INTERVENTIONAL CARDIOLOGY

Nonselected Use of Direct Coronary Stenting. The DISCO 2 Trial

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Introduction and objectives. Direct coronary stenting yields immediate long-term clinical results similar to those obtained with balloon predilation, with the advantage of lower costs and procedural times. Until now, direct stenting has been attempted only for selected lesions, so that the potential scope of its use in everyday practice remains unknown. The DISCO 2 trial was designed to identify the number and type of lesions that could be safely treated by direct stenting.

Patients and method. 1,269 lesions (886 patients) were treated consecutively in 7 different hospitals. Direct stenting was attempted in all cases, except for total chronic occlusions, severe tortuosity or calcification of the vessel, lesions in the sinus ostium, or bifurcated lesions and vessel diameter < 2.4 mm. If the procedure failed, the stent was recovered and the lesion dilated with a balloon before a second attempt at stenting.

Results. Direct stenting was attempted in 585 lesions (54.9% of all electively implanted stents and 46.1% of all angioplasties). This was successful in 553 (94.6%) and failed in 32 (5.4%). In 30 of these latter patients a stent was implanted after predilation. Predictors of failure were tortuosity, location in the nonproximal right coronary artery, age > 65 years and type B2 or C lesion. After 6 months of follow-up the total incidence of major adverse cardiovascular events in patients treated with direct stenting was 6.2%, with a target lesion revascularization rate of 4.45%.

Conclusions. In a mostly nonselected sample of coronary lesions, direct stenting was as safe as stenting with predilation. More than half of all elective stenting procedures can be attempted safely without balloon predilation. Greater need for predilation was associated with tortuosity, nonproximal right coronary artery location, older

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Received 7 November 2002. Accepted for publication 19 February 2003. age and lesion complexity (B2, C). The 6-month clinical outcome was excellent, with a low rate of repeat revascularization.

Key words: *Stent. Coronary angioplasty. Revascularization.*

Uso amplio de *stenting* coronario directo. Estudio DISCO 2

Introducción y objetivos. El *stenting* directo ofrece resultados inmediatos y a largo plazo similares a los del implante con predilatación, con la ventaja de una reducción en el coste y la duración del procedimiento. Hasta el momento, su uso se ha limitado a lesiones seleccionadas, por lo que el campo real de aplicación no se conoce. El estudio DISCO 2 pretende identificar el número y las características de las lesiones donde el *stenting* directo puede realizarse con seguridad en la práctica diaria.

Pacientes y método. Se trataron 1.269 lesiones coronarias consecutivas, intentándose *stenting* directo en todas excepto en los casos de oclusión completa crónica, tortuosidad o calcificación severas, lesión aortostial o en bifurcación y diámetro del vaso inferior a 2,4 mm. Si el procedimiento fracasaba, se recuperaba el *stent* y se dilataba la lesión con balón antes de realizar un segundo intento con *stent*.

Resultados. Se abordaron con *stent* directo 585 lesiones (el 54,9% de todos los *stents* implantados electivamente y el 46,1% de todos los procedimientos de angioplastia), con éxito en 553 (94,6%) y fracaso en 32 (5,4%), de los que en 30 se implantó *stent* tras realizar una predilatación. Se asociaron a la necesidad de predilatación la tortuosidad excesiva, la localización en la coronaria derecha no proximal, la edad superior a 65 años y el tipo de lesión B2 o C. A los 6 meses, la incidencia de acontecimientos cardiovasculares adversos mayores en los pacientes con *stenting* directo fue del 6,2%, con una tasa de revascularización repetida del 4,45%.

