

# Direct Stenting Without Predilatation: Influence of Stent Diameter on the Immediate Results

Íñigo Lozano, Ramón López-Palop, Eduardo Pinar, Daniel Saura, Francisco Picó, and Mariano Valdés

Servicio de Cardiología, Hospital Virgen de Arrixaca, Murcia, Spain.

The influence of stent diameter in a direct stenting technique was analyzed. We retrospectively identified 987 consecutive lesions in 773 patients in whom direct stenting was attempted. Lesions were divided into two groups: group 1, nominal stent diameter 2.5 mm (237 lesions) and group 2,  $\geq 2.75$  mm ( $n=750$ ). Differences between groups were found in age ( $64.4 [10.4]$  vs  $62.3 [11]$   $P=.009$ ), female sex (33.2% vs 17%;  $P<.0001$ ), diabetes (44% vs 33.1%;  $P=.003$ ), tortuosity (5.4% vs 2.5%;  $P=.034$ ), reference diameter ( $2.5 [0.3]$  vs  $3.3 [0.6]$ ;  $P<.0001$ ) and location in distal segments (44.5% vs 29.4%;  $P<.0001$ ). Primary deployment (85.5% vs 95.5%;  $P<.0001$ ) and postdilatation success rates (1.9% vs 4.8%;  $P=.039$ ) were higher in group 2, with no differences in vessel dissection rate (4.7% vs 4.4%;  $P=.85$ ). Direct stenting with 2.5 mm stents was associated with a lower success rate than larger stents. Vessel tortuosity, angulation, calcification, lesion severity and distal location were also associated with a higher failure rate. The predictive power of our model was 0.87 (95% CI, 0.82-0.92).

**Key words:** Stents. Angioplasty. Revascularization. Coronary disease.

## Implante de *stent* sin predilatación: influencia del diámetro del *stent* en los resultados inmediatos

Se analiza la influencia del diámetro del *stent* en el implante directo. Identificamos retrospectivamente 987 lesiones consecutivas, en 773 pacientes, tratadas con *stenting* directo. En el grupo 1, el diámetro nominal del *stent* fue de 2,5 mm ( $n = 237$  lesiones) y en el grupo 2,  $\geq 2,75$  mm ( $n = 750$  lesiones). Se encontraron diferencias en la edad ( $64,4 \pm 10,4$  frente a  $62,3 \pm 11$ ;  $p = 0,009$ ), ser mujer (33,2 frente a 17%,  $p < 0,0001$ ), diabetes (44 frente a 33,1%;  $p = 0,003$ ), tortuosidad (5,4 frente a 2,5%;  $p = 0,034$ ), diámetro de referencia ( $2,5 \pm 0,3$  frente a  $3,3 \pm 0,6$ ;  $p < 0,0001$ ) y localización en los segmentos distales (44,5 frente a 29,4%;  $p < 0,0001$ ). El éxito primario (85,5 frente a 95,5%;  $p < 0,0001$ ) y posdilatación (1,9 frente a 4,8%;  $p = 0,039$ ) fue superior en el grupo 2, sin diferencias en la tasa de disección (4,7 frente a 4,4%;  $p = 0,85$ ). El *stenting* directo con *stents* de 2,5 mm tiene una tasa de éxito primario menor que los *stents* de mayor calibre. La tortuosidad, angulación, calcificación, grado de estenosis y localización en segmentos más distales también se asociaron a una mayor tasa de fracaso primario. El poder predictivo del modelo fue del 0,87 (IC del 95%, 0,82-0,92).

**Palabras clave:** Stents. Angioplastia. Revascularización. Enfermedad coronaria.

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## INTRODUCTION

The benefits of stents in small vessels is still a controversial matter. Initial observational studies have suggested an increased rate of acute thrombosis,<sup>1,2</sup> whereas more recent ones showed a decrease.<sup>3,4</sup> Three random studies (ISAR-SMART, BESMART, and SISA) presented disparate results in the rate of restenosis.<sup>5-7</sup> Thus, not all of the conclusions derived

from studies on vessels  $>3$  mm can be extrapolated to smaller vessels.

Direct stenting (DS) has brought about changes in percutaneous coronary interventions (PCI) leading to savings in costs, imaging, radiation exposure, and procedural time.<sup>8,9</sup> Earlier research studied the predictors of the primary success rates of DS.<sup>10,11</sup> Most of these studies only included stents  $\geq 3$  mm. We evaluated the influence of stent diameter on the primary success rates of DS.

## PATIENTS AND METHODS

Based on our laboratory's interventions register, we identified those patients treated by DS, as defined

Correspondence: Dr. I. Lozano.  
2132 Carretera Piles-Infanzón. La Redonda. Somió.  
33203 Gijón. Asturias. España.  
E-mail: IMLML9@hotmail.com

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## ABREVIATURAS

SD: implante directo del stent.

