers (%)	89 (29.9)	132 (29.3)	0.88
Aspirin (%)	220 (73.8)	315 (70.0)	0.26
Warfarin (%)	122 (40.9)	168 (37.3)	0.32
Statins (%)	108 (36.2)	135 (30.0)	0.074
Others (%)	77 (25.8)	112 (24.9)	0.77
Procedure			
Acute coronary syndrome (%)	86 (28.9)	130 (28.9)	0.99
Previous CABG (%)	79 (18.1)	119 (18.0)	0.97
Vessel disease	1.6 ± 0.8	1.6 ± 0.8	0.85
Single (%)	158 (53.0)	244 (54.2)	0.93
Double (%)	90 (30.2)	130 (28.9)	
Triple (%)	50 (16.8)	76 (16.9)	
Protected LMT lesion (%)	5 (1.7)	6 (1.3)	0.70
LAD lesion (%)	141 (47.3)	242 (53.8)	0.083
SVG lesion (%)	23 (7.7)	41 (9.1)	0.51
Procedural success (%)	261 (87.6)	420 (93.3)	0.85
LVEF (%)	65.6 ± 12.9	67.7 ± 10.5	0.016

LDL, low-density lipoprotein; HDL, high-density lipoprotein; CAD, coronary artery disease; ACE, angiotensin-converting enzyme; CABG, coronary artery bypass graft; LMT, left main trunk; LAD, left anterior descending; SVG, saphenous vein graft; LVEF, left ventricular ejection fraction

Table 2. The risk of total and cardiovascular death in patients with diabetes

	Incidence, n (%)		Adjusted analysis	
	Diabetic (n = 298)	Nondiabetic (n = 450)	HR (95% CI)	P
Total death	47 (15.8)	41 (9.1)	1.71 (1.11–2.65)	0.013
Cardiovascular death	28 (9.4)	19 (4.2)	2.09 (1.14–3.81)	0.016

Hazard ratios (HR) and 95% confidence intervals (CI) were adjusted for age, gender, body mass index, LDL and HDL cholesterol level, triglyceride level, hypertension, smoking, kidney failure, prior coronary artery bypass graft, presentation of acute coronary syndrome, prior myocardial infarction, left ventricular ejection fraction, vessel disease, and procedural success

mortality (log-rank test $P = 0.002$) (Fig. 1a). In the analysis of cardiovascular death, the diabetic group had a significantly higher cardiovascular mortality than the non-diabetic group (log-rank test $P = 0.015$) (Fig. 1b).

Using the Cox proportional hazard model to adjust for covariates, the presence of diabetes at the time of PCI was an independent and significant risk factor for a long-term poor prognosis; both total mortality and cardiovascular mortality were increased (Table 2). Among diabetic patients, the results of multivariate analysis for total and cardiovascular death are shown in Tables 3 and 4. The HbA1c level

was one of the significant predictors of both total death and cardiovascular death. The other significant predictors for total mortality and cardiovascular mortality are also shown in Tables 3 and 4.

Discussion

Based on our institution's long-term follow-up (mean follow-up, 12 years) data which included patients with

Table 3. Independent risk factors for total death among diabetic patients

	HR (95% CI)	P
Age (1 year increase)	1.07 (1.03–1.11)	<0.0001
LVEF (1% increase)	0.96 (0.94–0.98)	<0.0001
Procedural success	0.45 (0.22–0.92)	0.028
HbA1c (1% increase)	1.25 (1.03–1.53)	0.024

Hazard ratios (HR) and 95% confidence intervals (CI) were calculated using multivariate Cox proportional hazard regression with a backward, stepwise likelihood ratio approach, including several covariates: age, gender, body mass index, LDL and HDL cholesterol level, triglyceride level, hypertension, HbA1c, smoking, kidney failure, prior coronary artery bypass graft, presentation of acute coronary syndrome, prior myocardial infarction, LVEF, vessel disease, and procedural success

LVEF, left ventricular ejection fraction; HbA1c, glycosylated hemoglobin

Table 4. Independent risk factors for cardiovascular death among diabetic patients

	HR (95% CI)	P
Age (1 year increase)	1.07 (1.01–1.12)	0.012
BMI (1 kg/m ² increase)	1.22 (1.07–1.39)	0.003
LVEF (1% increase)	0.95 (0.93–0.98)	<0.0001
Procedural success	0.24 (0.11–0.54)	0.001
HbA1c (1% increase)	1.30 (1.00–1.69)	0.048

