

Influence of Diabetes Mellitus on Clinical Outcome After Percutaneous Coronary Revascularization

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Introduction and objectives. Diabetes mellitus modifies the natural history of patients with coronary artery disease. The aim of this study was to assess the clinical outcome of diabetic patients with successful coronary angioplasty in our environment and to identify the factors predictive of complications during follow-up.

Methods. A retrospective analysis was made of a series of 198 diabetics and who underwent angioplasty from September 1996 to January 2000 in our hospital. A group of 198 nondiabetic patients who subsequently underwent the same procedure was used as the control group. Death, non-fatal myocardial infarction, unstable angina resulting in hospitalization and coronary revascularization were considered adverse events during a 1 year follow-up period.

Results. The overall frequency of coronary adverse events in a 1-year follow-up was higher in diabetics (37%) than in non-diabetics (24%; $p = 0.03$). Diabetics had a less favorable clinical and angiographic profile and more frequent incomplete revascularization (43 vs 30%). Diabetics with incomplete revascularization were older (66.5 vs 53.2 years), had previous angioplasty more often, anatomically more unfavorable lesions (70 vs 51% type B2-C), and a smaller ejection fraction (54.7 vs 59.4%). Diabetics had more complications at 1 year of follow-up (37 vs 24%; $p = 0.03$), mainly due to increased cardiovascular mortality in diabetics with incomplete revascularization (12 vs 2%). Multivariate analysis identified incomplete revascularization as the only correlate of clinical outcome. Diabetes *per se* was not predictive of complications during follow-up.

Conclusions. Diabetics who undergo successful coronary revascularization have a less favorable clinical outcome than non-diabetic patients undergoing the same procedure at 1 year of follow up. Incomplete revascularization is associated with a less favorable outcome.

Key words: *Coronary angioplasty. Diabetes mellitus. Coronary artery disease. Prognosis. Revascularization.*

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Influencia de la diabetes mellitus en los resultados clínicos tras revascularización coronaria percutánea

Introducción y objetivos. La diabetes mellitus modifica la historia natural de los pacientes con cardiopatía isquémica. El objetivo de nuestro trabajo ha sido describir las características y resultados de los diabéticos sometidos a revascularización coronaria percutánea y determinar los factores pronósticos de complicaciones tras la misma.

Métodos. Hemos analizado de manera retrospectiva una población no seleccionada de 198 diabéticos a los que se les realizó revascularización coronaria percutánea entre septiembre de 1996 y enero de 2000 en nuestro hospital, y como grupo control a 198 pacientes no diabéticos consecutivos a los primeros. La muerte, el infarto no mortal, el ingreso hospitalario por angina inestable y la necesidad de nueva revascularización miocárdica se consideraron acontecimientos adversos en un año de seguimiento.

Resultados. La frecuencia global de acontecimientos adversos en un año de seguimiento fue mayor en los diabéticos (37%) que en los no diabéticos (24%) ($p = 0,03$). Los diabéticos presentaban un peor perfil clínico y angiográfico, incluyendo un mayor porcentaje de revascularización incompleta (43 frente al 30%). Los diabéticos con revascularización incompleta tenían una mayor edad (66,5 frente a 53,2), más revascularización previa, lesiones más desfavorables anatómicamente (70% lesiones tipo B2-C frente a 51%) y una menor fracción de eyección (54,7 frente a 59,4%). Los diabéticos presentaron más complicaciones en el seguimiento medio de un año (37 frente al 24%; $p = 0,03$), debido fundamentalmente a una mayor mortalidad cardiovascular en los diabéticos con revascularización incompleta (12 frente al 2%). La revascularización incompleta, pero no la diabetes, fue el único factor predictor de complicaciones en el seguimiento.

Conclusiones. Los diabéticos sometidos a revascularización coronaria percutánea presentan unas peores características clínicas y anatómicas que los no diabéticos. La revascularización incompleta empeora el pronóstico durante el seguimiento.

