

Direct Stenting without Predilation: a Single-Center Experience with 1 000 Lesions

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Introduction. Direct stenting has been shown to save costs, procedural time, radiation, and contrast use. We analyze the results of direct stenting in daily practice.

Material and methods. We retrospectively analyzed the interventions in the first 1,000 lesions that were treated with direct stenting at our center. Primary success, dissection, need for additional dilation, embolism, stent loss, and side branch occlusion were the variables assessed.

Results. Direct stenting was attempted in 1,000 lesions in 784 patients (age 63 ± 11 years, females 21%, diabetes 37%). Primary or rescue angioplasty was performed in 8%. One or more thrombi were found in 16%, bifurcation in 9%, calcification in 5%, angulation in 2.3%, and tortuosity in 3.2%. The reference diameter was 3.0 ± 0.5 mm. The primary success rate was 93.1%. Failure of direct stenting (6.9%) was associated with the circumflex artery in 38%, calcification in 26%, angulation in 22%, and tortuosity in 31%. In 39 lesions, additional dilation with different balloons was required. Additional stenting was required for dissection in 40 lesions and secondary to incomplete coverage of the lesion in 27. Thrombus embolism occurred in 7 lesions, 6 of them with a previously visible thrombus and one in a vein graft. Stent embolisms occurred in 6 cases, 4 of which were retrieved. Four side branches became occluded, but 2 of them were recovered at the end of the procedure.

Conclusions. Direct stenting is a safe technique with low percentage of dissection, need for postdilation, thrombus embolism, and side branch occlusion. These results, in addition to those obtained in earlier findings of savings in procedural costs, intervention time, radiation exposure, and contrast use, confirm the advantages of this technique in selected lesions.

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

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Implante de *stent* directo sin predilatación: experiencia de un centro en 1.000 lesiones

Introducción. El implante directo de *stent* ha demostrado un ahorro en costes, tiempo, radiación y contraste. Analizamos los resultados del implante directo en la actividad de un centro.

Material y métodos. Estudiamos retrospectivamente las intervenciones de las primeras 1.000 lesiones tratadas con *stent* directo. Se analizó el éxito primario, disección, necesidad de posdilatación, embolización, pérdida de *stent* y afectación de ramas laterales.

Resultados. Se trataron 1.000 lesiones en 784 pacientes. Edad 63 ± 11 , mujeres 21%, diabetes 37%, angioplastia primaria o rescate 8%, trombo 16%, bifurcación 9%, calcificación 5%, angulación 2,3%, tortuosidad 3,2%. Diámetro de referencia $3,0 \pm 0,5$ mm. Éxito primario: 93,1%. El fracaso (6,9%) se asoció a localización en circunfleja en 38%, calcificación en 26%, angulación en 22% y tortuosidad en 31%. En 39 lesiones se requirió posdilatación con balón diferente, en 40 lesiones *stent* adicional por disección y en 27 por cobertura incompleta. Hubo embolización de trombo en 7 lesiones, seis con imagen de trombo previo y una en safena. Embolizaron 6 *stents*, de los cuales cuatro se recuperaron. Se ocluyeron 4 ramas laterales y dos de ellas también se pudieron recuperar.

Conclusiones. El implante directo de *stent* es una técnica segura con un bajo porcentaje de disección, necesidad de posdilatación, embolización de trombo y oclusión de ramas. Estos resultados, unidos a los de estudios previos referidos al ahorro en tiempo, coste, radiación y contraste, avalan las ventajas de esta técnica en lesiones seleccionadas.

Palabras clave: *Stent. Angioplastia coronaria. Revascularización.*

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ABBREVIATIONS

DS: direct stent procedure.
 IVUS: intravascular ultrasound studies.
 DISCO: Direct Stenting of Coronary Arteries study.
 FDA: Food and Drug Administration.

