Insulin-treated diabetes mellitus and predictors of mid-term clinical outcome after percutaneous coronary interventions with stent implantation

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Coronary artery disease; Diabetes mellitus; Prognosis; Stent.

Background. **Patients with type II, insulin-dependent diabetes mellitus have a high risk of death and repeat revascularization following successful percutaneous coronary interventions. The predictors of outcome in such patients after coronary stenting have not been clarified.**

Methods. **We studied 133 consecutive patients with type II, insulin-dependent diabetes mellitus who underwent coronary stenting from November 1992 to May 2001. The clinical outcome and predictors of major adverse cardiac events (MACE; that is death, myocardial infarction, target vessel revascularization) at follow-up were assessed.**

Results. **Out of 133 patients, 102 (76%) had multivessel (≥ 2 vessels) disease. Eight patients (6.0%) had in-hospital MACE. Clinical follow-up data at 19.5 months (range 6.1-100 months) were available for 121 (91%) patients. The MACE rate was 40.5%; 22 patients (18%) died, 17 (14%) of a cardiac death; 7 (5.8%) patients had a myocardial infarction, and target vessel revascularization was performed in 35 (28.9%) patients. At univariate analysis, hypertension (odds ratio-OR 5.5; confidence interval-CI 2.5-12.3; p < 0.001), hypercholesterolemia (OR 3.7; CI 1.7-8.2; p = 0.001), a prior percutaneous coronary intervention (OR 6.6; CI 2.9-15.4; p < 0.001), a prior myocardial infarction (OR 3.1; CI 1.5-6.7; p = 0.003) and the stent length (≥ 15 mm) (OR 2.7; CI 1.5-4.3; p = 0.008) were related to MACE. At multivariate analysis, hypertension (OR 4.1; CI 1.7-9.9; p = 0.002), a prior percutaneous coronary intervention (OR 4.8; CI 1.9-12; p = 0.001) and the stent length (OR 3.0; CI 1.3-7.4; p = 0.01) remained as independent predictors of MACE.**

Conclusions. **Patients with insulin-dependent diabetes mellitus continue to face a high mortality and incidence of adverse events after stenting. The occurrence of events was related to a history including hypertension, percutaneous coronary interventions and to the stent length.**

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Introduction

The choice of the best coronary revascularization strategy for diabetic patients is controversial. Type II diabetes, especially insulin-dependent diabetes mellitus (IDDM), has been associated with higher rates of acute and long-term adverse events after both percutaneous transluminal coronary angioplasty (PTCA)[1] and coronary artery bypass graft (CABG) surgery[2], thus rendering these approaches suboptimal. The results of the most important randomized trials[3-5], however, strongly suggest that bypass surgery is the best treatment compared to PTCA and stenting, especially in insulin-treated diabetic patients with advanced three-vessel coronary disease[6]. Indeed, diabetic patients seem to have an increased late loss index and restenosis percentage compared with non-diabetic patients even when stents are applied[7]. In a large consecutive series of subjects submitted to stent implantation, IDDM patients had higher in-hospital mortality and morbidity and an increased rate of coronary events at 1 year compared to non-IDDM and non-diabetic patients[8]. In the present study, we investigated the influence of clinical and procedural variables as predictors of in-hospital and mid-term outcome in IDDM patients who were referred to our institution for elective coronary stenting.

Methods

Study population. Between November 1992 and May 2001, a total of 133 consecutive IDDM patients underwent elective percutaneous coronary intervention (PCI) with stent implantation at our institute. The decision to treat via a percutaneous approach IDDM patients with multivessel (≥ 2 coronary arteries) disease, potential candidates for cardiac surgery, was taken on the basis of the following elements: 1) technical suitability for percutaneous revascularization in the knowledge that this approach would not have jeopardized any future surgical option; 2) the patient's and/or referring physician's preference. The patients treated for systemic hypertension or without a previous diagnosis of hypertension but with blood pressure values > 160 and/or 90 mmHg for the systolic and diastolic pressures respectively, were classified as hypertensive. Those treated for hypercholesterolemia or with total cholesterol serum levels > 220 mg% were classified as hypercholesterolemic patients.