Conclusiones. En lesiones coronarias poco seleccionadas, el *stenting* directo es tan seguro como el implante tras predilatación. Más de la mitad de las lesiones tratadas electivamente con un *stent* son adecuadas para *stenting* directo. La posibilidad de éxito se reduce con la tortuosidad excesiva, la localización en la coronaria

^{*}At the end of the article there is an appendix showing the centers and researchers involved in the DISCO trial

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ABBREVIATIONS

DS: direct stenting.
PTCA: percutaneous transluminal coronary angioplasty.
No-DS: PTCA without direct stenting.
MACE: major adverse cardiovascular events.
RCA: right coronary artery.
LADCA: left anterior descending coronary artery.
LCx: left circumflex coronary artery.

derecha no proximal, la mayor edad y la lesión compleja (B2, C). El curso a los 6 meses es excelente, con un índice muy bajo de revascularización repetida.

Palabras clave: Stent. Angioplastia coronaria. Revascularización.

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INTRODUCTION

The use of stents in percutaneous coronary revascularization procedures has increased exponentially in recent years. The latest available data, those of 2001, show their use in 88.1% of the 31 290 angioplasties performed in Spain, the great majority of which were elective.¹ With the improvement in stent design, direct implantation without predilation has become common practice; 40.9% of all implantations performed in 2001 were done in this way.¹

Several randomized²⁻⁴ and observational studies⁵⁻⁷ have demonstrated the safety of direct stenting (DS), the angiographic and clinical results achieved being similar to those obtained using the conventional technique with predilation. However, they also show the advantages of DS in terms of reduced procedure time, irradiation, contrast volume and a reduction in the number of consumables used — all factors with a favorable impact on total cost.^{6.8}

The true potential of the use of DS is not well known, however, since in published studies the lesions treated were preselected. Both randomized and observational studies have excluded potentially adverse anatomical situations (one must bear in mind — amongst other factors — the material available at the time). In the DISCO⁴ study, only 22% of the treated lesions treated by percutaneous transluminal coronary angioplasty (PTCA) were randomized during patient recruitment.

To precisely identify the types and characteristics of lesions that are suitable or non suitable for the DS approach, the treatment of all patients should

theoretically be attempted with this method. But this was impossible with earlier-generation stents because of the risk of loss, dislocation or deformation before reaching the target lesion, and the consequent probability of embolism or the need to deploy in a proximal segment. However, the sixth generation stents now in use can be recovered without risk in cases of access failure, and implantation can be re-attempted following predilation or substitution of the guiding catheter for another which offers better support. In this way, lesions that would once have been considered inappropriate for DS treatment can now be successfully treated, widening the use of this procedure. With this philosophy, a prospective, multi-center, observational and descriptive study was designed (Non-restricted Direct Coronary Stenting, DISCO 2), whose main aims were: a) to determine the percentage of lesions that can be treated with DS, and b) to evaluate the procedure's effectiveness, safety, and possible risks in nonselected lesions. The secondary aims were a) to define the characteristics of the lesions that negatively influence the primary success of DS, and b) to study the adverse ischemic events that might arise (death, acute myocardial infarction [AMI], and the need to revascularize the treated lesion) during the stay in hospital and at 1 and 6 months after the procedure. To explore the widest target population, the only anatomical situations excluded were those in which, according to current knowledge, DS had a high chance of failure or where there was a high risk of complications.

PATIENTS AND METHOD

Study population

Between January and June of 2001, 886 patients (1269 lesions) were recruited at seven Spanish hospitals. Each center included, in a consecutive manner, a number of patients subjected to coronariography (see Appendix) before knowing their coronary anatomy. The initial intention was to treat all by DS. Those with \geq 60% stenosis in one vessel with a diameter of \geq 2.4 mm were then identified. Exclusion criteria were calcification or acute tortuosity as evaluated by our own classification system, complete chronic occlusion (more than 4 weeks), recent chronic occlusion with an indefinable lesion after crossing the guidewire, aorto-ostial lesions and bifurcated lesions with a lateral branch of 2 mm or more.

Definitions

1. Success of DS: implantation with residual stenosis of <20% and flow of TIMI III.

2. Failure: impossibility of implantation without predilation.

3. Secondary success: successful implantation after

predilation with a balloon following DS failure.