ICP: intervención coronaria percutánea.

below, from among the PCI carried out between September 1998 and April 2001. Lesions were divided into 2 groups: group 1, nominal stent diameter 2.5 mm and group 2,  $\geq 2.75$  mm. Two cardiac surgeons independently examined the angiograms to describe angulation and tortuosity without knowing the result of the intervention, whereas the other variables were determined prospectively. The percentage of stenosis was determined visually and the methodology followed was as previously described.<sup>11</sup>

## Definitions

Primary success is defined as a stent implant without predilatation with a balloon or arterectomy, and secondary success as an implant with previous dilatation with a balloon following DS failure. The calcification density image visible on fluoroscopy was classified as moderate or severe. Tortuosity and angulation were classified as moderate or severe by subjective evaluation. Location was divided into two groups: proximal (segments proximal and medial to the principal arteries) and distal (distal segments and lateral branches).

## Statistical Analysis

Continuous variables were expressed as mean $\pm$ SD and categories as absolute value and percentage. Means

TABLE 1. Clinical Characteristics\*

	Stent =2.5 mm	Stent $\geq 2.75$ mm	P
Age, years	64.4 $\pm$ 10.4	62.3 $\pm$ 11	.009
Female sex, %	33.2	17	<.0001
Diabetes, %	44	33.1	.003
Hypertension, %	58.1	49.7	.014
Tobacco smoking, %	40.7	50.2	.006
Abciximab, %	37.8	29	.013
Hypercholesterolemia, %	51.9	54.8	NS
Prior infarction, %	45.6	45.3	NS
Prior PTCA, %	15.4	15.2	NS
Prior CABG, %	4.1	6.6	NS
Ejection fraction, %			—
>60	57	59	
45-60	19	20	
30-45	14	11	
<30	10	10	

\*PTCA indicates percutaneous transluminal coronary angioplasty; CABG, coronary artery grafting bypass.

TABLE 2. Lesion Characteristics

	Stent =2.5 mm (n=237 Lesions)	Stent $\geq 2.75$ mm (n=750 Lesions)	P
Percentage of DS	21.3	32.3	<.0001
CX, %	29.9	17.4	<.0001
VRD, mm	2.5 $\pm$ 0.3	3.3 $\pm$ 0.6	<.0001
Distal Location, %	44.5	29.2	<.0001
Tortuosity, %	5.4	2.5	.034
Angulation, %	2.5	2.2	NS
Calcification, %	5.4	4.9	NS
Pressure, atm	15.5 $\pm$ 2.3	15.8 $\pm$ 2.3	NS
Stenosis, %	77 $\pm$ 11	77 $\pm$ 12	NS
Lesion length, mm	10.4 $\pm$ 4.9	10.2 $\pm$ 4.6	NS
Nominal diameter stent, mm	2.5	3.2 $\pm$ 0.4	<.0001
Stent Length, mm	13.6 $\pm$ 4.6	13.9 $\pm$ 4.4	NS
Vessel, %			—
LMCA	0	0.01	
ADA	39.1	34.2	
CX	29.9	17.4	
RCA	30.2	43.2	
Graft	0.8	5.2	
ACC/AHA, %			—
A	14	18	
B1	43	44	
B2	41	37	
C	2	1	

\*CX indicates circumflex; VRD: vessel reference diameter; DS, direct stenting; LMCA, left main coronary artery; ADA, anterior descending artery; RCA, right coronary artery; NS, non-significant.

and proportions were compared by Student *t* test and  $\chi^2$ , respectively. Multivariable analysis was done to determine the predictors of the primary success rates of DS. A value of  $P=.05$  was considered significant. Data were analyzed with SPSS 10.0 for Windows.

## RESULTS

During the study period, 987 lesions in 773 patients were treated by DS. Lesions were divided into 2 groups: group 1, 237 lesions (21% of DS out of a total treated with a 2.5-mm stent in the same period) and group 2, the remaining 750 lesions (33% of DS out of a total treated with a stent  $\geq 2.75$  mm). Patient characteristics are shown in Table 1 and lesions in Table 2. Small vessel lesions were associated with age, female sex, diabetes, distal location, proximal tortuosity and location in the circumflex artery. The type of stent is shown in Table 3.

## Results of the Procedure

The primary success rate of DS was lower in the smaller vessel group and postdilatation was more frequent in group 2, with no differences in vessel dissection rate (Table 4).