INTRODUCTION

Intracoronary stents are the most important advance since the beginning of the use of percutaneous techniques for treatment of ischemic heart disease,^{1,2} and their benefit has been clearly demonstrated for treating angioplasty complications and in the prevention of same.³ The percentage of stent implantation procedures has progressively increased, and is close to 90% in some laboratories. According to the 2000 Registro de Actividad de la Sección de Hemodinámica (Registry of Hemodynamic Activity), stents are used in 77.2% of procedures in our country.⁴

At the beginning, stent utilization was limited to vessels 3 mm or more in size and with favorable anatomical conditions, implantation required previous dilatation, and post-procedure required oral anticoagulation treatment. The favorable results obtained in comparative studies with balloon angioplasty and the use of high pressure followed by antiaggregant treatment^{5,6} has allowed an increase in the indications for stent implantation, which has translated into an increase in the cost of interventions.^{7,8}

As a consequence of this increase in treatment indications cost, studies have been done and are underway to diminish the economic requirements. In recent years a modification of the conventional stent implantation technique has emerged in which previous balloon dilatation is not performed in certain lesions,⁹ achieving a savings in cost, time, contrast, and radiation.^{10,11} In spite of the initially unknown parameters of the results,¹² the number of procedures with direct stent implantation (DS) has increased considerably, and in our country was 39.8% during 2000.⁴

There are various prospective studies of DS that show the advantages of the technique.^{9,11,13-16} Nevertheless, the selection of cases in these prospective studies does not always correspond to situations found in daily practice. For this reason, we performed a retrospective study analyzing the results of DS in the first 1000 consecutive lesions treated with DS in our center. We studied *a)* the incidence of DS in daily practice; *b)* the initial success of the procedure; *c)* the complications (stent embolization, dissection, thrombus embolization or loss of branch), and *d)* clinical

hospital followup.

MATERIAL AND METHODS

The database of our hemodynamic unit was used to locate the first 1000 consecutive lesions in which DS was attempted.

We studied *a)* the clinical characteristics of the patients; *b)* the characteristics of the lesions (calcification, lesion angulation, proximal tortuosity, lesion length, and severity of stenosis); *c)* the percentage of implant success; *d)* the need for post-dilatation; *e)* the percentage of dissection; *f)* the incidence of thrombus embolization, and *g)* the involvement of lateral branches > 2 mm. Finally, we analyzed the clinical hospital course (death, acute myocardial infarction, need for revascularization) of the patients with all lesions treated with DS, excluding cases of primary or rescue angioplasty. We excluded from the analysis of the hospital course those patients who received treatment with techniques other than DS, as the analysis of the clinical results of this technique and the use of combined therapies would be made the examination difficult. Similarly, analysis of the hospital course did not include cases of primary or recovery angioplasty, as the clinical situation is different in these cases to the other cases involved. Since a considerable percentage of cases of this type exist, they will be analyzed in a future study.

Angiographic studies were analyzed retrospectively without previously knowing the result of the intervention subsequently performed. The gravity of the lesion was determined by visual quantification. Indications for revascularization were common, including primary and recovery angioplasty. The stents used were pre-mounted on a monorail system, were expandable by balloon, and in no case were of the coil type. The choice of stent was made by the surgeon. Six and 7F catheters were used according to the preferences of the interventionist. After stent implantation, if residual stenosis was present that could not be corrected by balloon stent, a non-compliant balloon of the same or greater diameter were used, per the physician's criteria. Post-DS dissections were treated by balloon inflation or an additional stent, also according to the surgeon's judgment. Tests of cardiac enzymes (CPK-MB) were performed every 8 hours in the 24 hours post-intervention as part of our usual protocol.

DEFINITIONS

DS implant

The attempt to implant an elective stent with previous balloon dilatation or arterectomy.

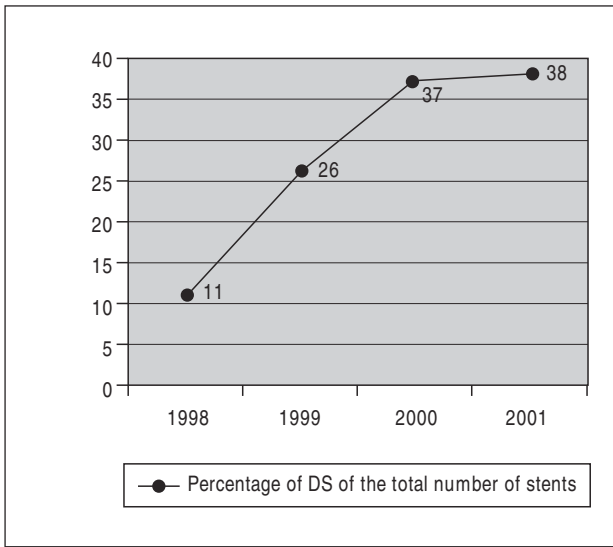


Figura 1.

Primary DS success

Implantation of an elective stent without the need for previous balloon dilatation or arterectomy.

Secondary DS success

Stent implantation with previous balloon dilatation after failed DS attempt.