Palabras clave: *Angioplastia coronaria. Diabetes mellitus. Enfermedad coronaria. Pronóstico. Revascularización.*

INTRODUCTION

Diabetes mellitus (DM) is associated with an important risk of coronary artery disease¹ and is known to be related with a greater risk of cardiac mortality since the Framingham studies.^{2,3} Diabetic patients have characteristics that differentiate them from the general population of ischemic patients: older age and associated cardiovascular risk factors,⁴ impossibility of revascularizing all arterial territories, and a greater progression of coronary artery disease.⁵ On the one hand, this means that the risk of death of diabetics without coronary artery disease is similar to that of non-diabetic patients with a history of acute myocardial infarction,⁶ and, on the other hand, that diabetics with coronary artery disease have a worse long-term prognosis than non-diabetics.⁷

Percutaneous coronary revascularization in diabetics has been a topic of debate since the technique was first introduced. Initially, series of patients were described in which DM was not an independent factor related with a less favorable prognosis,⁸ although most of the treated patients had single-vessel disease. With technical advances and the growing experience of hemodynamics units, more patients with multivessel disease have been treated in which diabetes is a factor predictive of complications in the follow-up period.^{9,10} In recent years, coronary interventionist procedures are experiencing progressive growth due, to a great extent, to good results and a low rate of complications.¹¹ The number of diabetic patients treated is increasing progressively; consequently, about 20% of the patients undergoing coronary interventionist procedures are diabetics.¹⁰

The aim of the present study has been, on the one hand, to describe the characteristics and outcome of an unselected population of diabetics undergoing percutaneous revascularization and, on the other hand, to analyze the factors predictive of complications in the follow-up period.

METHODS

Study population

Between September 1996 and January 2000, 1000 patients underwent percutaneous coronary revascularization in our center. In our study, 198 diabetic patients in which angioplasty was performed successfully were selected. The control group was formed by the next 198 consecutive non-diabetic patients in which angioplasty was performed successfully. Patients were classified as diabetics if they were diagnosed previously by the physician, if they were being treated with oral hypoglycemic agents or insulin, or if they presented repeatedly high glycemia levels (>200 mg/dL in at least two fasting determinations during hospital admission). In the group of diabetics, 29.1% were being tre-

ated with diet, 46.4% with oral antidiabetic agents, and 24.5% with insulin. Complete revascularization was defined as a situation in which no stenosis was greater than 70% in epicardial coronary arteries or branches of more than 2 mm, and incomplete when angioplasty was performed successfully but there was more than 70% stenosis in an epicardial coronary artery or branches greater than 2 mm.

Protocol of procedure

Conventional balloon angioplasty and stent implantation were carried out using conventional techniques. The balloon procedure was considered optimal when a residual stenosis of less than 30% with TIMI 3 flow was obtained. The stent was implanted while inflating the balloon catheter to intermediate pressures, at the discretion of the hemodynamics specialist, until an adequate angiographic result was obtained (residual lesion of less than 15%). Before dilation, all patients were administered 10 000 IU of intravenous heparin, or 70 IU/kg weight if abciximab was given concomitantly because of the high-risk criteria that the target lesion met. It was completed until coronary angioplasty was achieved to >300, or to 200-300 if abciximab had been administered at the same time. All patients received 150-200 mg of aspirin daily. The patients who underwent stent implantation were administered, in addition, 250/500 mg of ticlopidine for 30 days, according to body weight. Intracoronary nitroglycerin was administered to all patients before coronary dilation, during the procedure at the discretion of the operator, and before the final control angiography.

FOLLOW-UP

The clinical follow-up information was collected in the outpatient clinic or by telephone. Events considered during follow-up were death of cardiac origin, which was defined as any death not accounted for by another possible mechanism; non-fatal myocardial infarction; new hospital admissions for unstable angina; and need for new myocardial revascularization (by angioplasty or surgery).

STATISTICAL ANALYSIS

Data analysis was carried out with the SPSS statistical package (Statistical Package for Social Sciences, version 8.0 for Windows). Quantitative variables are expressed as mean±standard deviation. The qualitative variables are expressed as percentages. To compare qualitative variables the χ^2 test was used (or the Fisher exact test if the expected frequencies were less than 5). Quantitative variables were compared with the Student t test. Cox regression analysis was used to determine

factors predictive of complications during follow-up. Only the variables that were associated with a level of significance of less than 0.15 were included in the multivariate analysis. A test was considered statistically significant if $P < .05$.

RESULTS

Clinical and anatomic characteristics of the group of diabetic patients

The characteristics of the patients studied are described in Table 1. The diabetics were older, with a higher percentage of women and hypertensive patients and a lower percentage of smokers, and their ventricular function tended to be more impaired. The diabetics presented multivessel disease more frequently (56% versus 39%). We found no differences in the angioplasty indication. Among the diabetics who required insulin, there was a larger percentage of women and the number of smokers and patients with a history of hypercholesterolemia was smaller.

