

# Comparison of Intracoronary Ultrasound Expansion Parameters in Coronary Stents Implanted With or Without Balloon Predilatation. A Randomized Intravascular Ultrasound Study

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**Introduction and objectives.** Coronary stenting without balloon predilatation is a safe technique associated with similar clinical results and lower costs, use of contrast and exposure to radiation in comparison to stenting with predilatation. After direct stenting, expansion may be reduced if the stenotic lesion was not predilated. This study compared *a*) stent expansion with and without balloon predilatation (direct stenting), observed by intracoronary ultrasound, and *b*) angiographic results after 6 months and 1 year with the two implantation techniques.

**Patients and method.** 100 consecutive lesions eligible for direct stenting were randomized to stent implantation with or without balloon predilatation. Only  $\leq 25$ -mm Multilink Duet/Tri-Star/Tetra or NIR Sox/Elite stents were used. When the angiographic result was considered optimal, an independent operator who had not been involved in the procedure performed an intracoronary ultrasound study. The ultrasound examination was not used in decision making unless there was a potential risk for the patient. Ultrasound parameters of expansion were compared in the two implantation techniques with systematic 6- to 9-month angiographic examinations and 1-year clinical follow-up.

**Results.** There were no clinical or baseline angiographic differences between the two groups. No significant differences were observed in the ultrasound expansion parameters or the rate of clinical events after 12 months of follow-up. Binary angiographic restenosis (23% vs 20%) and late loss index (0.92 [0.81] vs 0.88 [0.60]) did not differ significantly between the predilatation and direct stenting groups.

**Conclusions.** Direct stenting was not associated with different ultrasound expansion parameters in comparison to the conventional technique. Angiographic restenosis and the rate of long-term clinical events were similar with both techniques.

**Key words:** *Coronary angioplasty. Interventional cardiology. Stent. Intravascular ultrasound.*

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## Comparación de parámetros de expansión de *stents* implantados con técnica convencional o directa. Estudio aleatorizado con ultrasonidos intracoronarios

**Introducción y objetivos.** El implante del *stent* sin predilatación es una técnica segura con resultados clínicos similares y menores costes, contraste y radiación que el implante con predilatación. En el implante directo, la expansión del *stent* podría ser menor al no haber una modificación previa de la placa con la predilatación. Los objetivos de este trabajo son comparar entre ambas técnicas: *a*) los parámetros de expansión del *stent* por ultrasonidos; *b*) los resultados angiográficos a 6 meses y clínicos a un año.

**Pacientes y método.** Se aleatorizaron 100 lesiones consecutivas susceptibles de implante directo de *stent* a implante con y sin predilatación. Se utilizaron *stents* Multilink Duet/Tri-Star/Tetra y NIR Sox/Elite de longitud  $\leq 25$  mm. Tras un resultado angiográfico óptimo, se realizó un estudio con ultrasonidos que no modificó el tratamiento de la lesión, salvo riesgo potencial para el paciente. Los parámetros de expansión por ultrasonidos fueron comparados entre las 2 técnicas de implante. Se realizó una revisión angiográfica sistemática a los 6-9 meses, y clínica al año.

**Resultados.** No hubo diferencias clínicas ni angiográficas basales entre los 2 grupos. No se encontraron diferencias significativas en los parámetros de expansión ni en los eventos clínicos. La reestenosis binaria (23 frente a 20%) y la pérdida tardía (0,92 [0,81] frente a 0,88 [0,60]) tampoco fueron significativamente diferentes entre ambos grupos.

**Conclusiones.** El implante directo de *stent* no se asocia con parámetros de expansión diferentes en comparación con la técnica convencional. La reestenosis angiográfica y los eventos clínicos a largo plazo son similares en ambos grupos.

**Palabras clave:** *Angioplastia coronaria. Cardiología intervencionista. Stent. Ultrasonidos intracoronarios.*

## ABBREVIATIONS

CSA: cross-sectional area.  
ECG: electrocardiogram.  
IVUS: intravascular ultrasound.  
PTCA: percutaneous transluminal coronary angioplasty.

## INTRODUCTION

Randomized studies have shown that coronary stenting reduces the incidence of restenosis and improves the short- and long-term prognosis of balloon angioplasty (percutaneous transluminal coronary angioplasty, PTCA).<sup>1-3</sup> More than 70%<sup>3</sup> of percutaneous procedures performed in the United States<sup>4,5</sup> and 45%<sup>6</sup> to 77%<sup>7</sup> of those done in Europe involve stent placement.

