Optimal Coronary Balloon Angioplasty With Provisional Stenting Versus Primary Stent (OCBAS)

Immediate and Long-Term Follow-up Results

ALFREDO RODRÍGUEZ, MD, PhD, FACC,* FRANCISCO AYALA, MD,* VICTOR BERNARDI, MD,* OMAR SANTAERA, MD,* EUGENIO MARCHAND, MD,* CESAR PARDIÑAS, MD,* CARLOS MAUVECIN, MD,* DANIEL VOGEL, MD,* LARI C. HARRELL, BS,† IGOR F. PALACIOS, MD, FACC,† ON BEHALF OF THE OCBAS INVESTIGATORS

Buenos Aires, Argentina and Boston, Massachusetts

Objective. This study sought to compare two strategies of revascularization in patients obtaining a good immediate angiographic result after percutaneous transluminal coronary angioplasty (PTCA): elective stenting versus optimal PTCA. A good immediate angiographic result with provisional stenting was considered to occur only if early loss in minimal luminal diameter (MLD) was documented at 30 min post-PTCA angiography.

Background. Coronary stenting reduces restenosis in lesions exhibiting early deterioration (>0.3 mm) in MLD within the first 24 hours (early loss) after successful PTCA. Lesions with no early loss after PTCA have a low restenosis rate.

Methods. To compare angiographic restenosis and target vessel revascularization (TVR) of lesions treated with coronary stenting versus those treated with optimal PTCA, 116 patients were randomized to stent (n = 57) or to optimal PTCA (n = 59). After randomization in the PTCA group, 13.5% of the patients crossed over to stent due to early loss (provisional stenting).

Results. Baseline demographic and angiographic characteristics were similar in both groups of patients. At 7.6 months, 96.6% of the entire population had a follow-up angiographic study: 98.2% in the stent and 94.9% in the PTCA group. Immediate and follow-up angiographic data showed that acute gain was significantly higher in the stent than in the PTCA group (1.95 vs. 1.15 mm; p < 0.03). However, late loss was significantly higher in the stent than the PTCA group (0.63 ± 0.59 vs. 0.26 ± 0.44, respectively; p = 0.01). Hence, net gain with both techniques was similar (1.32 ± 0.3 vs. 1.24 ± 0.29 mm for the stent and the PTCA groups, respectively; p = NS). Angiographic restenosis rate at follow-up (19.2% in stent vs. 16.4% in PTCA; p = NS) and TVR (17.5% in stent vs. 13.5% in PTCA; p = NS) were similar. Furthermore, event-free survival was 80.8% in the stent versus 83.1% in the PTCA group (p = NS). Overall costs (hospital and follow-up) were US $591,740 in the stent versus US $398,480 in the PTCA group (p < 0.02).

Conclusions. The strategy of PTCA with delay angiogram and provisional stent if early loss occurs had similar restenosis rate and TVR, but lower cost than primary stenting after PTCA.

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From the *Cardiac Unit Otamendi/Anchorena Hospital, Buenos Aires, Argentina; and the †Cardiac Unit, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts.

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Address for correspondence: Dr. Alfredo Rodriguez, Ayacucho 1547 10 “B,” 1112 Buenos Aires, Argentina. E-mail: selfcare@pinos.com.
low angiographic restenosis rates at follow-up (1). The use of coronary stents in this latter group of lesions with no early loss in MLD after successful PTCA (optimal PTCA) could be a subject of controversy. Therefore, the present study was undertaken to determine whether there was any significant difference in restenosis rate between lesions treated with primary elective stenting versus those treated with optimal balloon angioplasty (successful PTCA with delayed angiogram showing no evidence of early loss at 30 min after successful PTCA).

Methods

Patient population. The study population consisted of 116 consecutive patients with symptomatic coronary artery disease undergoing successful PTCA of the novo lesions in native coronary arteries enrolled in the participating centers of the Optimal Coronary Balloon Angioplasty With Provisional Stenting vs. Stent (OCBAS) Trial (a list of the OCBAS centers appears in the Acknowledgment). Patients were required to have a successful PTCA with a good immediate angiographic result before randomization. A good immediate angiographic PTCA result was defined as residual diameter stenosis ≤30%, determined by on-line quantitative coronary angiography (QCA) and no major dissections visualized in the first angiogram of the index artery after the last balloon inflation.