The most frequently revascularized artery was the anterior descending coronary or the diagonal branches, followed by the right coronary and circumflex or marginal branches. Revascularization was complete in 57% of the diabetics, versus 70% of the non-diabetics ($P < .001$). We found no differences in the percentage of patients who underwent stent implantation or in the number of lesions treated per patient. We found no differences in the characteristics described in diabetics, whether or not they were treated with insulin. The diabetics had coronary lesions that were more calcified, had a smaller minimum luminal diameter, and a greater percentage of type B2 and C injuries according to the ACC/AHA (62% versus 54%, $P = .05$). We found no differences in the angiographic characteristics of the diabetics, whether or not they were treated with insulin.

Clinical and anatomic characteristics of the group of patients with incomplete revascularization, depending on the presence of diabetes

The characteristics of the patients studied, including the presence of diabetes and type of complete/incomplete revascularization, are described in Table 2. The diabetic patients with incomplete revascularization were older, had a lower ejection fraction, and a larger percentage had been revascularized previously. The lesions treated were more complex, with a larger percentage of calcified lesions and a smaller luminal diameter of the post-angioplasty vessel.

Major clinical events during follow-up

The mean follow-up was 12.3 months (91% of dia-

TABLE 1. Clinical and angiographic characteristics of the diabetic and non-diabetic groups

	Diabetics (n=198)	Non-diabetics (n=198)P	
Age±SD (years)	64.7±8,1	58.9±12	.001
Female sex	75 (38)	42 (21)	.001
Arterial hypertension	108 (55)	82 (41)	.007
Smoking	86 (43)	129 (65)	.001
Hypercholesterolemia	81 (41)	85 (43)	.7
PTCA indication			.8
Stable angina	30 (15)	23 (12)	
Unstable angina	76 (38)	93 (47)	
Myocardial infarction	92 (47)	82 (41)	
Previous revascularization	15 (8)	16 (8)	.9
Multivessel disease	110 (56)	77 (39)	.001
Ejection fraction (%)	57.3±16	60.2±15	.07
Stent implantation	170 (86)	174 (88)	.8
Complete revascularization	111 (57)	140 (70)	.001
No. of lesions treated per patient	1.21±0,4	1.16±0,4	.6
Site of lesions (PTCA)			.6
AD/DG	126 (52)	114 (50)	
CX/MO	34 (14)	44 (19)	
RC/PD	82 (34)	62 (31)	
Type B2-C AHA-ACC	150 (62)	123 (54)	.05
Characteristics of lesion			
Presence of calcification	64 (32)	41 (20)	.02
Presence of defined thrombus	95 (48)	94 (47)	.9
Length of lesion (mm)	14.1±7.4	12.3±8.4	.2
Minimum lumen diameter (mm)	0.67±.4	0.78±0.4	.009
Post-PTCA diameter (mm)	2.75±0.4	2.96±0.4	.09

Data are expressed as the number of patients with the percentage of the total in parenthesis, or the mean±standard deviation (SD). AD indicates anterior descending coronary; DG, diagonal; CX, circumflex; MO, marginal obtuse; RC, right coronary; PD, posterior descending; PTCA, coronary angioplasty.

betic and non-diabetic patients). As follow-up events we studied death, non-fatal myocardial infarction, new hospital admissions for unstable angina, and the need for a new myocardial revascularization (by angioplasty or surgery) (Tables 3 and 4).

These events were more frequent in diabetics (37% versus 24%, $P = .03$), as was cardiac mortality during follow-up (6% versus 2%, $P = .03$), due mainly to the greater mortality of the diabetics in which complete coronary revascularization could not be performed (12% versus 2%, $P = .01$). The only factor predictive of events during follow-up in the Cox regression analysis was incomplete revascularization (odds ratio [OR]=1.7; $P = .04$) in both the overall group and in the subgroup of diabetics (Table 5). We did not appreciate any differences in the events that occurred during the follow-up of the group of diabetics, regardless of whether they were insulin-dependent or treated with oral hypoglycemics

TABLE 2. Clinical and angiographic characteristics of patients with complete versus incomplete revascularization in relation to the presence or absence of diabetes