Stent implantation without predilatation (direct stenting) is possible in selected lesions<sup>8,9</sup> and results in a reduction in the use of consumables and contrast material, a decrease in radiation exposure, and a shorter duration of the procedure.<sup>10,11</sup> The main limitation of this technique is the need for prior selection of candidate lesions. Almost 40% of the stents placed after predilatation exhibit suboptimal intravascular ultrasound (IVUS) results, even when high pressure is used.<sup>12</sup> This problem could be even more important with direct stenting, particularly if the favorable results extend the indications for this procedure.

Before the use of direct stenting is recommended for more complex lesions, it is essential to assess the results of this technique in terms of stent expansion. We conducted a randomized prospective study, initially postulating that no differences would be found in expansion between direct stenting and implantation with predilatation. The primary aim was to compare the most well-validated IVUS expansion parameters observed between both techniques. The secondary aim was to assess potential clinical and angiographic differences in the follow-up.

## PATIENTS AND METHODS

### Selection of Lesions

For the purpose of obtaining study results similar to those from clinical practice, the interventional radiologist's opinion on the patient's eligibility for direct stenting in lesions with  $\geq 70\%$  stenosis, as estimated visually, was the only inclusion criteria. This selection was based on current knowledge of the technique, and was intended to avoid lesions with severe calcification or evident proximal tortuosity. Once the decision was made concerning eligibility for direct stenting, the pa-

tient was randomized by the sealed envelope method to implantation with predilatation or to direct stenting. If a patient had two or more lesions treatable by direct stenting, all lesions were assigned to the same treatment group. The exclusion criteria were saphenous graft lesion, restenotic lesion, ostial location, myocardial infarction <24 h, lesion length >25 mm, impossible to treat with a  $\geq 2.5$  mm stent, left main coronary artery disease, scheduled heart surgery, allergy to aspirin, renal failure and follow-up impossible. All patients gave written informed consent to participate in the study, which was conducted in accordance with the Declaration of Helsinki.

For department-related logistical reasons, the study was planned for 100 consecutive lesions (50 per group) and the inclusion period was restricted to cases scheduled in the afternoon. At our hospital, the characteristics of patients treated in the afternoon are similar to those of patients treated in the morning.

### Procedure

The procedures were done by three experienced interventional radiologists (>300 angioplasties per radiologist and year). Prior to surgery, all patients received aspirin (200 mg/day) and intravenous heparin to achieve an activated coagulation time above 250 s. The use of glycoprotein IIb/IIIa-receptor inhibitors was decided by the radiologist. All patients were given systemic ticlopidine (loading dose of 20 mg during the procedure and 250 mg/12 h over the next four weeks) or clopidogrel (loading dose of 300 mg and 75 mg/day for four weeks after the procedure). The use of post-dilatation and the decision to end the procedure were based on angiographic criteria. Only second- and third-generation tubular stents (Multilink Tri-Star, Duet or Tetra, Guidant Inc., Temecula, California, USA; NIR Primo, and SOX, Scimed, Boston Scientific, Maple Grove, Minnesota, USA) were used. Lesions that could not be treated with stents of 2.5 to 4 mm diameter were excluded. Furthermore, only lesions allowing the use of stents  $\leq 25$  mm were included. The balloon type and size in the predilatation group and the stent implantation pressure were selected by the radiologist.

### Ultrasound (IVUS) Analysis

Two commercially available catheters (30 MHz, 3.2 French UltraCross and 40 MHz, 2.5 French Atlantis, Boston Scientific Corp., Watertown, Massachusetts) were used. Intravascular ultrasound study was not allowed at baseline. After the administration of intracoronary nitroglycerin, the transducer was advanced >10 mm distal to the lesion. The images were recorded (Super-VHS) with an automatic pullback at 0.5 mm/s along the entire length of the stent until the aorto-

ostial segment of the artery being examined. When the angiographic result was satisfactory, an IVUS study was performed by another interventional cardiologist (blinded) different from the person doing the PTCA. Blinding was unmasked only when the interventional cardiologist in charge of the IVUS perceived potential danger for the patient. The expansion parameters analyzed were the minimum stent cross-sectional area (CSA), percentage of residual stenosis per reference area (minimum stent CSA divided by the mean reference lumen CSA), percentage of distal residual stenosis per reference area (minimum stent CSA divided by the distal reference lumen CSA), stent symmetry index (minimum stent diameter divided by maximum stent diameter) and good apposition (defined as sufficiently close contact to preclude blood flow between the stent mesh and the artery wall).