Patients were excluded when they met angiographic or clinical exclusion criteria. Angiographic exclusions included lesions >20 mm in length, lesions in coronary artery bypass grafts (CABGs), vessels with unsuitable anatomy for stenting (reference diameter <2.5 mm, diffuse disease, severe left main stenosis, severe vessel tortuosity) and lesions with acute complications or suboptimal results during PTCA. Patients initially treated with interventional devices different than balloon angioplasty were also excluded. Clinical exclusions included contraindications for anticoagulation or antiplatelet therapy, aspirin or ticlopidine hypersensitivity, noncardiac illness with less than 1-year life expectancy and previous inclusion in other randomization protocol. All patients signed a written consent form approved by the human study committee before the procedure. The study was carried out according to the principles of the Declaration of Helsinki and was monitored by a Safety and Data Monitoring Committee.

Randomization and study protocol. Patients were pretreated with aspirin 325 mg/day for at least 24 h before the procedure. A weight-based intravenous heparin bolus was given to achieve an activated clotting time greater than 280 s during the procedure. Ticlopidine 250 mg twice a day orally for 4 weeks was given to patients receiving stents. In addition, patients in both groups received a calcium channel antagonist for 3 months. Balloon angioplasty was performed according to standard technique (10). Stenosis were crossed with a 0.014 high-torque floppy guide wire and dilated with noncompliant high-pressure balloons using a 1.1:1 balloon-to-artery ratio at a pressure between 8.0 and 12.0 atm for ≤60 s. Patients with a good immediate angiographic result previously enrolled in the study were randomly assigned to either the stent or the optimal PTCA groups. Randomization of the patients was carried out by means of sealed envelopes. A randomization sequence was developed so that an equal number of patients were assigned to each treatment strategy at each center.

Patients assigned to the PTCA group had a repeat coronary angiogram of the index artery 30 min after successful PTCA. If early loss was demonstrated in the repeat angiogram, patients crossed over to the stent group (provisional stenting). Early loss was defined as >0.3 mm loss in MLD and/or >10% increase in the diameter stenosis severity occurring in repeat coronary arteriogram performed 30 min after successful PTCA. All the catheterization laboratories participating in the study have on-line quantitative coronary angiography.

Patients assigned to the stent group underwent stent implantation immediately after randomization. Stent deployment and implantation was performed using high-pressure noncompliant balloons at >13 atm of pressure. Intravascular ultrasound guidance was not mandatory. Commercially available stents were used in this trial: they included Gianturco Roubin II (n = 33), Palmaz–Schatz (n = 21), Multilink (n = 5), Wiktor (n = 3), Wallstent (n = 3) and AVE (n = 2).

Study end points. The primary end points of the study were the binary angiographic restenosis and target vessel revascularization at 6-month follow-up. Angiographic restenosis was defined as ≥50% of stenosis of the index artery at follow-up angiography determined by QCA cineaangiography.

The secondary end point was a composite end point defined as event-free survival (freedom from death, myocardial infarction, angina and need for repeated TVR) at 6-month follow-up. Death included those deaths from cardiac causes. Myocardial infarction included both Q-wave and non–Q-wave infarcts. In addition, procedural, hospital and follow-up costs were included in the comparison of both treatment strategies. The PTCA and stent costs were estimated according the average costs for these procedures in Argentina, Chile and Uruguay. The procedural and hospital estimated cost for a noncomplicated PTCA was US $4,500. Additional stent cost was US $3,000 per stent. These costs include hospital charges, physician fees and 48-h hospital stay. An additional cost of US $600 was added for each additional day of hospitalization. The costs for an emergent or elective CABG and for a surgical vascular repair were US $14,000 and $3,000, respectively. The cost for CABG included 7 days of hospital stay.

Clinical and angiographic data were forwarded to the Data
Coordinating Center at the Interventional Cardiovascular Research Center in Buenos Aires for statistical and QCA analysis.