	Diabetics		Non-diabetics	
	Complete revascularization (n=111)	Incomplete revascularization (n=87)	Complete revascularization (n=140)	Complete revascularization (n=60)
Age±SD (years)	63.2±8.2	66.5±7.7*	57±11.6	63±11.7*
Female sex	39 (35)	36 (41)	30 (21)	13 (22)
Arterial hypertension	58 (52)	50 (57)	55 (39)	27 (45)
Smoking	52 (47)	34 (39)	96 (69)	33 (55)
Hypercholesterolemia	40 (36)	41 (47)	64 (46)	21 (35)
PTCA indication				
Stable angina	17 (15)	13 (15)	16 (11)	7 (12)
Unstable angina	41 (37)	35 (40)	64 (46)	31 (52)
Myocardial infarction	53 (48)	39 (45)	60 (43)	22 (36)
Partial revascularization	0 (0)	8 (9)	1 (1)	7 (12)*
Ejection fraction (%)	59.4±15.5	54.7±16*	60.8±14.6	58.8±14.5
Stent implantation	100 (90)	70 (81)	120 (86)	56 (93)
No. of lesions/patient	1.27±0.5	1.16±0.4	1.15±0.4	1.15±0.4
Site of lesions (PTCA)				
AD/DG	79 (56)	44 (44)	90 (56)	26 (38)
CX/MO	19 (13)	18 (18)	29 (18)	14 (20)
RC/PD	43 (30)	37 (37)	42 (26)	29 (42)
Type B2-C AHA-ACC	72 (51)	70 (70)*	78 (48)	44 (73)*
Characteristics of the lesion				
Presence of calcification	24 (22)	37 (44)*	21 (16)	19 (32)
Presence of definite thrombus	48 (43)	47 (54)	66 (47)	28 (46)
Length of lesion (mm)	13.7±7	14.7±8	12.2±8.6	12.7±8
Minimal lumen diameter (mm)	0.71±0.4	0.61±0.4	0.77±0.4	0.8 ± 0.4
Post-PTCA diameter (mm)	3±0.5	2.75±0.6*	3.1±0.5	3±0.5

Data are expressed as the number of patients, with the percentage of the total in parenthesis, or as the mean±standard deviation (SD). AD indicates anterior descending coronary; DG: diagonal; CX: circumflex; MO, marginal obtuse; RC, right coronary; PD, descending; PTCA, coronary angioplasty. *P<.05.

TABLE 3. Adverse events in the follow-up of diabetics and non-diabetics

	Diabetics (n=179)	Non-diabetics (n=180)	P
Major events	62 (37)	44 (24)	.032
Death	11 (6)	3 (2)	.031
Myocardial infarction	2 (1)	4 (2)	.4
Revascularization	30 (17)	21 (12)	.3
Admission for UA	42 (24)	38 (21)	.6

Data are expressed as the number of patients, with the percentage of the total in parenthesis. UA indicates unstable angina.

TABLE 4. Adverse events in the follow-up of patients with complete versus incomplete revascularization in relation to the presence or absence of diabetes

	Diabetics		Non-diabetics	
	Complete revascularization (n=102)	Incomplete revascularization (n=77)	Complete revascularization (n=116)	Complete revascularization (n = 55)
Major events	32 (31)	30 (39)	27 (21)	17 (31)
Death	2 (2)	9 (12)	2 (2)	1 (1)
Myocardial infarction	1 (1)	1 (1)	3 (2)	1 (2)
Revascularization	16 (16)	14 (18)	15 (12)	6 (11)
Admission for UA	24 (24)	18 (23)	23 (18)	15 (27)

Data are expressed as the number of patients, with the percentage of the total in parentheses. UA indicates unstable angina.

*P<.01

or diet.

DISCUSSION

In the present study the diabetic patients who underwent percutaneous revascularization in routine clinical practice had a worse evolution than non-diabetic patients did, due fundamentally to a greater cardiovascular mortality. Nevertheless, this worse clinical evolution seemed to correspond more to patients with incomplete revascularization than to diabetics *per se*. In our series, complete coronary revascularization was

achieved in only 57% of diabetics versus 70% of non-diabetics.

The baseline and angiographic characteristics of the diabetics studied here did not differ from those reported in previous series:^{10,12-19} older age, a larger percentage of women and arterial hypertension, a smaller percentage of smokers, and lower ejection fraction and complete revascularization. Nevertheless, many series that have examined the prognosis of diabetics undergoing percutaneous revascularization do not indicate, or even systematically study, the percentage of diabetics who achieve complete anatomic revascularization. In our series the diabetic patients that underwent only incomplete revascularization had an unfavorable clinical profile: older age, a larger percentage of previous revascularization procedures, anatomically less favorable injuries, and a smaller ejection fraction.