4. AMI: raised creatine kinase (CK) levels (over twice normal) and compatible electrocardiograph recordings.

5. Tortuosity: *a*) moderate, 2 curves $>75^{\circ}$ or one curve $>90^{\circ}$ in front of the lesion, and *b*) severe, 2 curves $>90^{\circ}$ in front of the lesion.

6. Calcification: *a*) mild, single or multiple image of circumscript calcification, nonlinear, on the lesion; *b*) moderate: image of linear calcification on one side of the lesion, not visible in the detained fluoroscopic image, and *c*) severe: image of linear calcification on both sides of the lesion, visible in the detained fluoroscopic image.

Angioplasty

PTCA was performed using the femoral approach following the standard practice of each center, employing at least a 6 Fr guiding catheter and medium or high support intracoronary guidewire. The stents used were MultiLink Tetra, Penta and Pixel models (Guidant Inc., Temecula, California, USA.), long enough and of adequate diameter to achieve a 1.1-1.2:1 ratio with respect to the reference obtained by digital angiographic quantification. The stents were deployed at a pressure of ≥ 8 atmospheres. Postdilation with the same or another balloon was performed if a suboptimal result was achieved. When the stent could not be directly implanted properly, a new attempt was made after dilating the lesion with a balloon. If, despite predilation, the stent could not be implanted, dilation was optimized with the balloon, and PTCA was concluded. All patients received a heparin bolus, aspirin and either ticlopidine or clopidogrel at the usual dose either starting four days prior to the procedure, or receiving a loading dose (500 mg aspirin, 500 mg ticlopidine or 300 mg clopidogrel) immediately before PTCA. Glycoprotein IIb/IIIa inhibitors were used according to the criterion of the operator. Aspirin was prescribed indefinitely along with ticlopidine or clopidogrel for 4 weeks.

Angiographic assessment

The lesions treated by DS were analyzed both before and after stent implantation by digital angiographic quantification using MEDIS QCA-CMS software at a care laboratory (Hospital Universitario de la Princesa, Madrid). Classification was according to the guidelines of the American Heart Association (ACC/AHA). The left ventricular ejection fraction was assessed in most patients.

Follow-up

CPK and CPK-MB concentrations were determined before the procedure, at 6 h and at discharge from hospital. If values were increased, the tests were repeated every 8 h until normal levels were reached. Patients treated by DS were followed-up after discharge by monthly home visits, or by telephone for 6 months. Major adverse cardiovascular events (MACE) were recorded (death, nonfatal AMI and repeat surgical or percutaneous revascularization, throughout hospitalization and follow-up).

Statistical methods

Variables are presented as means±SD and percentages. Comparisons between qualitative variables were performed using the χ^2 test; quantitative variables were compared using the Student t test. Significance was set at *P*<.05. All statistical analyses were performed using SPSS version 10.0 software. With the aim of identifying the variables associated with the need to predilate, and their relative importance, a multivariate statistical model was designed, including the discriminating variables identified in the prior bivariate analysis.

RESULTS

The study involved 886 patients and a total of 1269 lesions, of which 1066 (84.0%) were treated using stents. Direct stenting was attempted in 585 lesions (46.1% of all PTCAs performed, and 54.9% of all stents implanted; this last percentage varied between 43.2% and 75.9% depending on hospital). DS was not attempted in 684 lesions; 481 were treated with a stent after predilation, the rest were treated by balloon. The most common reason for not using DS was complete chronic occlusion (Table 1). The operator criterion for exclusion included anatomical situations not specified in the study protocol, such as intra-stent restenosis, diffuse disease of the treated vessel, the inability to clearly define the distal bed in lesions with subtotal occlusion. and enrollment in other protocols that required ballon predilation and the use of a different stent.