Stent diameter was a predictor of the primary success rate of DS, as were location of the most distal

TABLE 3. Type of Stent\*

	Stent =2.5 mm (n=237 lesions)	Stent ≥2.75 mm (n=750 lesions)
Multilink	32.6	36
NIR	21.5	20.6
AVE	26.8	23.2
BX velocity	4.1	7.8
Others	15	12.4

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

segment, calcification, proximal tortuosity, angulation and stenosis. Age and stent length acted as confounding factors (Table 5). The predictive power of the model under the ROC curve was 0.87 (confidence interval [CI] 95%, 0.82-0.92).

## DISCUSSION

This is the first work to analyze the influence of stent diameter on the primary success rate of DS. The most important finding is that stents of 2.5 mm are associated with a lower primary success rate, even after adjusting this for predictors found in previous studies.<sup>10,11</sup>

### Primary Success

Three factors may have contributed to the lower rate of success in the first group:

1. Despite correcting for variables which acted as predictors for DS failure in previous studies, less favorable, unknown characteristics not included in the analysis may have led to this poor result. Specifically, the lower sensitivity of angiography to detect calcification compared to ultrasound<sup>12</sup> could have played a role. This is more marked in small vessels.<sup>13</sup>

2. The use of smaller diameter stents was associated with more distal locations, which also act as predictors for implant failure.

3. Finally, the stents used in smaller vessels may not have behaved like larger diameter stents. A design specific to small vessels should adapt to the marked tortuosity and angulation often associated with these vessels. On the other hand, the nominal diameter is not proportional to the profile, and that of small vessels has a higher nominal profile/diameter relationship than large vessels. Consequently, with a certain percentage of stenosis, it would be more difficult to cross the lesion in small vessels. Given the period in which PCI was performed, an appreciable percentage of the stents used for small vessels were not specifically designed for them. Thus, we think that current trends aimed at designing platforms for small-caliber vessels,

TABLE 4. Results of Procedure\*

	Stent =2.5 mm (n=237 Lesions)	Stent ≥2.75 mm (n=750 Lesions)	P
Primary success of DS, %	85.5	95.5	<.0001
Postdilatation, %	1.9	4.8	.039
DS dissection, %	4.7	4.4	NS
Residual stenosis, %	3.6	3.3	NS
Thromboembolization, n	1	6	NS
Loss of stent, n	2	4	NS

\*DS indicates direct stenting; NS, non-significant.

TABLE 5. Predictors of Direct Stenting Failure

	Odds Ratio	P	95% CI
Angulation	34.5	.000	11.1-106.7
Tortuosity	24.3	.000	9.1-65.6
Calcium	10.5	.000	4.2-26.7
Stent =2.5 mm	4.2	.000	2.2-8.0
Distal location	2.6	.003	1.4-4.9
Stenosis, %	1.05	.003	1.01-1.08
Stent length	1.03	.32	0.98-1.1
Age	1.01	.41	0.98-1.04

especially those made from the new alloys, will probably help to improve the results.

### Results of the Procedure

In addition to the difference in primary success rates, post-dilatation is required more frequently in large vessels. During our study period, the smallest-diameter stent was 2.5 mm. Thus, stents of 2.5 mm might have been implanted in vessels with a reference diameter less than the nominal stent diameter, leading to an acceptable degree of residual stenosis in small vessels. No differences were found in the percentage of vessel dissection rates.

### Clinical Profile

Group 1 lesions were associated with patients with the least favorable clinical profiles. Although the aim of this study was to analyze the immediate results of the procedure and not to describe clinical evolution, both groups displayed differences regarding factors associated with poor prognosis, such as age, female sex, and diabetes.<sup>14</sup> These differences could have led to poor results.

### LIMITATIONS

In this study, the percentage of lesions treated with DS is similar to that in contemporary studies, but less than in current use.<sup>15,16</sup> In our center, similar to others,

the percentage of DS increased from 11% in 1998 to 40% in 2001.<sup>17</sup> The percentage of primary success has decreased since 1998 to 90.1%, probably because of a less stringent selection of lesions. The period analyzed and the types of stent used could limit, to certain extent, the applicability of the conclusions to current techniques.

Some variables, such as tortuosity, calcification and angulation, are qualitative, and thus a subjective component cannot be ruled out from their description.

This study lacks angiographic quantification of the lesions. However, we think that the differentiation into 2 groups according to the size of the stent allows the lesions to be divided into 2 well-defined groups, thus facilitating the main aim of the study.

## CONCLUSIONS

Direct implantation of a 2.5-mm stent is associated with a significantly lower percentage of primary success than that obtained with stents with a bigger diameter. In addition to the unfavorable anatomy of lesions in small vessels, the actual diameter of the stent acts as an independent predictor of implant failure.

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