Interventional procedure. Before angioplasty, oral aspirin and an intravenous bolus of unfractionated heparin (100 U/kg until the end of 1997; then 70 U/kg) were administered to all patients. Ticlopidine or clopidogrel were also administered. Angiograms in multiple views were obtained using mainly the transfemoral approach. Lesions were pre-treated using debulking devices, such as directional atherectomy, if the vessels had a large plaque mass or by means of rotational atherectomy in case of extensive calcifications. Intracoronary stenting was performed according to standard technique[9]. Coronary stents were used whenever possible, but lesions in vessels < 2 mm in diameter were treated mostly by means of balloon angioplasty. Intravenous glycoprotein IIb/IIIa antagonists were administered according to clinical judgement. Complete anatomical revascularization was defined angiographically after PCI, as the absence of severe (≥ 70%) residual stenosis in any major epicardial vessel. The left ventricular ejection fraction was calculated at left ventriculography using the area-length method with a correction for the 30° right anterior oblique projection. The post-procedure creatine kinase levels were measured for all patients 8 and 24 hours after the procedure or before discharge.

Angiographic analysis and clinical follow-up. We used a computer-based QCA-CMS system version 4.0 (MEDIS Medical Imaging Systems Inc., Leiden, the Netherlands) for quantitative coronary angiography, with the dye-filled catheter as reference. The reference diameter, lesion length and minimum luminal diameter were measured before and after angioplasty, and at the time of follow-up angiography. The diameter of the normal segment proximal to the traced area in the vessel was used to determine the parent vessel diameter. The lesion length was defined as the distance from the proximal to the distal shoulder of the lesion. Angiographic success was defined as the achievement of a residual stenosis < 50% with TIMI flow 3 (assessed at angiography)[10]. Procedural success was defined as the achievement of angiographic success in the absence of any in-hospital major adverse cardiac events (MACE) including death, a non-Q or Q wave myocardial infarction (MI), and the need for repeat revascularization by redo-CABG or repeat percutaneous intervention. Death due to cardiac causes was defined as any death for which there was no clearly documented non-cardiac cause. A diagnosis of a Q wave MI was made when there was documentation of new pathological Q waves (> 0.04 s) on the electrocardiogram with an elevation in creatine kinase > 3 times the upper limit of normal or associated with an increase in the creatine kinase-MB serum levels > 6% of the upper limit of normal. A diagnosis of a non-Q wave MI was made when an elevation of cardiac enzymes > 3 times the normal value was documented without the development of new pathological Q waves. Emergency coronary bypass surgery was defined as bypass surgery involving immediate transfer of the patient from the catheterization laboratory to the operating room or within 24 hours of the procedure. Follow-up angiography was planned for all patients at 6 months, or earlier if deemed clinically necessary. Restenosis was defined as > 50% diameter stenosis of the treated lesion. Clinical follow-up was obtained by telephone or direct patient interview. Target vessel revascularization was defined as any repeat percutaneous intervention on the target vessel or as any coronary bypass graft on the treated vessel during follow-up. Total MACE were defined as death, MI (non-Q or Q wave) or target vessel revascularization during the follow-up period including the in-hospital events.

Statistical analysis. Data are expressed as mean ± SD for continuous variables and as numbers with the respective percentages for categorical variables. Continuous data were compared using the unpaired Student's t-test, and frequencies were compared using the χ^2 test or Fisher's exact test. The association between MACE and the potential predictors was assessed using logistic regression methods. The outcome related to patients was evaluated on a per patient basis. All the angiographic and procedural variables were evaluated in relation to the patient's events so as to focalize their influence on the event-free survival. Those factors that were biologically relevant and statistically significant at univariate analysis were included in the multivariate analysis. The univariate and multivariate odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) are provided. A p value of ≤ 0.05 was considered as statistically significant. A cumulative survival curve for the event-free survival was constructed using the Kaplan Meier method. Data were analyzed using SPSS for windows, release 10.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline demographics. The baseline clinical characteristics of all treated patients are shown in table I.

Table I. Baseline clinical characteristics of the study patients.

No. patients	133
Age (years)	63.9 ± 10.4
Male	90 (66.7%)
Risk factors	
Hypertension	69 (52%)
Hypercholesterolemia	66 (49.6%)
Current smokers	11 (8.3%)
Prior myocardial infarction	66 (49.6%)
Previous coronary angioplasty	41 (31%)
Previous coronary bypass	29 (21.8%)
Left ventricular ejection fraction (%)	51 ± 16
Unstable angina	48 (39.7%)
Multivessel disease	102 (76%)

There were a high prevalence of men (66.7%), previous MI (49.6%) and multivessel disease (76%). Hypertension and hypercholesterolemia were present in 52 and 49.6% of the patients respectively.