Moderate or serious calcification

Calcification clearly visible on fluoroscopy.

Moderate or serious angulation

Lesion angle 45°.

Tortuosity

In the segment proximal to the lesion. Its classification as moderate or serious was made subjectively.

Thrombus

Globular contrast opacification defect visible on multiple projections, or in the case of total occlusion, an image of a convex border with contrast retention that persisted during various cardiac cycles.

Stent embolization

Detachment and loss of its guide and balloon fixation points.

Statistical analysis

The results are expressed as mean±standard deviation or as percentages. Comparison of the mean values of independent samples was performed via the Student *t* test and comparison of the proportions by means of the χ^2 test. A value of *P* .05 was considered statistically significant. The SPSS® version 10.0 package was used.

RESULTS

The period studied included from the beginning of the use of DS procedures in our center in September, 1998 to March, 2001. DS implantation was attempted in 1000 lesions in 784 patients, representing 31.2% of total stent implants during this period, with a progressive increase from the beginning of the period to the end of the period, as shown in Figure 1. Clinical characteristics are shown in Table 1. Twenty-one percent of the patients were women and 37% were diabetic. The lesion characteristics are given in table 2. Sixteen percent of patients presented an image of a thrombus and 9.3% were bifurcated with lateral branches 2 mm. Table 3 shows the types of stents, and Table 4 shows the diameters of the stents used.

TABLE 1. Clinical characteristics of the patients treated with stent implantation without predilatation

(N=784)	Number	%
Age, years*	63 (11)	-
Female	164	20.9
DM	290	37.0
AHT	455	58.0
Dyslipemia	423	54.0
Smoking	376	48.0
Previous angina	306	39.0
Previous AMI	353	45.0
Previous CAP	118	15.1
Previous RVS	47	6.0
Diseased vessels		
One vessel	315	40
Two vessels	258	33
Three vessels	211	27
Ventricular dysfunction		
Normal	455	58
Slight (45%-60%)	149	19
Moderate (30%-45%)	110	14
Serious (<30%)	70	9
IIb/IIIa inhibitors	243	31
Indications		
Stable angina	243	31
Unstable angina	455	58
Primary or rescue	62	8
Others	24	3

* Mean (standard deviation); AHT indicates arterial hypertension; AMI, acute myocardial infarction; DM, diabetes mellitus; CAP, coronary angioplasty; RVS, revascularization surgery.

TABLE 2. Angiographic characteristics of the lesions treated with stent without predilatation

(N=1000)	Number	%
Vessel treated		
LCT	10	1.0
DA	354	35.4
CX	203	20.3
RC	402	40.2
Saphenous	31	3.1
Calcification	50	5.0
Tortuosity	32	3.2
Angulation	23	2.3
ACC/AHA		
A	270	27.0
B1	410	41.0
B2	280	28.0
C	40	4.0
Reference diameter, mm	3.0±0.5	-
Previous stenosis	-	77±17
Longitude, mm	14±4	-
Thrombus	162	16.2
Bifurcation	93	9.3
Character		
<i>De novo</i>	971	97.1
Restenosis	29	2.9
Intrastent restenosis	10	0.1
Ostial	28	2.8

LCT indicates left coronary trunk; AD, anterior descending; CX, circumflex; RC, right coronary

TABLE 3. Types of stents used in the attempt to implant without predilatation

(N=1000)	Number	%
Multilink	365	36.5
NIR	205	20.5
AVE	230	23.0
Bx Velocity	80	8.0
Others	120	12.0

Multilink indicates Duet, Tristar, Tetra; NIR, Primo, Royal, SOX, Elite; AVE, GFX II, S540, S660, S670.

Primary success was achieved in 931 of the 1 000 lesions (93.1%), and secondary success was achieved in 68 of the remaining 69. Secondary success was not achieved in 1 case of primary angioplasty with a seriously calcified lesion; an adequate examination of the lesion would have resulted in finding DS not advisable for treatment. The lesion was treated satisfactorily with balloon angioplasty. Implant pressure was 15.7±2.3 atm. The amount of contrast used in the cases with only 1 lesion, including coronary angiography, was 202±54 ml and the cine time was 8.54±5.9 minutes.