Hazard ratios (HR) and 95% confidence intervals (CI) were calculated using multivariate Cox proportional hazard regression with a backward, stepwise likelihood ratio approach, including several covariates such as age, gender, BMI, LDL and HDL cholesterol level, triglyceride level, hypertension, HbA1c, smoking, kidney failure, prior coronary artery bypass graft, presentation of acute coronary syndrome, prior myocardial infarction, LVEF, vessel disease, and procedural success. BMI, body mass index; LVEF, left ventricular ejection fraction; HbA1c, glycosylated hemoglobin

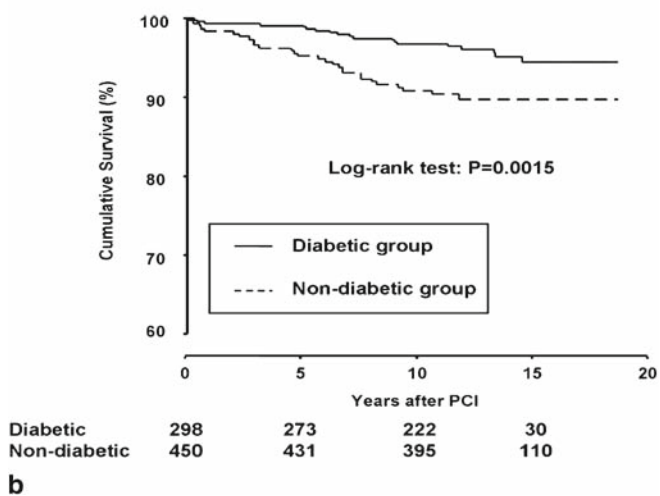
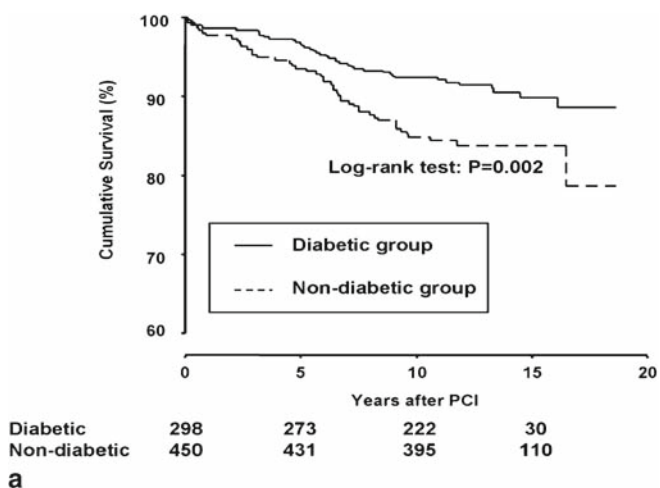


Fig. 1a,b. Kaplan–Meier estimation of survival for total and cardiovascular mortality. **a** There was a statistically significant difference of cumulative survival between patients with and without diabetes at the time of percutaneous coronary intervention (PCI). **b** There was a statistically significant difference of cumulative survival between patients with and without diabetes at the time of PCI

leaner body mass than Western patient population, the present study demonstrated that the presence of diabetes at the time of PCI was associated with an increased total and cardiovascular mortality. The presence of diabetes was significant even after adjustment for several covariates that are established predictors for increased mortality following PCI as well as in the other studies investigated in the Western patient population. Furthermore, on multivariate analysis, the degree of glycemic control at the time of PCI was related to the long-term outcome in the diabetic group. Thus, the level of glycemic control at the time of PCI was a significant predictor of long-term outcome among diabetic patients.

The association between the presence of diabetes at the time of PCI and increased long-term mortality has been previously reported by numerous studies.^{6–8} Hasdai et al., for example, in an American population, showed that there was an increase in cardiovascular events in diabetic patients more than 10 years following PCI.²⁵ Van Domburg et al. showed similar long-term (up to 17 years) follow-up results after PCI in a European population.¹² The current study involving Asian patients found that the presence of diabetes at the time of PCI was a significant predictor for long-term mortality, along with older age, impaired left ventricular ejection fraction, and severity of CAD. Furthermore, several other reports, though their follow-up term was less than 10 years, have found similar results in Western countries. There have been only a few studies that have investigated the association between type 2 diabetes and long-term outcome after PCI in the Asian population. Otsuka et al., with a follow-up period of 8 years, showed that there was a link between the presence of abnormal glucose tolerance (diabetes or impaired glucose tolerance) and increased long-term incidence of cardiac events in the Japanese population in which no specific data about obesity were supplied.²⁶ No previous studies involving Asian populations with a follow-up period of >10 years have been done to investigate whether the long-term outcome after PCI was affected by the presence of type 2 diabetes among patients with leaner body mass at the time of procedure. For this

reason, the results of the present study have several clinical implications.