Angiographic and procedural characteristics. The angiographic and procedural characteristics are shown in tables II and III. The angiographic success rate was 94.6%. The number of vessels treated was 1.5 ± 0.6 per patient. The number of lesions treated was 2 ± 1 per patient. Complete revascularization was performed in 30% of patients.

Table II. Qualitative and quantitative angiographic analysis of the study patients.

Lesion location	
Ostial	26 (9.8%)
Proximal	98 (37%)
Mid	90 (34%)
Distal	50 (19.8%)
Target vessel	
LM	9 (3.4%)
LAD	89 (33.7%)
LCx/OM	58 (21.9%)
RCA	56 (21.2%)
SVG	12 (4.5%)
IMA	1 (0.3%)
Others	39 (14.7%)
Stented lesions	170 (71%)
Lesion type (ACC/AHA)	
B1	56 (21%)
B2	80 (30.3%)
C	104 (39.4%)
Total occlusion	40 (15.1%)
Calcified lesion	30 (11.3%)
Quantitative measurements	
Baseline	
Reference vessel diameter (mm)	2.65 ± 0.69
Minimal lumen diameter (mm)	0.8 ± 0.6
Diameter stenosis (%)	69 ± 19.5
Lesion length (mm)	13.3 ± 8
Post-procedure	
Proximal reference diameter (mm)	2.8 ± 0.66
Minimal lumen diameter (mm)	2.37 ± 0.9
Diameter stenosis (%)	16.7 ± 23.8

ACC/AHA = American College of Cardiology/American Heart Association; IMA = internal mammary artery; LAD = left anterior descending artery; LCx/OM = left circumflex artery/obtuse marginal; LM = left main; Others = Diagonal or septal branch or acute marginal branch or ventricular branch or ramus intermedius; RCA = right coronary artery; SVG = saphenous vein graft.

Table III. Procedural characteristics of the study patients.

Angiographic success	250 (94.6%)
Treated vessels per patient	1.5 ± 0.6
Treated lesions per patient	2 ± 1
Interventional procedure	
Cutting balloon	20 (7.5%)
Directional atherectomy	5 (1.9%)
Rotational atherectomy	7 (2.6%)
Stent length (mm)	20.4 ± 9.7
Stent/lesion	1.3 ± 0.75
Final balloon size (mm)	3.1 ± 0.58
Final balloon-artery ratio	1.16 ± 0.12
Maximum inflation pressure (atm)	13.5 ± 3.4

In-hospital and mid-term outcomes. The overall procedural success rate was 94%. Eight patients (6.0%) developed in-hospital MACE (Table IV). Four patients died (3%), and 5 developed an acute MI (3.7%) (3 non-Q wave, 2 Q wave). One patient presented with acute stent thrombosis, which was treated with balloon angioplasty and abciximab. Rescue abciximab was administered, intravenously or intracoronary, in another 7 patients because of slow reflow after stenting. One patient underwent urgent bypass surgery because of severe dissection of the left main. A clinical follow-up of 19.5 months (range 6.1-100 months) was available for 121 patients (91%). The overall prevalence of MACE (cardiac death, MI, target vessel revascularization) was 40.5% (Table IV). Twenty-two (18%) patients died, 17 (14%) of cardiac causes. Seven patients (5.8%) had a

Table IV. In-hospital and mid-term outcomes.

Overall in hospital MACE	8 (6.0%)
Death	4 (3%)
CABG	1 (0.7%)
MI	5 (3.7%)
Non-Q wave	3
Q wave	2
Repeat target vessel PCI*	1 (0.7%)
Overall total MACE	49 (40.5%)
Patients with clinical follow-up	121 (91%)
Follow-up interval (months)	19.5 (6.1-100)
Death	22 (18%)
Cardiac death	17 (14%)
MI	7 (5.8%)
Overall MI and or death	22 (18%)
CABG	5 (4.1%)
Re-PTCA	41 (34%)
Target lesion revascularization	30 (24.7%)
Target vessel revascularization	35 (28.9%)

CABG = coronary artery bypass surgery; MACE = major adverse cardiac events; MI = myocardial infarction; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty. * because of acute stent thrombosis.

MI. Target vessel revascularization was performed in 35 (28.9%) patients (5 CABG and 30 coronary angioplasty), whereas the overall repeat revascularization procedure rate was 38%. The estimated event-free survival rate is shown in figure 1.