### Follow-up

Creatine kinase (CK) and creatine kinase MB isoenzyme (CK-MB) levels and the electrocardiogram (ECG) were systematically recorded immediately after the procedure and at 6, 12 and 18 h post-procedure, as well as every 6 h thereafter if the patient had chest pain. In-hospital events, including death, nonfatal myocardial infarction and new revascularization (PTCA or surgery) of lesions, whether included in the study or not, were recorded during the 12 months post-procedure. Routine follow-up angiography was performed between 7 and 9 months after the procedure. During the follow-up, binary restenosis was defined as >50% stenosis on quantitative analysis.

### Angiographic Measurements and Statistical Analysis

Two expert interventional radiologists performed measurements after the procedure using an automatic contour detection system (CAAS II, V4.1.1, Pie Medical Imaging, Maastricht, Netherlands). Clinical and revascularization events were analyzed on an intent-to-treat basis. Comparisons between the stent expansion IVUS parameters were also based on an intent-to-treat principle, according to the actual treatment received. Continuous variables are shown as mean  $\pm$  standard deviation. Differences between groups were calculated using Student's *t* test for continuous variables and the chi-square test for proportions. A *P*-value of .05 was considered statistically significant. SPSS for Windows, version 11.0, was used for the statistical analysis.

### RESULTS

From 1 May 2000 to 15 July 2001, a total of 247 patients with 299 new lesions were treated by stent placement in the afternoon schedule at our hospital. Of

the 299 lesions, 100 (33.4%) in 82 patients consecutively met the inclusion criteria (43 patients in the predilatation group and 39 in the direct stenting group). The difference in the use of direct stenting between the morning and afternoon scheduled procedures was not statistically significant (33.4% vs 30.2%; *P*=.091). We retrospectively analyzed all patients treated in the afternoon schedule between 1 May 2000 and 15 July 2001 to investigate inclusion bias. Two patients were not available for follow-up and were not included in the study. All the other patients who met the inclusion criteria were included consecutively.

### Clinical and Angiographic Characteristics at Baseline

There were no significant differences in the clinical characteristics of the 2 groups including age, sex, hypertension, diabetes, hypercholesterolemia, active smoker, prior infarction, prior revascularization, ejection fraction, number of diseased vessels, and indica-

TABLE 1. Clinical Characteristics at Baseline and Procedure Characteristics\*

Characteristics	Predilatation (n=43)	Direct (n=39)	<i>P</i>
Age, years	60.9 $\pm$ 10.2	60.0 $\pm$ 10.7	
Female	7 (16)	7 (18)	1.00
Diabetes	13 (30)	13 (30)	.81
Hypertension	20 (47)	25 (64)	.12
Hypercholesterolemia	27 (64)	26 (67)	.82
Prior AMI	14 (33)	15 (38)	.65
Prior PTCA	7 (16)	5 (13)	.76
Indication for procedure			
Stable angina	6 (15)	4 (9)	.24
Unstable angina/non-Q-wave AMI	29 (75)	39 (77)	
Post-AMI angina	4 (10)	6 (14)	
Number of vessels with stenosis			
>70%	1.49 $\pm$ 0.7	1.62 $\pm$ 0.7	.43
1	27 $\pm$ 63	20 $\pm$ 51	
2	12 $\pm$ 28	14 $\pm$ 36	
3	4 $\pm$ 9	5 $\pm$ 13	
LVEF <40%	5 (16)	4 (16)	.90
Lesions treated	1.74 $\pm$ 0.8	1.64 $\pm$ 0.9	.60
1	20 $\pm$ 47	23 $\pm$ 54	.60
2	16 $\pm$ 37	10 $\pm$ 26	
3	5 $\pm$ 12	3 $\pm$ 8	
4	2 $\pm$ 5	3 $\pm$ 8	
Lesions included	1.16 $\pm$ 0.4	1.28 $\pm$ 0.6	.30
1	37 (86)	30 (77)	.40
2	5 (12)	8 (21)	
3	1 (2)	0 (0)	
4	0 (0)	1 (3)	
Use of abciximab	6 (13.9)	7 (17.9)	.76

\*PTCA indicates percutaneous transluminal coronary angioplasty; LVEF, left ventricular ejection fraction; AMI, myocardial infarction.

tion for the procedure (Table 1). Among the patients studied, 25 additional lesions that did not meet the inclusion criteria or that presented exclusion criteria were treated in the predilatation group and 14 in the direct stenting group. These lesions were not included in the angiographic or IVUS study. Angiographic characteristics at baseline were similar in both groups. No differences were observed in calcification, lesion length, reference diameter or percent stenosis (Table 2).