The association between glycemic control and the incidence of cardiovascular events has been discussed in several large-scale clinical trial reports that mainly focused on the primary prevention of cardiovascular disease. One of these studies, done among elderly Finnish patients, clearly showed that the higher HbA1c at baseline, the greater the cardiovascular disease risk.¹⁸ In the United Kingdom Prospective Diabetes Study (UKPDS 33), intensive treatment for type 2 diabetes to lower the median HbA1c to 7.0%, reduced the long-term (>10 years follow-up) risk of CAD, but the decrease was not statistically significant.¹⁹ Therefore, as far as primary prevention of diabetes is concerned, the association between the degree of glycemic control and incidence of macrovascular disease in diabetes patients remains questionable. The correlation between the glycemic control level and the incidence of cardiovascular events following PCI has also been investigated. In 2001, Hasdai et al. reported that the baseline glycemic control level, assessed using the HbA1c level,²¹ was not associated with all-cause mortality and the incidence of cardiovascular events. Unfortunately, the study by Hasdai et al. had several limitations, since the HbA1c values were not all available. However, subsequent studies have investigated the relationship between mortality after PCI and baseline glycemic control using glucose concentrations. One of these studies showed a significant association between baseline glucose concentration and mortality after PCI.²² Therefore, the association between baseline glycemic control and poor outcome once again became an issue. The present study is valuable because it is the first to show a significant association between baseline HbA1c level and long-term mortality after PCI in diabetic patients.

Based on the results of the present study, the mechanisms that link baseline glycemic control to long-term mortality are not clear. However, it has been reported that strictly controlled diabetes reduced subsequent myocardial injury and target vessel revascularization in patients who had PCI,²⁷ and that this may improve long-term mortality. Furthermore, strict glycemic control is reported to restore impaired platelet function and to reduce the high plasma activity of plasminogen activator inhibitor that is found in diabetic patients.^{28,29} These two effects may prevent an increase in the incidence of short-term and long-term cardiovascular events that are associated with long-term mortality. To clarify the mechanisms of this association, further large-scale, long-term studies that would investigate the relationship of specific biomarkers to clinical events are needed.

Limitations

The small number of clinical events, due to the small sample size and the low risk status of the patients, resulted in a limited statistical power for detecting differences in outcome. However, since the present study was observational in nature, even if the adjusted analysis were performed, other

unknown confounders might have affected the outcomes. Nevertheless, it should be emphasized that the presence of diabetes at the time of PCI was associated with an increase in total and cardiovascular mortality over the very long term (>10 years).

Given the study design, we could not determine how long the diabetic patients had been diagnosed as having diabetes. However, duration of diabetes has been established as an important predictor of long-term poor prognosis.¹⁸ Therefore, since we could not distinguish between recently diagnosed diabetic patients with elevated HbA1c levels from long-term, poorly controlled diabetic patients, the results of the present study should be interpreted with caution. Additionally, in the present study, there were no considerations about impaired glucose tolerance (IGT) or postprandial hyperglycemia which has been associated with increased risk for CAD because these data were not available. There might be several cases with IGT or postprandial hyperglycemia in patients without diabetes. However, this would probably have led to underestimation of the association between diabetes and survival. Therefore, this further emphasizes that diabetes at the time of PCI was associated with increased long-term mortality.

Another limitation of the present study was that all patients were treated with only balloon angioplasty. The influence of restenosis after balloon angioplasty which might be associated with the long-term mortality was not considered in the present study. If stents and other supportive devices or treatment strategy that are currently available and established had been used the results may have been different.^{30,31} Thus, further investigation is needed to clarify whether the presence of diabetes at the time of PCI, as well as the degree of glycemic control at baseline in diabetic patients, would modulate the long-term outcome after stenting.

Conclusions

The presence of diabetes at the time of PCI was associated with an increased long-term (>10 years) total and cardiovascular mortality. These risks were significant even after multivariate adjustment. Furthermore, on multivariate analysis the degree of glycemic control at the time of PCI was linked with long-term outcome in the diabetic patients.

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