At univariate analysis (Table V), hypertension, hypercholesterolemia, a prior PCI, a prior MI and the stent length were significantly related to MACE. At multivariate analysis (Table V) only hypertension (OR 4.1; CI 1.7-9.9; p = 0.002), a prior PCI (OR 4.8; CI 1.9-12; p = 0.001) and the stent length (OR 3.0; CI 1.3-7.4; p = 0.01) remained as independent predictors of MACE. In contrast, no angiographic or procedural variables were significantly related to the need of target vessel revascularization (Table VI).

Discussion

Diabetes mellitus is an independent predictor of an unfavorable event-free survival after coronary revascularization[2,6,10]. Compared with balloon angioplasty, stenting has been shown to have the potential of improving the intermediate outcome for diabetic patients, mostly by reducing the restenosis rate[11]. Nevertheless, even in the era of stents, diabetic patients continue to be burdened by higher mortality rates and a worse outcome than non-diabetics after percutaneous revascularization. The recent subanalysis of the ARTS trial[12] reveals that in patients with diabetes mellitus and multivessel coronary artery disease, surgical revascularization with the routine use of arterial bypass conduits provides a better 1-year clinical outcome (freedom from death, stroke, MI, CABG and repeat PTCA) compared to percutaneous treatment. This study did not distinguish between IDDM and non-IDDM patients. Stein et al.[13] first analyzed IDDM and non-IDDM patients treated by PCI. They reported that IDDM patients have similar procedural results, but a worse long-term outcome compared to non-IDDM subjects. In our large consecutive series of IDDM patients treated with elective stent implantation, the event-free survival was 59.5% at 19.5 months. Similar results have been reported by Abizaid et al.[8] in IDDM patients following intravascular ultrasound-guided elective stent implantation. In our study, the in-hospital death rate was 3%, close to the values of 3.2% reported in the NHLBI[1] and of 3.9% reported in the MAHI databases[14]. A recent analysis on 18 309 patients undergoing a PCI[15] confirms that diabetic patients have an increased in-hospital death rate, suggesting an early hazard for death following a PCI. However, in these reports as well as in our study abciximab, that seems to improve the safety profile of percutaneous revascularization, was rarely administered[16]. In our study there was a high prevalence (76%) of multivessel disease; 46% of patients had three-vessel disease. This datum is comparable with the 44 and the 52% reported in the randomized BARI trial[17] and the Mid America Heart Institute database[14] respectively.

The lower mortality of PCI-treated diabetic patients of other trials[18-20] may be explained by the lower prevalence (from 16 to 35%) of three-vessel disease. The severity of coronary artery disease may be a particularly important determinant of the long-term survival. Diabetic patients, especially those with IDDM, usually

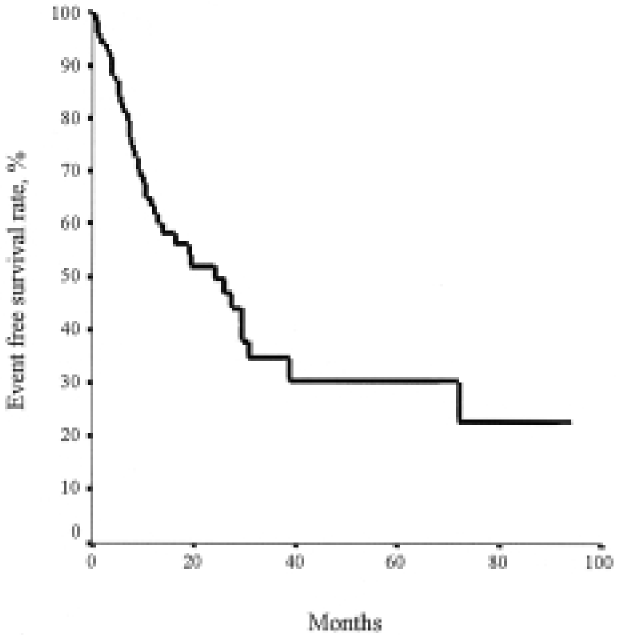

Figure 1. *Event-free survival rate in patients with type II, insulin-treated diabetes mellitus after the index percutaneous coronary intervention with stent implantation.*

Table V. Univariate and multivariate predictors related to the overall major adverse cardiac events.