Statistics. The primary analysis of angiographic and clinical outcomes was based on the intentions-to-treat principle. The results are expressed as mean ± SD. For comparison of continuous variables between the two treatment groups, the unpaired two-tailed Student $t$ test was used. Comparison of categorical variables between the two groups was performed using the chi-square method. Comparison of the composite clinical end point (death, myocardial infarction and repeat revascularization) was performed using the Kaplan–Meier and Wilcoxon tests (10). Differences between the groups were considered to be statistically significant when the $p$ value was <0.05. Assuming an incidence of restenosis of 40 ± 5% for conventional balloon angioplasty and 20 ± 5% for coronary stenting (5,6) and a decrease in the incidence of restenosis to 20 ± 5% for the optimal PTCA group, the power of this pilot study to detect a difference between both groups of patients ($n=57$ vs. optimal PTCA = 59) with a $p<0.05$ was 65%.

Follow-up. Clinical assessment was obtained at 1-, 3- and 6-month follow-up. Coronary angiography was performed at 6-month follow-up in all patients, except those who had died or had previously undergone a repeat revascularization procedure for any reason during the early follow-up. Although angiography performed before 3 months of follow-up was allowed on the basis of clinical indications, a subsequent angiogram was obtained after 4 months if restenosis was not documented in the former angiogram.

Quantitative angiographic data. Patients assigned to the optimal PTCA group were examined angiographically before, immediately after, at 30 min after and at 6 months after successful PTCA. Patients assigned to the stent group were examined angiographically before and immediately after PTCA, immediately after stenting and at 6 months after stent placement. For each lesion, the single view showing the most severe degree of stenosis was used for analysis. Similar single-view projections were used at each angiographic examination. The percent degree of coronary stenosis and reference and minimal diameter were determined using quantitative coronary analysis after the intracoronary administration of 100 μg of nitroglycerin using an angiographic core laboratory. The system used was a validated automated edge detection algorithm (11) (Computer Measurements Systems, Medis, the Netherlands). Absolute reference and MLD in millimeters were determined using the guiding catheter filled with contrast for calibration. In additional coronary lesions, morphology was classified according to the American Heart Association/American College of Cardiology (AHA/ACC) lesion type classification utilizing the modification suggested by Ellis et al. (12).

Results

Patient population. Between December 1995 and July 1996, 953 interventional procedures were performed in the participating centers in the OCBAS study. From this cohort, 206 consecutive patients treated with balloon angioplasty met the clinical and angiographic inclusion criteria and were enrolled in the study. From those, 86 patients (41.7%) were excluded due to suboptimal results or acute complications. A good immediate PTCA result (residual diameter stenosis ≥30% determined by on-line QCA and no major dissections visualized in the first angiogram of the index artery after last balloon inflation) was obtained in 120 (58.3%) patients. Four patients refused to participate in the study and 116 were randomized to stent ($n=57$) or optimal PTCA ($n=59$) and are the subject of this study. After randomization, the 57 patients assigned to the stent group received immediate coronary stenting (group I). The 59 patients assigned to the optimal PTCA group (group II) had a repeat coronary arteriogram of the index artery 30 min after PTCA. In this latter group coronary stenting was allowed only if early loss in MLD was detected in the 30 min post-PTCA angiogram. There were no significant differences in demographic, baseline clinical and angiographic characteristics between the two groups of patients (Table 1).

In-hospital outcome. Stents were successfully deployed in all patients in the stent group. One patient required multiple stent placements due to distal dissection. The stents used in this group of patients included 29 Gianturco Roubin II, 20 Palmaz–Schatz, 3 Wallstents, 3 Wiktors, 2 Multilinks and 2 AVE. Eight patients (13.5%) from the optimal PTCA group crossed over to stent due to the presence of early loss. In these eight patients, four Gianturco Roubin II, one Palmaz–Schatz and three Multiilinks stents were successfully deployed. There were no deaths, emergency CABG, Q-wave myocardial infarction or abrupt closure in either group. One patient in the stent group sustained a non–Q-wave myocardial infarction secound-

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### Table 1. Baseline Demographic and Angiographic Characteristics