Dissection following DS was produced in 42 lesions (4.5% of the primary success implants). Of these, 2 resolved with balloon inflation, 35 required a new stent

TABLE 4. Diameters of stents used for implant without predilatation

(N=1000)	Number	%
2.5 mm	240	24.0
2.75 mm	58	5.8
3.0 mm	427	42.7
3.5 mm	210	21.0
4.0 mm	57	5.7
4.5 mm	4	0.4
5.0 mm	4	0.4

TABLE 5. Angiographic results of the lesions treated with stent implantation without predilatation

N=1000	
Primary success, %	93.1
Pressure, atm	15.7±2.3
Dissection, n	42
Balloon	2
Additional stent	35
Two additional stents	3
Three additional stents	2
Cover deficit, n	41
Additional stent	39
Two additional stents	2
Need for post-dilatation, n	4.2
Embolization, n	7
Initial thrombus	6
Saphenous	1
Occlusion of lateral branch, n	4
Recuperated	2
Lost	2
Dismounted stents, n	6
Recuperated	4
Lost	2
Contrast, ml*	202±54
Cine time, min*	8.5±5.8

*Including coronary angiography. Cases with a single lesion treated.

implantation, 2 lesions required 2 new stents, and the remainder needed 3 additional stents. In 27 lesions (2.9% of the primary success implants) adequate lesion coverage was not achieved, and implantation of an additional stent was required in 25 of these, with 2 additional stents required in the remaining 2 cases. In 4.2% of the lesions post-procedure dilatation with a different balloon was required due to residual stenosis >20%. Seven lesion presented distal thrombus embolization. In six of these lesions, a thrombus was seen at the beginning of the procedure, and the remainder occurred in a saphenous vein. In 6 cases (0.6%) the stents embolized; 4 of these were recovered and 2 lost to the lower limbs, without consequences for the patient. A total of 93 lesions (9.3%) were bifurcated and

TABLE 6. Clinical intrahospital results for patients treated only with stent implantation without predilatation

N=369*	Number	%
Patients		
One lesion	288	78
Two lesions	71	19
Three lesions	10	3
Acute occlusion	3	0.8
Non-fatal AMI**	6	1.7
Mortality	4	1.0
Hemorrhage	1	0.3
RVS	0	0.0
CVA	0	0.0

*Patients whose lesions were only treated with direct stent implantation and excluding indications for primary or rescue ACTP. **AMI indicates acute myocardial infarction with CPK elevation CPK>2 times control on routine analysis; RVS, urgent revascularization surgery; CVA, cerebrovascular accident.

TABLE 7. Angiography characteristics associated with less primary success in stent implantation without predilatation

	Implant success	Implant failure	P
Previous stenosis, %	76±11	81±9	.03
Circumflex, %	19	37.7	<.001
Tortuosity, %	1.0	31.0	<.0001
Angulation, %	1.0	22.0	<.0001
Calcification, %	4.0	26.0	<.0001
Longitude, mm	13.7±4	14.4±4	NS

the lateral branch was lost in 4 cases with DS placement. In 2 cases they were recovered. Table 5 shows the results for the lesions treated.

Intrahospital followup was analyzed for those patients who underwent attempted DS for their lesions (n=369), and cases of primary or recovery angioplasty were excluded. Four patients presented with acute occlusion and were treated with angioplasty, in 6 patients an elevation in cardiac enzyme levels more than twice the normal limit was found on routine analysis, and 1 patient had a hemorrhage and required transfusion. There was no need for urgent surgical revascularization in any of the cases, and there were no cases of cerebrovascular accident.

Four patients died before hospital discharge. Two were diabetics with cardiac insufficiency, severely depressed ventricular function, and moderate renal insufficiency prior to the intervention. One of them required endotracheal intubation before the procedure. Death occurred on the fourth and sixth days after the procedure, respectively, due to worsening of renal function and cardiac insufficiency. The third patient, who had had 3 lesions dilated in the same procedure, also died of renal insufficiency 5 days after the inter-

TABLE 8. Comparison with the DISCO* study

	Our study (n=369)	DISCO study (n=210)
Design	Retrospective	Prospective
Age, years	61±11	59.4±10.4
Female, %	17.7	15.7
Hypertension, %	51	38.1
Dyslipemia, %	51	49
Smoking, %	53	44.8
Diabetes mellitus, %	28.3	17.1
Previous infarct, %	46.5	40.5
Previous angioplasty, %	13.3	6.7
Previous bypass surgery, %	6.8	1
Ejection fraction, %	53±12	64.6±11
Nominal stent diameter, mm	3.1	3.3
Stent<3 mm, %	21.4	0
Saphenous bridges, %	4.3	0
Primary success, %	93.1	97
Maximum implant pressure, atm	15.7±2.3	12.9±2.6
Dissection with DS, %	4.5	4
Post-dilatation with different balloon, n	4.2	4.9
Death, n**	4	0
Non-fatal infarct, n**	6	1
Angioplasty due to acute occlusion**	4	0
Emergency surgery, n**	0	0