Characteristics of the study population

Table 2 shows the clinical characteristics of the patients. The incidence of prior heart problems was significantly lower among those treated by DS than among those requiring predilation before stent implantation. All characteristics were distributed homogeneously. The most frequent indication for PTCA

TABLE 1. Exclusion criteria	a (684 lesions)
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Complete occlusion	24%
Diameter <2.4 mm	19%
Operator criterion	18%
Bifurcated lesion	14%
Severe tortuosity	14%
Severe calcification	10%
Aortoostial lesion	1%

	DS group	No DS group	Ρ
Age, years	63.16±11.076	64.63±11.87	NS
Masculine sex	84.9	79.9	NS
Diabetes mellitus	22.0	25.4	NS
Type 2	14.6	17.2	NS
Type 1	7.4	8.2	NS
High blood pressure	47.3	53.7	NS
Hypercholesterolemia	49.2	47.7	NS
Smoking habit	58.6	55.4	NS
Ex-smoker	25.0	25.6	NS
Smoker	33.6	29.8	NS
History			
Family history	7.2	11.1	NS
History of heart problems			<.01
Prior AMI	36.6	43.9	
Prior PTCA	9.6	11.3	
Prior surgery	4.6	6.5	
Ejection fraction	61.11±13.26	57.92±13.64	NS

TABLE 2. Patient characteristics (%)

AMI indicates acute myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.

TABLE 3. Indication for angioplasty, and number of lesions per patient (%)

	DS group	No DS group	P
PTCA indicated			NS
Instable angina	57.0	51.6	
Stable angina	19.6	20.9	
AMI	14.3	21.0	
Silent ischemia	8.7	6.5	
Others	0.4	0.0	
Number of patients			<.01
With 1 lesion	82.0	50.3	
With 2 lesions	16.0	35.9	
With 3 lesions	1.6	12.2	
With 4 lesions	0.4	1.6	

AMI indicates acute myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.

was unstable angina. More than half of the patients in the DS group had a single coronary lesion (Table 3).

Lesion characteristics

Tables 4 and 5 show the characteristics of the lesions treated with stents. No significant differences were found between the DS and no-DS groups with respect to the artery treated, although significant differences were seen with respect to the site of the lesion (fewer DS were performed in distal segments and secondary branches), and with respect to ACC/AHA type (fewer type C lesions were seen in the no-DS group), TIMI flow, degree of tortuosity, and degree of calcification.

TABLE 4. Lesion characteristics (%)

	DS group	No DS group	Р
Dilated artery			NS
LC Trunk	0.3	1.0	
LADCA	40.9	46.6	
LCx	21.9	23.7	
RCA	35.2	27.7	
Bifurcation	0.7	0.4	
Saphenal	1.0	0.6	
Segments			<.01
Trunk	0.3	1.0	
Proximal	36.6	39.7	
Medial	46.5	35.1	
Distal	12.1	17.0	
Branches	3.4	6.4	
Saphenal	1.0	0.6	

LC indicates left coronary.

TABLE 5. Lesion characteristics (%)

	DS group	No DS group	Р
Type of lesion ^a			<.01
A	12.3	1.7	
B1	42.6	16.6	
B2	35.4	45.5	
С	9.7	36.2	
Prior flow ^b			<.01
0	2.1	25.2	
1	3.2	4.4	
2	13.5	14.6	
3	81.2	55.9	
With clotting	13.5	20.2	<.05
Tortuosity			<.01
Minimum/nil	72.3	52.2	
Moderate	27.7	31.4	
Severe	0.0	16.4	
Calcification			<.01
Minimum/nil	88.7	66.3	
Moderate	11.3	20.6	
Severe	0.0	13.1	

^aACC/AHA. ^bTIMI.

Digital angiographic quantification

The reference diameter was 3.09 ± 0.48 mm, the minimum lumen diameter was 0.79 ± 0.32 mm, and the percentage stenosis was $74.25\%\pm9.46\%$. After PTCA, the percentage stenosis fell to $11.45\%\pm5.34\%$, the reference diameter was 3.2 ± 0.51 mm, and the minimum lumen diameter was 2.72 ± 0.46 mm.

PTCA data

In 90.3% of cases, a 6 Fr guidewire catheter was used.