### Procedure Characteristics and Immediate Results

All procedures in both treatment groups were performed satisfactorily (Table 3). In all cases of predilatation, only a conventional balloon was used. There were no cases of in-hospital mortality, acute thrombo-

sis of the stent or emergency surgery. One (2%) and two (5%) non-Q-wave AMI episodes were observed in the predilatation and direct stenting groups, respectively ( $P=NS$ ). Direct stenting was unsuccessful in four patients (crossover to predilatation group). There were no significant differences in the diameter, implantation pressure or use of additional stents between the two groups (Table 2). The stents used in the predilatation group were significantly longer than those used in direct stenting group. Additional post-dilation was used in four (8%) lesions in each group in order to achieve optimal angiographic results in the operator's opinion, with these results similar in both groups. There were no cases of stent loss.

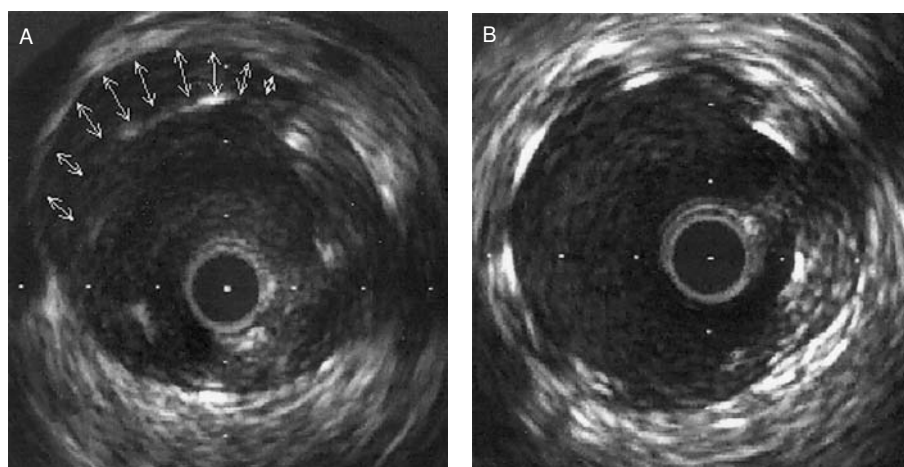
### Ultrasound Assessment

Intravascular ultrasound study was possible in 99 of

TABLE 2. Angiographic Characteristics at Baseline. Angiographic Characteristics of the Procedure. Immediate Results (by Intent-to-Treat)\*

	Predilatation (n=50)	Direct (n=50)	P
Angiographic characteristics at baseline			
Vessel			
AD	25 (50%)	18 (36%)	.29
CX	11 (22%)	14 (28%)	
RCA	14 (28%)	18 (36%)	
Coronary segment			
Proximal	20 (40%)	18 (36%)	.48
Middle	24 (48%)	22 (44%)	
Distal	6 (12%)	10 (20%)	
Reference diameter, mm	3.06±0.51	2.93±0.44	.19
MLD, mm	0.76±0.35	0.71±0.39	.52
Stenosis, %	75.28±0.63	77.24±11.17	.37
Length, mm	10.52±4.45	9.68±3.63	.30
Calcium	2 (4%)	6 (12%)	.27
Thrombus	5 (10%)	6 (12%)	1.00
Procedure characteristics			
Predilatation balloon diameter, mm	3.0±0.4	—	
Predilatation pressure, atmospheres	8.9±2.6	—	
Predilatation balloon diameter to reference diameter ratio	0.9±0.1	—	
Stent diameter 3.1±0.4	3.1±0.4	.40	
Nominal stent diameter <3.0 mm	11 (22%)	13 (26%)	.81
Stent length, mm	15.0±4.9	12.9±4.1	.02
Implantation pressure, atmospheres	16.6±1.4	16.6±1.8	.86
Stent balloon diameter to reference diameter ratio	1.17±0.13	1.17±0.10	.93
Primary success, %	—	46 (92)	—
Predilatation, %	50 (100)	4 (0.8)	—
Post-balloon dilation, %	4 (8)	4 (8)	1.00
Additional stent, %	5 (10)	3 (6)	.71
Stent loss, %	0 (0)	0 (0)	—
Final angiographic results			
Reference diameter, mm	3.06±0.51	2.94±0.46	.21
MLD	2.93±0.44	2.84±0.44	.33
Residual stenosis, %	5.32±6.08	5.21±7.27	.93
Acute gain, mm	2.17±0.48	2.13±0.46	.71