*The cohort of patients in the DISCO study treated with DS were compared with the patients in our study in whom all lesions were treated with DS, excluding primary or recovery ACTP. **Intrahospital.

vention. A fourth patient, in whom a right coronary stent had been implanted, suffered central stent occlusion 48 hours after the procedure. The patient was treated with systemic thrombolysis, with resolution of chest pain and electrocardiographic changes. Nevertheless, the patient died 7 hours later due to intracranial hemorrhage. Table 6 shows the clinical hospital course.

Table 7 shows the bivariate analysis of the characteristics of the lesions that in previous studies had been shown to be independent predictors of implantation failure. Significant differences were found in the percentage of stenosis, location of the circumflex artery, proximal tortuosity, lesion angulation, and vessel calcification. There were no significant differences in the length of the lesion.

DISCUSSION

Since the initiation of DS procedures, the number of prostheses implanted with this technique has increased considerably. Various prospective studies, among those 1 published in this magazine,¹³ have established the characteristics of lesions suitable for this procedure and the possible complications associated with DS, and its use has increased notably due to the good results obtained. The retrospective character of our study, where the only selection criterion was the judgment of the surgeon regarding the viability of using DS, allowed

us to find out the results that would be obtained with this technique on a daily basis. The percentage of DS used during this period represents 31.2% of total stent implantations, with a progression analogous to that experienced in different centers in our country.^{4,17,18}

Primary implant success was 93.1%, a number that agrees with the results of previous studies.^{13,14,16} Implantation was achieved in one form or another in all cases except 1 (99.9%), where a more rigorous examination of the lesion would have advised against DS.

Primary failure was associated with greater calcification, angulation, proximal tortuosity, a greater percentage of stenosis, and location in a circumflex artery (Table 7). In previous studies, all these characteristics were associated with DS failure.^{13,15,16}

The percentage of lesions presenting with dissection was approximately 4%, and these were resolved with new balloon inflation or the implantation of an additional stent. The dissection rate following DS is no greater than that found in previous studies using the conventional technique and agrees with the frequency found in prospective studies of DS.¹¹

An additional stent implantation was needed due to lack of lesion coverage in 2.7% of cases. The inclusion of a relatively high percentage of lesions with a visible thrombus (16.2%) could have influenced the use of additional stents by producing movement of same toward the lesion ends after DS, causing a suboptimal angiographic result after the first stent.

One of the most controversial aspects of DS is the correct amount of stent expansion. The results of previous studies¹⁹⁻²¹ seem to indicate that there are no differences from the conventional technique, but its use in more complicated lesions (ostial, bifurcated, with greater lengths of calcification) could be associated with a lower amount of expansion. In our experience, the percentage of cases in which posterior dilatation had to be performed was low, as was the percentage of acute thrombosis, similar to that published in other series with conventional implant technique.²² Both of these facts indirectly support the idea that there are no clear differences between the amount of DS expansion or that used in the conventional technique, although additional studies with intracoronary ultrasound (ICUS) would probably provide additional data.

Another very important point is the safety of the stents used for DS, concretely stent consolidation with the balloon and the impossibility of its displacement.^{23,24} In our series, stent embolization was produced in 6 cases (0.6%), and the prosthesis was recovered in 4 cases. The other 2 were lost in the legs, without consequences for the patients. The incidence of embolization in our study is lower than that of previous studies,^{23,24} probably due to the use of stents that are manually mounted in the hemodynamic laboratory in previous series, although we cannot discard an infra-evaluation derived from the retrospective

character of our study. The moment the stent came unstuck was after the implant failure upon attempting to recover it within the catheter. This cause of embolization, basically with 6 and 7F catheters, has been described previously.^{13,23,25-27} Other possible causes that have been described are location in the circumflex artery,^{23,28} vessel calcification,^{23,29} lesion angulation,^{23,28,29} the use of manually mounted stents,²³⁻²⁵ and the attempt to place the stent via another stent.^{23-25,28} Although in the United States restrictions exist with respect to stent models to be used for DS, in Europe this limitation does not exist. In our series, none of the 6 cases of embolization were models approved by the Food and Drug Administration (FDA). Although technical improvements have made some models almost impossible to dislodge, there is still a certain heterogeneity among the existing models on the market with differences in DS suitability. Currently, the progressive use of DS should not be accompanied by generalization regarding the models used, particularly in the case of lesions with an unfavorable anatomy.