	Primary successes	Failures	Ρ
Location			<.05
RCA			
Proximal	9.6	6.7	
Media	15.7	40.0	
Distal 8.1	3.3		
Posteroilateral	0.5	3.3	
LADCA			
Proximal	17.2	10.0	
Media	23.0	13.3	
LCx			
Proximal	10.3	3.3	
Distal	9.8 13.3		
Saphenal	0.7	6.7	
Type*			<.01
A/B1	56.2	33.3	
B2/C	43.8	66.7	
Tortuosity			<.01
Minimum/nil	74.7	30.0	
Moderate	25.3	70.0	
Calcification			<.01
Minimum/nil	89.7	73.3	
Moderate	10.3	26.7	

TABLE 6. Characteristics associated with	need
to predilate (%)	

*ACC/AHA

TABLE 7. Predictive	model for	need of	predilation
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	Coefficient	Maximum	Minimum	Deviation
Tortuosity	0.38	0.69	0.22	0.07
Mean RCA	0.33	0.59	0.22	0.06
Age >65 years	0.29	0.65	0.18	0.06
Type of lesion*	0.26	0.56	0.18	0.04

*ACC/AHA. RCA indicates right coronary artery.

A high support guidewire was used with 37.2% of lesions and a medium support guidewire with 62.8%. The mean length of stent in the DS group was 14.86 ± 4.84 mm with a diameter of 3.11 ± 0.4 mm (46.3% with 3 mm, 8.2% with 2.75 mm, 13.3% with 2.5 mm, and the rest with 3.5 or 4 mm diameter). The mean deployment pressure was 13.26 ± 2.38 atm; mean inflation time was 38.1 ± 20.58 s.

Results of DS

Success was achieved in 553 of the 585 lesions treated (94.6%); DS failed in the remaining 32 (5.4%). In 30 of the latter, implantation was achieved after predilation; in two, PTCA could not be performed at all. Such was the case of one patient undergoing primary PTCA for AMI who showed a proximal occlusive dissection of the right coronary artery (RCA). This

impeded the passage of any device. The second patient had a type C lesion with thrombus of the proximal left anterior descending coronary artery (LADCA), which became occluded during implantation and the patient died. No losses or stent embolization were seen. A second stent was required in 34 lesions (5.8%), the majority (2.7%) to cover a dissection at the edge of the stent, and the rest because of the inadequate length of the first stent. In 117 patients (24.2%) glycoprotein IIb/IIIa inhibitors were used, mostly abciximab (76.3%). Forty six lesions required overdilation (7.9%) and a final TIMI flow of 3 was achieved in 98.1%.

Characteristics of secondary successes

The mean age of the patients for whom predilation was necessary was significantly higher than those in whom primary success was achieved (69.70 compared to 62.89 years; P < .01). No differences were seen with respect to other clinical characteristics. Table 6 shows the anatomical characteristics of the 30 lesions that had to be predilated. Univariate analysis identified DS failure risk factors as age, location in the medial segment of RCA, type B2 and C lesions, and the degree of tortuosity and calcification. In multivariate analysis the factors were type of lesion, location in the medial RCA, age above 65 years, and tortuosity of the lesion. Any one of these factors on its own was insufficient to determine a possible preventive action, although any two combined certainly did (Table 7). The need to predilate was not related to the severity of stenosis, the length of the lesion or its location in the left circumflex coronary artery (LCx).

Complications during hospital stay

Table 8 shows the complications encountered in the DS and no-DS groups prior to discharge from hospital. Of the five deaths, two were due to AMI following primary PTCA with good angiographic results, two to thrombosis of the stent, and one to cardiac arrest caused by ventricular fibrillation. Of the nonfatal AMIs, four showed no rise in the ST segment; two did show such a rise. The two repeated PTCA procedures were owed to acute or subacute thrombosis of the stent.