Our work showed that diabetic patients had a worse clinical prognosis at one year of follow-up, as has been found in previous studies that have investigated the prognosis of diabetics undergoing percutaneous revascularization with stent implantation, like most of our patients.¹²⁻¹⁸ As reported in a recently published Spanish study,²⁰ the difference in the frequently of events conditions cardiovascular mortality. Abizaid et al¹⁸ only found insulin-dependent diabetes mellitus associated with a worse prognosis, whereas non-insulin-dependent diabetes presented short and long-term results similar to those of non-diabetics. In spite of its importance, in none of them was incomplete revascularization studied as a factor predictive of complications. Thus, Weintraub et al,¹⁹ in the experience of Emory University Hospital in diabetics with multivessel disease, only achieved complete coronary revascularization in 16% of the patients who underwent percutaneous revascularization, versus 56% in our study, in which we also included patients with single-vessel disease.

Incomplete coronary revascularization in diabetic patients

The studies published on the prognosis of diabetic patients have demonstrated an improvement in prognosis with revascularization, whether percutaneous or surgical.²¹ Patient selection is fundamental for choosing the best mode of revascularization in diabetic patients with multivessel disease, as demonstrated by the registry of the BARI study,²² where diabetics with multivessel disease did not have a mortality different from those treated surgically, in contrast with patients participating in the clinical trial.

Incomplete coronary revascularization is a common finding in clinical practice, whether for clinical reasons, treatment of the responsible vessel, or anatomic causes, such as chronic occlusion. The literature indicates that this strategy may not jeopardize the long-

TABLE 5. Analysis of factors related with MACE

	Univariate		Multivariate	
	P	P	OR	95% CI
Diabetes	.03	.16	1.38	0.87-2.20
Insulin treatment	.6	.4	1.23	0.75-2.02
Incomplete revascularization	.03	.04	1.7	1.002-2.88
Arterial hypertension	.09	.14	1.4	0.89-2.21

Variables included in the analysis, but not associated with MACE: age, sex, multivessel disease, vessel diameter less than 3 mm, and ejection fraction. OR indicates odds ratio; CI, confidence interval.

term survival of non-diabetic patients with multivessel disease and good distal vessels for surgery or angioplasty.²³ However, we do not have evidence suggestive of the prognosis of diabetic patients, who are known to have more diffuse coronary involvement and a greater progression of atherosclerotic disease. Bell et al²⁴ studied 867 patients in which conventional angioplasty without stent implantation was performed. The patients with incomplete revascularization more frequently presented cardiovascular events, which was attributed to differences in their baseline characteristics and not to incomplete revascularization in the multivariate analysis. Nevertheless, O'Keefe et al²⁵ found a worse evolution in diabetics who underwent incomplete revascularization.

Nowadays, as reported by Alonso,²⁶ it seems reasonable to indicate angioplasty in diabetics, especially non-insulin-dependent diabetics with disease of one or two vessels that do not present another factor favoring restenosis (such as a size of less than 3 mm, long lesions, or lesions with residual stenosis),²⁰ and in patients with a high incidence of complications associated with surgery. Nonetheless, many of the patients that we usually see are not candidates for surgical treatment, due to the anatomic characteristics of their coronary arteries, and partial coronary revascularization is performed. Information on their prognosis must be obtained from observational studies because these patients generally do not meet inclusion criteria for any randomized study.

From the results of our study, the importance of myocardial segments with non-revascularized coronary artery disease should be underlined. New approaches to the treatment of diabetics with coronary artery disease, such as strict metabolic control,²⁷ hybrid revascularization,²⁸ minimally invasive surgery, or laser revascularization can improve prognosis and alleviate the complications derived from incomplete revascularization. Likewise, the new anti-IIb/IIIa platelet antiaggregants²⁹ have been shown to have a very beneficial effect after percutaneous revascularization,

producing an important decrease in long-term complications, especially in the group of diabetics.

Study limitations

This is a retrospective study of cohorts and is subject to the limitations inherent to the study design. The diversity of the percutaneous revascularization methods (15% of patients were revascularized by conventional angioplasty), absence of information about the control of blood sugar levels in the patients assigned to each treatment group, and scant temporal follow-up of some of the patients are other limitations. The definition of coronary revascularization is limited, referring only to its anatomic concept.

CONCLUSION

The diabetic population undergoing percutaneous coronary revascularization in our setting has clinical characteristics that differ from those of non-diabetic patients: older age, a greater percentage of women, and a higher prevalence of arterial hypertension, which could accelerate the progression of coronary artery disease in these patients and worsen the anatomic profile, thus leading to higher rates of incomplete revascularization. This incomplete revascularization can affect intermediate-term results, increasing cardiovascular mortality. Finally, there is hope that new therapies can modify the natural history of these patients.

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