In spite of the high number of lesions presenting with a picture of thrombus (16.2%), there were only 7 cases (4.3% of those who presented with a thrombus and 0.7% of the total lesions) of embolization of same. The inclusion of patients with indications for primary or recovery angioplasty (7.8%) and the high percentage of patients with unstable angina (58%) could have favored this complication. According to previous studies,^{30,31} this technique is very safe when treating lesions with an image compatible with thrombus.

Two studies have recently been published on the performance of DS in bifurcated lesions^{32,33} that indicate that the technique is safe. In our series, up to 9.3% of the lesions were bifurcated, affecting branches >2 mm. In only 5% of the bifurcation cases was a branch lost, and in half of the cases it was recovered.

In those patients in whom we studied intrahospital events, the result of DS, with regard to death, non-fatal infarct, and acute occlusion were no different than the results published in other series using the conventional technique. The rate of nosocomial death (1%) coincided with that in studies of elective procedures, although in our study we did not exclude patients with significant co-morbidity. Three of the 4 deaths were clearly attributable to factors other than the stent implantation technique used (worsening of the deteriorated baseline situation), while the fourth was due to a side-effect of treatment of a subacute stent occlusion; however, even with this occurrence the incidence rate coincided with that reported for stent procedures with predilatation.

Finally, the results of our study could be compared to the cohort of patients treated with DS in the DISCO study,¹¹ a multicenter, prospective, randomized study carried out in our country (Table 8). In this study we compared the DS technique with the conventional es-

tablished technique, having as our primary objectives the analysis of DS safety, the rate of angiographic restenosis at 6 months, and the major cardiac events that occurred, and an analysis of the cost-benefit ratio was a secondary objective. For the lesions selected, we concluded that DS is at least no less effective than the conventional technique in terms of immediate angiographic results and medium-term clinical course. On the other hand, we did not find a decrease in the restenosis rate, but we did find a lower rate of immediate complications and lower costs. The retrospective character of our study contrasts with the prospective design of the DISCO study. The primary success rate and the intrahospital clinical results of the latter were clearly superior (only 1 cases of non-Q AMI and no cases of Q-wave AMI, death, or new revascularization). The disparity in the results is probably due to the fact that our series was retrospective and therefore more complex lesions were included, such as bifurcated lesions, lesions in smaller vessels (up to 21% were stents <3 mm), and saphenous bridges, as were patients with a worse clinical profile. The dissection rate requiring a new stent is similar in both studies, although in our series there is an additional percentage of stents implanted due to a deficit in lesion coverage. The need for posterior dilatation with a balloon different to that used for the stent also occurred at a similar rate. Finally, it is impossible to compare outpatient clinical or angiographic followup because our study design did not allow this.

LIMITATIONS

Given the retrospective character of our study, we cannot discard the possibility of an error in the estimated DS numbers, as some of the cases that were not primary successes could appear as stent procedures with predilatation. The exact number could only be obtained by a prospective collection of the data.

The introduction of qualitative variables in evaluation of the types of lesions treated, such as the amount of calcification, tortuosity and angulation, and even the description of the same has a subjective component and depends on the investigator analyzing the angiography. This is a limitation noted before in previous studies, and one that makes it difficult to determine the conditions associated with DS failure.

On the other hand, although it is probable that differences exist between the various types of stent found on the market, the present study did not analyze this aspect. The choice of stent was always according to the criteria of the interventionist, and for this reason descriptive comparisons of the various models could not be undertaken.

CONCLUSIONS

The quotidian use in a clinical context of DS and lesions is similar to that obtained in randomized clinical studies that have been carried out up to the present time. The percentage of primary success is approximately 93%. The principal complication, although it occurred infrequently (0.6% of patients) and without clinical repercussions in any patients, is embolization of the stent. Therefore, when stents not specially designed for this technique are used, a precise post-procedure analysis must be performed of the lesion characteristics, and use of these stents must be rejected in those who do not have a favorable anatomy.

Complications during the procedure (dissection, occlusion of the lateral branch and distal embolization) are infrequent, and their rate of occurrence does not exceed those published on the conventional technique for stent implantation. On the other hand, intrahospital events are also infrequent and, are also similar in occurrence to those obtained in studies of the conventional technique in elective procedures.

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