Follow-up

Follow-up was performed at one and six months in the DS group (Table 9). In the first month, five patients (1.03%) were lost to follow-up. There were no MACEs. In the sixth month, 38 patients (7.8%) were lost to follow-up.

DISCUSSION

This study tries to identify the different types of lesion

During the procedure	
Dissection	4.6%
Proximal	3.2%
Distal	1.4%
Stent thrombosis	1.02%
Intra-hospital complications	
Cardiac death	1.02%
Non-fatal AMI	1.57%
Re-PTCA	0.41%

TABLE 8. Hospital complications in the DS group

AMI indicates acute myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.

TABLE 9. Extra-hospital follow-up

	One month (n=480)	Six months (n=449)
Hospitalization	1.04	9.13
Catheterization	0.63	8.02
Coronary event	-	14.03
Angina	-	7.35
Death	-	0.89
AMI	-	0.67
Surgery	-	1.11
Re-PTCA	-	3.34
Non-cardiac death	-	0.67

AMI indicates acute myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.

and coronary anatomy in which a stent can be directly implanted with safety.

Determining the exact number of lesions that can be treated by direct stent implantation, theoretically requires all patients be treated using this technique. However, at the present time this would appear unwise; failure is possible when lesions are potentially nondilatable or cannot be properly defined. For this reason, patients whose lesions were strongly calcified, were in an aortoostial location, or were recent, complete occlusions with the segment requiring treatment unclear, were all excluded. Also excluded were patients falling into two risk categories: those with high tortuosity of the vessel, and those with possible damage to side branches of sufficient importance. In agreement with current knowledge, systematic stent implantation was deemed inappropriate when vessels were small (diameter <2.4mm) — although habitually using a stent in vessels of these characteristics does not seem to present difficulty. Even with these exceptions, an appreciable number of lesions were treated which, because of their anatomical characteristics, had never been included in earlier studies (whose main aims were to demonstrate the effectivity and safety of DS rather than to show the range of the population in which such techniques might be used). Thus, the present data probably more closely reflect what DS might be used for in the «real world» of daily practice.

The results obtained show that 55% of lesions in which a stent is indicated can be treated by DS with an overall success rate of 99.7% (94.6% for primary success and an additional 5.1% after predilation). Great use is made of stents in revascularizations (84% of all PTCAs in our series), and in this work almost half of the patients underwent percutaneous DS. The overall percentage of DS found possible seems reliable since this was constant in five of the seven participating hospitals, with little deviation. The strong variability seen in the remaining two (43.2 and 75.9% — at the extremes of variation) might be explained by their treating two populations with very different anatomies and their having been a greater number of exclusions in the former and fewer in the latter, or by different attitudes towards the same type of lesion. Since the design of the study did not include angiographic revision of patients not treated with DS, no definitive answer can be given. However, the large number of lesions included in the study by each center (in patients who were not preselected) suggests that the second explanation might be better, and shows that a subjective component (and probably personal experience) often modulates the use of this technique over and above the requirements of the protocol.

Another important aspect of the study is the identification of those factors that negatively influence the primary success of DS. Multivariate analysis showed that the combination of any two factors from excessive vessel tortuosity before the lesion, location in the medial segment of the RCA, age above 65 years and type B2 or C lesions, predict the failure of DS on 85% of occasions. Location in the RCA has not previously been recorded as an adverse factor. Common experience shows that the stability of the guiding catheter in the latter vessel is suboptimal — sufficient for the passage of a balloon catheter, but not a stent, particularly if the aorta is dilated or when the coronary artery shows moderate tortuosity. In these cases, and in others where difficulties are expected, one should ensure a solid platform, selecting the most adequate guiding catheter curve as well as a high support intracoronary guidewire if DS is to be attempted. Maximum support can be achieved with deep canulization, if necessary advancing a soft ended 6 Fr guiding catheter over the guiding catheter to gain a superselective position in the proximal segment of the lesion.