<table>
<thead>
<tr>
<th>Lesions data</th>
<th>Stent ($n=57$)</th>
<th>PTCA ($n=59$)</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>1/57 (1.7%)</td>
<td>1/59 (1.7%)</td>
<td>NS</td>
</tr>
<tr>
<td>B1</td>
<td>16/57 (28%)</td>
<td>25/59 (42.3%)</td>
<td>NS</td>
</tr>
<tr>
<td>B2</td>
<td>28/57 (49%)</td>
<td>22/59 (37.3%)</td>
<td>NS</td>
</tr>
<tr>
<td>C</td>
<td>12/57 (21.3%)</td>
<td>11/59 (18.7%)</td>
<td>NS</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>5/57 (8.8%)</td>
<td>10/59 (16.9%)</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up angiogram</td>
<td>56/57 (98.2%)</td>
<td>56/59 (95%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Abbreviations: AMI = acute myocardial infarction; LAD = left anterior descending; LCX = left circumflex; NS = not significant; RCA = right coronary artery.
ary to a side branch closure. Length of hospital stay was similar in both the stent and optimal PTCA groups (3.2 ± 1 vs. 2.4 ± 2 days, respectively).

**Angiographic results.** The QCA data including reference and MLD and stenosis for both groups of patients are shown in Table 2. There were no significant differences in reference luminal diameter between the stent (3.1 ± 0.56 mm) and the optimal PTCA (2.81 ± 0.55 mm) groups (p = 0.07). Similarly, there were no significant differences in the pre-PTCA MLD (0.80 ± 0.46 mm vs. 0.70 ± 0.46 mm; p = 0.4 for stent and optimal PTCA groups, respectively). However, postintervention MLD in the stent group was significantly larger than the 30 min post-PTCA MLD in the optimal PTCA group (2.7 ± 0.59 mm vs. 2.2 ± 0.49 mm for the stent and optimal PTCA groups, respectively; p < 0.0001). The corresponding acute gain was significantly larger with the stent than with the optimal PTCA strategy (1.95 vs. 1.5 mm; p = 0.03). The MLD at follow-up was similar with stent or PTCA strategy (2.1 ± 0.9 mm vs. 1.94 ± 0.68 mm for the stent and optimal PTCA groups, respectively; p = NS) (Fig. 1). Late loss was significantly greater in the stent than in the optimal PTCA group (0.63 ± 0.59 vs. 0.26 ± 0.44 mm; p < 0.001). There were no significant differences in the net gain (acute gain – late loss) between the stent and the optimal PTCA groups (1.32 ± 0.33 vs. 1.24 ± 0.29 mm for the stent and optimal PTCA groups, respectively; p = 0.42).

Pre-PTCA diameter stenosis was similar in the stent and the optimal PTCA groups (73.06 ± 13% vs. 74.07 ± 15%; p = NS). Postintervention diameter stenosis was significantly lower in the stent than in the optimal PTCA group (12.8 ± 9% vs. 22.1 ± 11%; p = 0.001). However, at follow-up, angiography percent residual diameter stenosis was similar for the stent and the optimal PTCA groups (29.4 ± 2.1% vs. 30.3 ± 2.1%, respectively, p = 0.8).

**Angiographic restenosis and clinical follow-up.** Follow-up angiogram was performed at 7.6 ± 0.4 months in 112 of 116 (96.6%) patients in the entire group, in 56 of 57 (98.2%) patients in the stent group and in 56 of 57 (94.9%) in the PTCA group. As shown in Table 3, angiographic restenosis was 19.2% in the stent and 16.1% in the optimal PTCA group (p = 0.9). Since the data were analyzed according to intention to treat, the numbers in the PTCA group included 13.5% of

### Table 2. Quantitative Angiographic Data

<table>
<thead>
<tr>
<th></th>
<th>Stent (n = 56)</th>
<th>PTCA (n = 56)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>RD (mm)</td>
<td>3.1 ± 0.56</td>
<td>2.81 ± 0.55</td>
<td>NS</td>
</tr>
<tr>
<td>MLD pre (mm)</td>
<td>0.80 ± 0.46</td>
<td>0.70 ± 0.46</td>
<td>NS</td>
</tr>
<tr>
<td>MLD post (mm)</td>
<td>2.7 ± 0.59</td>
<td>2.2 ± 0.49</td>
<td>= 0.0001</td>
</tr>
<tr>
<td>Acute gain (mm)</td>
<td>1.95</td>
<td>1.5</td>
<td>= 0.03</td>
</tr>
<tr>
<td>MLD follow-up (mm)</td>
<td>2.1 ± 0.9</td>
<td>1.94 ± 0.68</td>
<td>NS</td>
</tr>
<tr>
<td>Late loss (mm)</td>
<td>0.63 ± 0.59</td>
<td>0.26 ± 0.44</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Net gain (mm)</td>
<td>1.32 ± 0.33</td>
<td>1.24 ± 0.29</td>
<td></td>
</tr>
<tr>
<td>Gain stent/PTCA (mm)</td>
<td>0.08</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Percent stenosis