Variables	Univariate analysis			Multivariate analysis		
	OR	95% CI	p	OR	95% CI	p
Hypertension	5.5	2.5-12.3	< 0.001	4.1	1.7-9.9	0.002
Hypercholesterolemia	3.7	1.7-8.2	0.001	2.1	0.9-5.2	0.09
Prior PCI	6.6	2.9-15.4	< 0.001	4.8	1.9-12	0.001
Prior MI	3.1	1.5-6.7	0.003	1.7	0.7-4.1	0.25
Stent length ≥ 15 mm	2.7	1.5-4.3	0.008	3.0	1.3-7.4	0.01
Reference vessel diameter ≤ 3.0 mm	1.4	0.7-2.8	0.36	1.4	0.6-3.3	0.4

CI = confidence interval; MI = myocardial infarction; OR = odds ratio; PCI = percutaneous coronary interventions.

Table VI. Angiographic and procedural predictors of target vessel revascularization (TVR).

	Without TVR (n = 181)	With TVR (n = 61)	p
Lesion site			
Ostial	15 (8.2%)	8 (13.1%)	0.3
Proximal	71 (39.2%)	18 (29.5%)	0.1
Mid	61 (33.1%)	25 (40.9%)	0.4
Distal	34 (18.7%)	10 (16.3%)	0.7
Target vessel			
LAD	60 (33.1%)	24 (39.3%)	0.4
LCx/OM	42 (23.2%)	12 (9.7%)	0.6
RCA	37 (20.4%)	15 (24.6%)	0.59
LM	7 (3.8%)	2 (3.2%)	1
SVG	11 (6.0%)	1 (1.6)	0.19
LIMA	0	1 (1.6%)	0.2
Others	23 (12.7%)	5 (8.2%)	0.37
Lesion type (ACC/AHA)			
B1	44 (24.3%)	11 (18.0%)	0.8
B2	58 (32.0%)	20 (32.7%)	
C	70 (38.6%)	26 (42.6%)	
Total occlusion	23 (12.7%)	11 (18.0%)	0.4
Calcified lesions	22 (12.1%)	8 (13.1%)	0.7
Procedural characteristics			
Balloon diameter (mm)	3.1 ± 0.6	3.1 ± 0.5	0.5
Stent	108 (60%)	40 (66%)	0.4
Stent/lesion	1.3 ± 0.7	1.2 ± 0.7	0.7
Quantitative measurements			
Baseline			
Reference vessel diameter (mm)	2.66 ± 0.6	2.68 ± 0.59	0.7
Minimal lumen diameter (mm)	0.83 ± 0.5	0.83 ± 0.7	0.9
Diameter stenosis (%)	68.2 ± 18	69.2 ± 21	0.7
Lesion length (mm)	13.7 ± 7.6	12 ± 5.9	0.11
Post-procedure			
Reference vessel diameter (mm)	2.81 ± 0.6	2.83 ± 0.6	0.8
Minimal lumen diameter (mm)	2.38 ± 0.9	2.46 ± 0.7	0.57
Diameter stenosis (%)	16.9 ± 24.6	14 ± 15	0.39
Stent length (mm)	19.6 ± 7.1	21.4 ± 8.5	0.10

ACC/AHA = American College of Cardiology/American Heart Association; LAD = left anterior descending artery; LCx/OM = left circumflex artery/obtuse marginal; LIMA = left internal mammary artery; LM = left main; Others = diagonal or septal branch or acute marginal branch or ventricular branch or ramus intermedius; RCA = right coronary artery; SVG = saphenous vein graft.

have extensive coronary disease, and most of them will not be completely revascularized following PTCA. In our study 30% of the patients underwent a complete revascularization and this datum is consistent with those of previous reports in which > 70% of PCI patients were incompletely revascularized[14,19,20]. In PTCA-treated patients, after the initial revascularization, the progression of the atherosclerotic lesion in the non-treated coronary segments impacts the percentage of jeopardized myocardium in a more adverse manner compared to CABG-treated diabetic patients and is responsible for the increased mortality in those patients with multivessel disease[21,22]. In the BARI trial, the finding of a stronger treatment effect among randomized patients using insulin at the time of enrolment in the study, which was also seen to a smaller extent in the registry patients, suggests a dose-response treatment difference between CABG and PTCA that increases with the severity and duration of diabetes[6,21] and with the severity of atherosclerosis before treatment. Furthermore, the progression of atherosclerosis depends not only on the extent of the atherosclerosis already present but also on the presence of those risk factors that are known to accelerate this degenerative process[21]. In our study, at multivariate analysis, hypertension ($p = 0.002$) and hypercholesterolemia ($p = 0.09$) were related to outcome. The recently revised guidelines for the treatment of hypertension by the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure recommend a blood pressure approximating 130/85 mmHg for diabetic patients[23,24]. As regards hypercholesterolemia and lipid lowering therapy, diabetes is just as important as the presence of coronary heart disease and a more intensive prevention strategy is warranted with a recommended LDL-cholesterol goal of < 100 mg/dl[25]. Previous angioplasty and the stent length were the other independent factors correlated with MACE.