\*AD indicates anterior descending; CX, circumflex artery; MLD, minimum lumen diameter; RCA, right coronary artery.



**Fig. 1.** A: Poor apposition of stent mesh in the vessel wall in lesion number 22 treated by direct stenting. The white arrows indicate the area between the vessel wall and the mesh. B: Final ultrasound result after post-dilatation with a larger diameter balloon.

the 100 lesions. In the remaining case in the predilatation group, the catheter did not advance through a circumflex artery with a large kink, hindering satisfactory study of an obtuse marginal artery stent. Ultrasound results are shown in Table 4. There were no differences in the reference or expansion parameters between the two groups. Only 17% of the stents achieved a stent CSA >9 mm (45.7% in stents  $\geq 3.5$  mm). Poor apposition was observed in one lesion after placement at high pressure; in this case, a larger diameter balloon had been used despite the excellent angiographic results (Figure 1).

### Clinical and Angiographic Follow-up

Clinical follow-up was performed in 100% of the

patients, with no differences found between the 2 groups after 12 months (Table 3). Scheduled or symptom-guided angiographic follow-up was possible in 43 lesions (86%) per group. There were no significant differences in binary restenosis (23% vs 20%) or late loss index (0.92 [0.81] vs 0.88 [0.60]) between the 2 groups (Table 4 and Figure 2).

### DISCUSSION

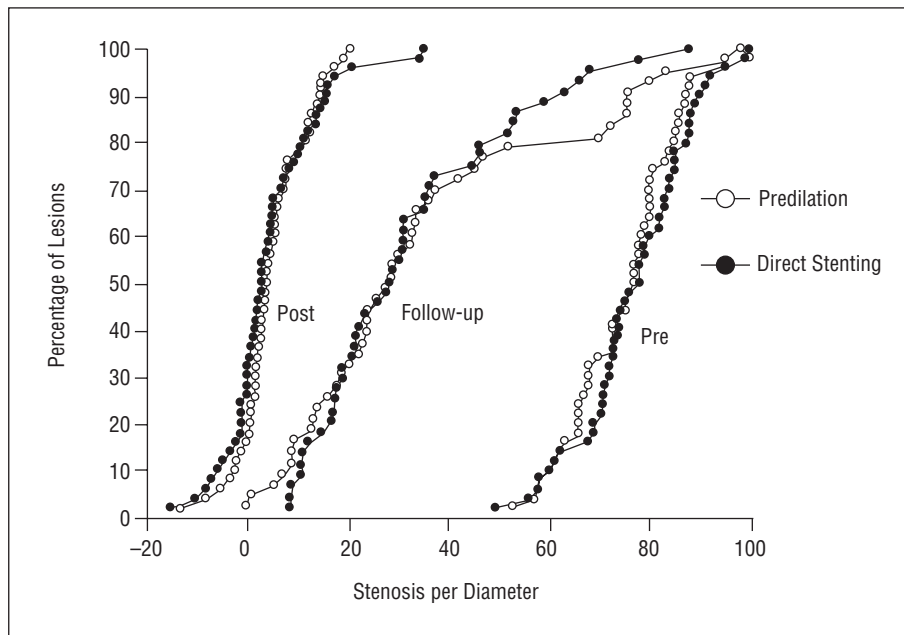
The present study, designed to replicate normal direct stenting activity, showed no differences in IVUS expansion parameters as compared to those obtained with the predilatation technique. Furthermore there were no differences in the clinical or angiographic follow-up, and similar results were observed in the incidence of restenosis at 6 months.

The current frequent use of direct stenting is supported by numerous studies demonstrating the safety of this technique,<sup>8,9,11,13-23</sup> with clinical and angiographic results that are similar<sup>11,13,20,24,25</sup> or even better<sup>26,27</sup> than those obtained with traditional implantation. Loss or incomplete expansion could be two potential risks of direct stenting. Because of the progressive advances in stent design and fixation by the balloon, the incidence of stent dislodgement or embolization is low or non-existent (<1%)<sup>10,20,21,28</sup> (0% in our study).