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre</td>
<td>73.06 ± 13</td>
<td>74.07 ± 15</td>
<td>NS</td>
</tr>
<tr>
<td>Post</td>
<td>12.8 ± 9</td>
<td>22.1 ± 11</td>
<td>= 0.0001</td>
</tr>
<tr>
<td>Follow-up</td>
<td>29.4 ± 21</td>
<td>30.3 ± 2.1</td>
<td>NS</td>
</tr>
</tbody>
</table>

Abbreviations: MLD = minimal luminal diameter; PTCA = percutaneous transluminal coronary angioplasty; RD = reference diameter.

### Table 3. Six-month Angiographic Restenosis and 1-year Follow-up Clinical Events for the Stent and Optimal PTCA Groups

<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>PTCA</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiographic restenosis (%)</td>
<td>11/56 (19.2)</td>
<td>9/56 (16.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Death (%)</td>
<td>0/57 (0)</td>
<td>1/59 (1.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Non-Q-AMI (%)</td>
<td>0/57 (0)</td>
<td>1/59 (1.6)</td>
<td>NS</td>
</tr>
<tr>
<td>TVR (%)</td>
<td>10/57 (17.5)</td>
<td>8/59 (13.5)</td>
<td>NS</td>
</tr>
<tr>
<td>CABG (%)</td>
<td>4/57 (6.7)</td>
<td>2/59 (1.7)</td>
<td>NS</td>
</tr>
<tr>
<td>PTCA/PTCA + stent (%)</td>
<td>6/57 (10.5)</td>
<td>6/59 (10.1)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Any clinical events (%)* 80.8 83.1 NS

*Included procedural and hospital events. Abbreviations: AMI = acute myocardial infarction; CABG = coronary artery bypass graft; PTCA = percutaneous transluminal coronary artery; TVR = target vessel revascularization.
Discussion

In this trial we compared two strategies of revascularization in patients obtaining a good immediate angiographic PTCA result: elective stent versus a conservative therapy (optimal PTCA) with a delayed angiogram 30 min after the end of the procedure to assess changes in MLD. In this latter group, patients were allowed to cross over to stent only when early loss in MLD occurred (provisional stenting). The central finding of the present study is that angiographic restenosis, TVR and freedom from major combined events at follow-up were similar in both groups of patients. Furthermore, despite similar angiographic restenosis and event-free survival at 1-year follow-up, overall costs were significantly higher in the stent than in the optimal PTCA with provisional stenting group.

In the present study, the stent strategy resulted in a greater acute gain than in the optimal PTCA with provisional stenting approach. However, net gain and angiographic restenosis rates with both techniques were similar as a result of a significantly greater late loss in the stent group. These findings are in agreement with previous studies demonstrating that late loss due to neointimal proliferation is greater with stents than with balloon angioplasty (5,6,13,14). Although compared with stenting, optimal PTCA resulted in a smaller post-PTCA MLD, the smaller late loss occurring after PTCA resulted in a similar net gain and angiographic restenosis rate at follow-up. Our results were analyzed according to intention to treat and provisional stenting was necessary in 13.5% of lesions in the optimal PTCA group. Since 75% of lesions exhibiting early loss after successful PTCA develop restenosis (8,9), the restenosis rate of the PTCA group without provisional stenting would have been 25 to 30%.