Although it is widely reported that the mortality rate after MI is considerably higher among patients with diabetes[26-28], in our study population, prior MI was not an independent covariate of the outcome at multivariate analysis. To this regard, it is noteworthy that 70% of our patients with a prior PCI also had a prior MI.

Previous CABG has a more favorable influence on the prognosis after an acute MI allowing for a more complete revascularization and a more effective "safety net" for the protection of the myocardial beds from acute ischemic syndromes caused by ulcerated plaques[29]. However, the excess of adverse events associated with angioplasty is not only due to an adverse outcome after MI, but also to the persistence of chronic ischemia and restenosis, particularly in patients with multivessel disease[17,29]. Van Belle et al.[11] provide evidence that the incidence of both non-occlusive and occlusive restenosis is higher in diabetic subjects. Furthermore, they reported that occlusive restenosis is a "strong, independent correlate of the long-term mortality". Stenting does not obviate accelerated restenosis with diabetes[30] even though it reduces its incidence in some patients and in some vessels[31]. In our study, the length of the stent was the only procedural factor correlated with event-free survival. This result could be explained by the established relation between the stent length and restenosis[32] which, considering that reported relationship between restenosis and mortality in diabetic subjects[11], could be even stronger in the subset of IDDM patients who underwent a PCI. The discrepancy between lesion length and the stented segment length, observed in our study, reflects the attempts by the interventional cardiologist to more completely cover the visible vessel narrowing beyond the segment of significant stenosis or to treat consecutive lesions with a single stent. In addition, in lesions with dissection after PTCA, the stented segment length might be longer than the lesion length. Intravascular ultrasound was not used routinely. However, if the lesion length was measured at intravascular ultrasound, it would be longer than that measured at angiography. Modern adjunctive therapies have been proposed to improve the outcome of this high-risk population. In the EPISTENT trial, the revascularization rate of the target vessel in diabetic patients who received stent plus abciximab was approximately 50% less than in patients who received stent plus placebo[16]. It is also encouraging to note that intravascular radiation therapy and stents coated with drugs such as sirolimus are showing promising results[33] in reducing the restenosis rate in both diabetic and non-diabetic patients[34]. Whether the adverse outcome associated with angioplasty would be attenuated if diabetics received optimal treatment to reduce their risk factors for cardiovascular disease and control their glycemia is not known[35].

Study limitations. This was a retrospective analysis of the clinical, angiographic and procedural data of a relatively large group of consecutively studied patients with an accurate, although not complete, follow-up. The retrospective nature and the possibility of selection and referral biases may limit the application of these results to all IDDM patients who require a revascularization procedure. It is noteworthy that our patients presented with a high risk profile (e.g. widespread coronary disease that is difficult to completely revascularize at PTCA) and that to date are considered "potential" better candidates for bypass surgery[10].

The problem with the identification of the adjunctive diabetes-related predictors of outcome following percutaneous coronary revascularization in our study as well as in most of the articles currently published in the literature is that very little has been reported about the rate of diabetic-dependent covariates, such as the complications of diabetes (e.g. retinopathy, nephropathy, duration of diabetes, therapeutic modality, and glycemic control). In particular, in our study, the absence of reliable data regarding drug treatment (i.e. ACE-inhibitors, statins), dosage and correction of risk factors during follow-up is one of the major limitations[36]. In our study, glycoprotein IIb/IIIa receptor antagonists were used in a small percentage of cases, while it has been shown that these drugs may lower the rate of complications, target vessel revascularization and even the mortality in diabetic patients[15,16]. The clinical follow-up was not complete and a telephone interview may not have sufficed for an accurate evaluation of the recurrence of silent ischemic events. Finally, an angiographic follow-up was available only for 34% of patients so we could not estimate the true incidence of angiographic restenosis.

This study constitutes a single center experience providing some insight into the prognosis and predictors of the event-free survival of high-risk IDDM patients who underwent a PCI.

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