Correct deployment of the stent is related not only to the stent design and implantation pressure; the characteristics of the lesion also represent an important conditioning factor. In cases of severe calcification unidentified before direct stenting, correct deployment may be impossible despite elevated implantation pressures. Suboptimal expansion has been associated with a risk of acute occlusion and restenosis.<sup>29,30</sup> In addition, angiography is limited to ensure correct expansion of the stent.<sup>12,31,33</sup> A high percentage of stents with excellent angiographic results present poor expansion as visualized by IVUS. Up to now, there is little available information on the degree of expansion achieved

**TABLE 3. Procedure Results, in-Hospital Events and Clinical Events at 12 Months**

	Predilatation (n=43)	Direct (n=39)	P
<b>In-hospital events</b>			
Procedure success, %	43 (100)	39 (100)	–
In-hospital mortality, %	0 (0)	0 (0)	–
Non-Q-wave infarction, %	1 (2)	2 (5)	.59
Stent thrombosis, %	0 (0)	0 (0)	–
Coronary surgery, %	0 (0)	0 (0)	–
Hematoma, %	3 (7)	0 (0)	.24
Hemorrhaging, %	0 (0)	0 (0)	–
Post-procedural hospitalization, days	1.02±0.16	1.16±0.63	.21
<b>Clinical follow-up at 12 months</b>			
Completed follow-up	43 (100)	39 (100)	–
Mortality	0 (0)	0 (0)	–
Myocardial infarction	1 (2.3)	0 (0)	.30
Revascularization of study lesion	6 (14)	7 (18)	.76
Revascularization of treated lesions	6 (14)	9 (23)	.39
Surgical revascularization	0 (0)	0 (0)	–



**Fig. 2.** Cumulative distribution curves of the percentage of stenosis found on quantitative angiographic analysis at baseline after stent implantation and during follow-up, for direct stenting and implantation with predilatation.

with direct stenting. In a descriptive study conducted in the early years of this technique, correct expansion was found in 66% of the patients.<sup>34</sup> Two substu-

dies,<sup>19,20</sup> one with 3D-IVUS in a small number of patients<sup>35</sup> and a recent randomized study with IVUS,<sup>36</sup> showed no differences in expansion between the two

**TABLE 4. Immediate Results by Intravascular Ultrasound and Angiography at 8 Months\***

	Predilatation (n=50)	Direct (n=50)	P
<b>Immediate IVUS results</b>			
Available for analysis, %	49 (98)	50 (100)	1.00
In-stent MLD, mm	2.69±0.43	2.77±0.46	.41
Mean reference diameter, mm	3.14±0.48	3.12±0.54	.91
EEM reference diameter, mm	4.17±0.59	4.08±0.63	.50
Mean reference lumen CSA, mm <sup>2</sup>	9.00±2.98	9.08±3.60	.90
Mean reference EEM CSA, mm <sup>2</sup>	14.07±3.90	13.70±4.45	.67
Stent symmetry index	0.88±0.09	0.90±0.09	.21
Good apposition, %	49 (100)	48 (98)	.30
<b>Expansion parameters</b>			
Min. stent CSA, mm <sup>2</sup>	6.82±1.98	6.99±2.31	.71
Min. stent CSA/Distal reference min. lumen CSA	0.84±0.21	0.88±0.22	.37
Min. stent CSA/Reference min. lumen CSA	0.79±0.17	0.80±0.17	.83
Min. stent CSA/Mean reference EEM CSA	0.49±0.09	0.53±0.13	.14
<b>Min. lumen CSA</b>			
<5 mm <sup>2</sup>	9 (18)	10 (20)	.35
5 to <7 mm <sup>2</sup>	13 (27)	14 (28)	
7 to <9 mm <sup>2</sup>	19 (39)	17 (34)	
≥9 mm <sup>2</sup>	8 (16)	9 (18)	
<b>Angiographic follow-up at 8 months</b>			
Available for analysis, %	43 (86)	43 (86)	1.00
Reference diameter, mm	3.09±0.51	2.96±0.42	.18
<b>In-stent angiographic measurements</b>			
Minimum lumen diameter, mm	1.98±0.94	2.00±0.68	.91
Binary restenosis, %	10 (23)	9 (21)	.79
Net gain, mm	1.23±0.94	1.26±0.71	.89
Late loss, mm	0.91±0.81	0.89±0.60	.89
Loss index	0.45±0.43	0.43±0.32	.84