The findings of this trial are in agreement with the hypothesis of lower restenosis rate after balloon angioplasty in those lesions with no early MLD loss after PTCA (7). As we previously reported, total loss after successful PTCA has at least two components: an early loss component detected within minutes or hours after PTCA and a late component manifested at 6-month follow-up angiography. Early loss in MLD after successful PTCA is associated with higher restenosis rates at follow-up (1,7–9,15–17). A loss in MLD of greater than 0.3 mm at 24 h after successful PTCA identifies a group of patients with a 6-month angiographic restenosis rate of 70% (1,9). We have also demonstrated that coronary stent significantly reduces angiographic restenosis in these patients with early loss of MLD after successful PTCA (9). However, a good initial PTCA result without early loss in MLD at 24-h follow-up angiography (“stentlike results”) identified a subgroup of patients with a low angiographic restenosis rate and a good long-term outcome (1).

Although the BENESTENT I (5) and STRESS (6) trials have shown a 30% reduction in late restenosis with the use of Palmaz–Schatz stents, hospital stays and costs were increased in these studies. In both trials stent restenosis was similar to the restenosis rate of the stent group reported in the present study.
Our findings of a low restenosis rate and good long-term outcome in lesions with no early loss in MLD after successful PTCA are in agreement with those of the BENESTENT I trial, showing a 16% restenosis rate in lesions with PTCA stentlike results (18).

In the present study we have a high number of patients with unstable angina and therefore complex coronary lesion morphology. We have previously demonstrated that early loss in MLD after successful PTCA occurred in 60% of AHA/ACC type B and C coronary lesions, and that this angiographic phenomenon was associated with a high restenosis rate at follow-up (1). However, it is early loss after successful PTCA rather than coronary lesion morphology that is the main determinant of coronary restenosis. No early loss in MLD and a restenosis rate of 10% occurred in 40% of patients undergoing successful PTCA of type B and C lesions (1). Thus, regardless of coronary lesion morphology, those lesions without early loss after successful PTCA have a low incidence of restenosis at follow-up.

Coronary stents have had a dramatic impact in the immediate and long-term outcome of percutaneous revascularization procedures. They reduce the incidence of the acute complications of failed balloon angioplasty and improve suboptimal results after PTCA. Furthermore, coronary stents are the only intervention that has been demonstrated to reduce both clinical and angiographic restenosis. Coronary stenting reduces restenosis by achieving a greater acute gain, preventing the phenomenon of early loss in MLD occurring during the first 24 h after successful PTCA (8,19,20) and reducing arterial remodeling. As a result of these beneficial effects, nowadays stent implantation is used in more than 60% of percutaneous revascularization procedures. However, compared with conventional balloon angioplasty, coronary stenting has several potential limitations, including increased cost, a greater degree of smooth muscle cell proliferation and neointimal formation, difficult use in some lesion subsets and the increasing problem of in-stent restenosis. Actually, difficulty in the management of in-stent restenosis, including the discouraging results of balloon angioplasty due to the high recurrence of restenosis at follow-up, prompted more patients in the stent group of this study who developed restenosis to be treated by bypass surgery.

In parallel with the development of the second generation of percutaneous revascularization devices and adjunctive pharmacology, the immediate and long-term results of conventional balloon angioplasty have also improved significantly. This improvement is the result of operator experience, the use of IIB-IIIa receptor blockers and the availability of coronary stents to treat acute complications (abrupt and threatening occlusion) and suboptimal results of conventional balloon angioplasty. Thus, nowadays a more aggressive conventional balloon angioplasty can be performed as the predominant technique of percutaneous coronary revascularization with a provisional stenting strategy for the treatment of abrupt and threatening occlusion or suboptimal results. In fact, a lower target lesion revascularization was achieved in the PTCA arm of the BENESTENT II, BOAT and EPILOG trials. In those studies, similar to the present study, the PTCA strategy required 14% provisional stenting. These findings provide preliminary evidence that a strategy of aggressive conventional balloon angioplasty with the limited use of provisional stenting to treat angioplasty complications or suboptimal results may be highly effective. Our pilot study provides the basis for larger randomized trials to compare the strategy of universal stenting with one of optimal angioplasty with provisional stenting.

A coronary intervention strategy including a delayed coronary angiogram 30 min after a good immediate angiographic result of PTCA allowing crossover to provisional stenting only if early loss occurs adds additional cost and decreases the efficiency of the interventional procedure. Since in the DEBATE trial an impaired post-PTCA coronary flow reserve predicted subsequent clinical events (21), it is possible that intracoronary Doppler would allow early identification and stenting of coronary lesions prone to experience early loss in MLD after successful PTCA.