It is interesting to note that the need for predilation was not associated with the severity of stenosis, the diameter of the stent implanted, or location in the LCx. The difficulty associated with the latter circumstance (previously mentioned as a failure predictor⁹⁻¹²) nearly always lies in an excessively angled origin of the vessel — which impedes the passage of the stent to the proximal segment. In our experience, this can often be solved by using an Amplatz curve guiding catheter and high support catheter. It cannot be ruled out, however, that the low incidence of failure in stenting of the LCx in the present study was due to a more strict selection of patients, where the operator bore in mind the results of previous studies in which this location is cited as an independent predictor.

It seems understandable that the success of primary DS in the DISCO 2 trial (94.6%) was slightly less than that of the DISCO trial, $(96.8\%)^4$ given the inclusion criteria in both studies (significantly greater number of adverse cases in the former). The influence of the inclusion criteria is confirmed by the fact that successful stent implantation after predilation (95.2%) was also lower than in the DISCO trial (100% success).

The complications related to stent implantation were independent of the technique used. It is interesting to note that displacement or loss of the stent did not occur. Compared to earlier, controlled studies,²⁻⁴ the small increase seen in mortality, acute thrombosis and other major events might be explained by the inclusion of patients with more complex coronary anatomy and a significant percentage (14%) who suffered AMI after primary PTCA. The five deaths in the DS group occurred through AMI after successful angioplasty.

Finally, the clinical outcome of patients over the 6 month follow-up period was excellent. MACEs were few (6.2%), and clinical restenosis (8.91% including the reappearance of angina, mortality and nonfatal AMI) and repeat revascularization (4.45%) were very low (figures very similar with those published earlier for $DS^{4,5,13-15}$).

Limitations of the study

The real percentage of patients that might have successfully received DS could be underestimated in this study since 18% did not undergo such treatment based on operators' criterion — even though the patients'

APPENDIX

DISCO 2 Researchers

Hospital Universitario de la Princesa, Madrid: L. Martínez Elbal, S. Mingo Santos, A. Benedicto Buendía, C. Romero (243 lesions).

Hospital Marqués de Valdecilla, Santander: J. Zueco, T. Colman, A. Figueroa, J.M. de la Torre (412 lesions).

- Hospital Miguel Servet, Zaragoza: I. Calvo, J.A. Diarte, J.G. Galache (175 lesions).
- Hospital Virgen de la Salud, Toledo: J. Moreu, T. Cantón (135 lesions).
- Hospital Infanta Cristina, Badajoz: A. Merchán, J.R. López Mínguez (111 lesions).
- Hospital Universitario Virgen de las Nieves. Granada: R. Melgares, J.A. Ramírez, J.A. Romero (102 lesions).

Hospital de León: F. Fernández Vázquez, A. Pérez de Prado (91 lesions).

lesions did not meet exclusion criteria (intra-stent restenosis, poorly defined or poor distal vessel quality, assignment to another protocol and other factors not well determined) — and because small vessels were excluded. The identification of all the factors that prevent primary success may not be complete since the small number of lesions in which DS was not successful necessarily reduces the predictive power — although the statistical model used did partialy correct for this. Finally, the results obtained refer exclusively to the type of stent used, and should not be extrapolated to other models.

CONCLUSIONS

DS was performed safely and with a primary success rate of 94.6% in more than half (55%) of all elective implants with a wide range of coronary lesions — many of which have been excluded from prior studies. Given the wide use of stents, this figure reflects 46% of all percutaneous coronary revascularization procedures. In agreement with that shown in earlier investigations, this implies important reductions in terms of cost, time and irradiation.

The type of stent used allowed them to be implanted without risk of their loss or displacement in cases of access failure (only 5%).

DS failure predictors in the population analyzed were excessive vessel tortuosity, type B2 or C lesions, nonproximal location in the RCA, and age over 65. The clinical outcome with respect to adverse events while in hospital and at six months was favorable: it was no different to that communicated in other DS or conventional stenting studies with a low incidence of clinical restenosis, and, in consequence a low rate of repeat revascularization during follow-up.

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