\*CSA indicates cross-sectional area; MLD, minimum lumen diameter; loss index, late loss/acute gain; stent symmetry index, minimum stent diameter divided by maximum diameter; EEM, external elastic membrane

implantation techniques. Our work shows two main differences with respect to previous studies: it was specifically designed to analyze direct stent expansion with IVUS and it was intended to replicate the usual practice in stent placement. In order to ensure the latter point, baseline IVUS was not allowed and the IVUS data were not used to optimize the results.

The balloon-to-artery ratio in patients with predilatation was slightly below 1 (0.9). This undersizing in the predilatation, along with the high pressures used in both subgroups when placing the stent, may have contributed to the absence of differences between the 2 techniques in terms of expansion, decreasing or minimizing the predilatation balloon value. The use of undersized balloons for predilatation is currently common practice, in an era in which the stent is elective in virtually all lesions. We believe the results observed in our study in this regard are representative of those seen in daily practice at any hospital in which this type of lesion is treated.

Although high inflation pressures are used, the percentage of lesions with a minimum stent CSA >9 mm in our study was lower than that found in previous studies with an optimized technique according to sonographic criteria.<sup>37,38</sup> The observational, blind use of IVUS and implantation of up to 24% of stents <3.0 mm might have been the main causes. In many cases, calcification not visualized on IVUS could have caused suboptimal expansion. Consistent with lower expansion, the incidence of restenosis at 8 months was higher than in previous studies with IVUS optimization.<sup>30</sup>

There was only one case (2%) of poor stent apposition in the direct stenting group. This potential cause of acute thrombosis led to unmasking of IVUS blinding and the use of IVUS for stent optimization with a larger diameter balloon. No conclusions can be drawn from this single case. However, it suggests that IVUS follow-up of lesions treated by direct stenting might be beneficial in complex anatomies.

The results of the present study cannot be extrapolated to other types of lesions. Forty percent of direct stenting procedures require considerable effort to select the lesions, although this could reflect a figure similar to the number of lesions that can be treated by direct stenting.<sup>39</sup> Based on the results of our study, it is impossible to predict correct expansion in lesions with severe calcification, in bifurcations and small vessels, in ostial lesions, long lesions, restenosis and other complex lesions. In one recently published study<sup>40</sup> with 128 patients treated by direct stenting in long lesions (>18 mm), the authors found 2.3% of acute occlusion and 9.4% of non-Q-wave infarction despite optimal angiographic results in 99% of the cases. Optimal expansion on angiography was not confirmed by IVUS in that series. Inadvertent stent underexpansion could have been the cause of these complications.

Until randomized IVUS studies in more complex lesions are conducted, it is impossible to ensure that no expansion differences between the 2 techniques exist in these types of lesions.

## Limitations

The present study was conducted in a single hospital and the only inclusion criterion was the decision that direct stenting was possible. Therefore, although the percentage of lesions included was similar to the percentage seen in daily practice at our hospital during the study period and similar to that of other published series,<sup>7,25</sup> it is evident that the interventional radiologists performing the procedures selected the lesions considered optimal for direct stenting. As mentioned, the results cannot be compared to series with a greater use of direct stenting, to stenting in long lesions or small vessels, or to lesions treated in hospitals with less experience.

Although the sample size was not calculated and the number was chosen for logistic reasons, the number of lesions included was higher than in previous studies on stent expansion in direct implantation.<sup>19,20,35,36</sup> Moreover, it is unlikely that a larger number of lesions would have led to clinically relevant differences in the expansion parameters, since no trend toward differences was observed with the number of patients in our study. Nevertheless, the sample size was clearly insufficient to study differences in the incidence of restenosis and the clinical events, as is evident when our study is compared with others specifically oriented toward these objectives.<sup>11,19,20</sup>

## CONCLUSIONS

Direct stenting in the lesions normally selected for this technique was associated with expansion parameters similar to those obtained with conventional placement after predilatation. Both implantation techniques showed similar rates of angiographic restenosis and clinical events at 1 year of follow-up.

The generalized use of direct stenting in more complex lesions should be based on future studies showing that the expansion parameters and the long-term clinical and angiographic results are similar to those obtained with predilatation.

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