**Study limitations.** We recognize certain limitations of this study. First, our sample size was small and it is possible that a type 2 error could have occurred in this equivalency trial. Therefore larger randomized studies are necessary to address definite conclusions. Furthermore, although there were no statistically significant differences in baseline characteristics between the two groups, there were some important differences, including a higher incidence of left anterior descending lesions in the stent group and an incidence of diabetes in the PTCA group that was twice that of the stent group.

Second, the estimated cost of interventional procedures in the study was analyzed on the basis of their costs in the countries involved in the OCBAS trial, and would be different if the PTCA and stents procedures had been performed in the United States or Europe. However, the costs were calculated following the criteria of the National Social Security System of Argentina, Chile and Uruguay. Third, a heterogeneity of stent designs was used in this study, including a large percentage of Gianturco Roubin II stents. Although the multicenter study comparing the Gianturco Roubin II versus Palmaz–Schatz appears to show a lower restenosis rate in the Palmaz group, these results are controversial (22). Our study demonstrated a lack of correlation between angiographic restenosis, late outcome and stent design. Restenosis was documented in 12.1% of the Gianturco Roubin II stents versus 20.5% of the remaining stent designs (p = NS). These findings are in agreement with those of the FRESCO and the GRAMI trials (23,24), demonstrating low target lesion revascularization after Gianturco Roubin II stent implantation.

**Conclusions.** Compared with coronary stenting, a strategy of optimal PTCA with provisional stenting resulted in similar angiographic restenosis rates. TVR and freedom from major combined events at 1 year of follow-up. Furthermore, the overall cost of the stent strategy was significantly higher.

A delayed angiogram after a good immediate angiographic result of PTCA identifies a group of patients with good long-term outcome, allowing to crossover to provisional stent
only if early loss in MLD occurs. Therefore, stenting after successful PTCA should be avoided if early loss in MLD is not present.

Optimal Coronary Balloon Angioplasty with Provisional Stenting vs. Stent (OCBAS)

Study Organization and participants:

Coordinating Center: Centro de Estudios en Cardiologia Intervencionista (CECI). Alfredo Rodríguez, MD, PhD, Buenos Aires, Argentina; Igor F. Palacios, MD, Massachusetts General Hospital, Harvard Medical School, Boston, MA.

Participating Centers:

Sanatorio Otamendi: Alfredo Rodriguez, MD, PhD; Carlos Maurecia, MD; Victor Bernardi, MD; Jorge Martinez; Pablo Bosiks, Buenos Aires, Argentina.
Sanatorio Anchoena: Alfredo Rodriguez, MD, PhD; Omar Santaera, MD; Mario Fernandez, MD, Buenos Aires, Argentina.
Hospital Español: Alfredo Rodriguez, MD, PhD; Alberto Cristiano, MD; Daniel Vogel, MD, Bahia Blanca, Argentina.
Clinica Belgrano: Omar Santaera, MD; Alejandro Delacasa, MD, Mar del Plata, Argentina.
Universidad Nacional de Chile: Francisco Ayala, MD; Gaston Dussallian, MD, Santiago de Chile, Chile.
Universidad Catolica de Chile: Eugenio Marchand, MD; Alejandro Martinez, MD, Santiago de Chile, Chile.
Hospital Militar de Chile: Rene Pumalino, MD; Oscar Novoa, MD, Santiago de Chile, Chile.
Instituto de Cirugia Cardiaca: Cesar Parida, MD, Montevideo, Uruguay.
Central Core Laboratory: Igor F. Palacios, MD, Lari C. Harrell, BS, Massachusetts General Hospital, Harvard University, Boston, MA.
Safety and Data Monitoring Committee: Ramon Corbalan, MD, Santiago, Chile; Nestor Perez Balitto, MD, Buenos Aires, Argentina.
Statistics: Ulises Questa, MD, PhD, Buenos Aires, Argentina; Lari C. Harrell, BS, Massachusetts General Hospital, Harvard Medical School, Boston, MA.

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