The use of coronary stents in interventional cardiology has increased exponentially over the last decade. The popular evolution of stenting strategies extends from bail out stenting and provisional stenting to routine stenting. However, these standard stent implantation techniques involve predilatation of the target lesion with a balloon catheter or debulking devices to allow easy passage of the stent and to improve the likelihood of complete stent expansion. With improvement in stent design, in cluding re duction of the crossing profile, greater flexibility and stable adhesion on the balloon delivery system, direct stenting without balloon predilatation is becoming increasingly popular. Animal studies have shown that stents used without balloon predilatation may provide a means for dilating arteries while avoiding complications, leading to less neointimal hyperplasia and lower restenosis rate. The short-term results re vealed safety and feasibility, but data regarding the long-term clinical outcomes are rare. The aim of this study was to investigate the long-term clinical outcome of successful direct stenting with out predilatation.

**Background.** Direct stent implantation with out predilatation is considered a promising new technique that may reduce procedural time, radiation exposure, ischemic time and costs, but little information is available concerning the long-term outcome. The aim of this study was to investigate the long-term clinical outcome of successful direct stenting with out predilatation.

**Methods.** We prospectively undertook a clinical follow-up program (minimum 8 months) in a consecutive series of 101 patients (113 lesions) who were successfully treated with direct stenting with out predilatation.

**Results.** Clinical follow-up was obtained in all 101 patients at a mean period of 12.8 months (range 8 to 18.9). Stress test results were available in 94 patients (94%). During the follow-up period, 23 patients (23%) had one or more events, which included deaths in 2 patients (2%), target vessel revascularization in 14 (14%), myocardial infarction in 1 (1%) and positive stress test results or recurrence of symptoms (Canadian Cardiovascular Society I to II) treated medically in 6 (6%). Cumulative event-free survival at 8 and 18 months was 80% and 72%, respectively. Long-term clinical event rate was not significantly different among the clinical presentations, lesion types, or stent types. Angiographic follow-up was performed in 43 (43%) patients with 45 lesions. Restenosis (defined as 50% diameter stenosis) was observed in 14 of the lesions (31%).

**Conclusions.** Direct stenting with out predilatation is an effective method of coronary intervention in terms of low long-term clinical event rate.

**Original**

Long-Term Clinical Follow-up after Successful Direct Coronary Stenting without Predilatation

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**Key Words**
angioplasty;
coronary interventions;
direct stenting;
stents

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Methods

Patients

Between September 1999 and September 2000, 299 patients underwent intracoronary stenting at our center. Our study consisted of 112 (38%) consecutive patients from this population who underwent direct stenting without predilation. Direct stenting was considered suitable in cases with objective evidence of myocardial ischemia and acceptable lesion characteristics as follows: (1) a reference vessel ≥2.7 mm in diameter; (2) stenosis length ≤22 mm; (3) absence of total or subtotal coronary occlusion; (4) absence of moderate to severe coronary calcification; (5) absence of severe tortuosity of the vessel proximal to the stenosis; and (6) absence of significant angulation (bend > 90°).

Stenting with out predilation was successful in 113 of the 124 lesions (90%) treated in 112 patients. In eleven lesions (10%), the stent could not be delivered properly. The unexpanded stents were successfully removed through the guiding catheter, and stenting with the removed stent was performed again after predilation (10 lesions) or rotablation (1 lesion). Therefore, the study included 101 patients (113 lesions) who had successful direct stenting, and all 101 had clinical follow-up for at least 8 months.

Follow-up

For clinical follow-up, patients were seen monthly at outpatient clinic after the successful direct stenting. Follow-up in for ma tion was collected on uniform questionnaires filled out with the medical records. Angina symptoms were characterized according to the Canadian Cardiovascular Society classification. Treadmill exercise testing was performed according to the Bruce protocol. Thallium scan was ordered if there was ischemic exercise test or intolerance to exercise. Angiographic follow-up was performed if there was a positive stress test or suspected syndrome recurrence. For patients who had clinical events, the clinical follow-up ended at the time of the event.

Definitions

A clinical event was defined as death from any cause, Q wave or non-Q wave myocardial infarction, repeat lesion-related angioplasty, lesion-related coronary bypass surgery, recurrent heart attack, or in-hospital death. Recurrence of symptoms included the presence of Canadian Cardiovascular Society class I to IV angina during the follow-up period. Stent restenosis was defined as a ≥50% diameter stenosis at the stented site or at the proximal or distal adjacent sites. Diffuse restenosis was defined as a ≥50% lesion narrowing 10 mm in length, whereas shorter restenosis was defined as focal.

Statistical analysis

Categorical variables are presented as absolute numbers (percent). Continuous variables are presented as mean ± SD. Differences between groups were evaluated by chi-square analysis and the Student t test for continuous variables. The Kaplan-Meier method was used to generate event-free curves. P values <0.05 were considered statistically significant.

Results

Clinical, angiographic and procedural characteristics

Clinical presentation and other baseline characteristics are presented in Tables 1 and 2. There were 88 males. Mean age was 68 ± 8 years. Indication for angioplasty was stable angina pectoris in 67 patients, new-onset unstable angina pectoris in 16 patients, and post-myocardial infarction angina in 18 patients. There were 100 (88%) primary and 13 (12%) restenotic lesions. Irregularity was present in 23 lesions (20%), ostium in 6 (5%), bifurcation in 7 (6%), and bending (>45°) in 22 (20%). The lesion type was A in 26 (23%), B1 in 45 (40%), B2 in 29 (26%) and C in 13 (11%). The procedural characteristics and quantitative angiographic analysis are presented in Tables 3 and 4.
The transradial approach was used in 71 patients and transfemoral approach in the remaining 30 patients. All stents were second-generation stents and included the NIR stent (Boston Scientific Corporation) (38%), Cordis stent (John son & John son interventional systems) (36%), AVE stent (Arterial Vascular Engineering, Inc) (16%), ACS (Advanced Cardiovascular Systems, Inc) (9%) and other (1%). The total number of implanted stents was 118. Most pa tients (96%) received a single stent per lesion site. The lesion length was 11.16 ± 5.85 mm. The stents were deployed at a mean inflation pressure 14 ± 2 atm. Reference vessel diameter was 3.09 ± 0.3 mm, and minimal luminal diameter increased from 0.88 ± 0.37 mm to 3.01 ± 0.61 mm, and diameter stenosis decreased from 71.8 ± 

### Table 1. Clinical characteristics

| Patients | 101 |
| Age (years) | 68 ± 8 |
| Male/female | 88/13 |

#### Risk factors
- Hypertension: 60
- Diabetes mellitus: 23
- Hypercholesterolemia: 27
- Current smoker: 26

#### Clinical presentations
- Stable angina pectoris: 67
- Unstable angina: 16
- Recent MI with post-MI angina: 18
- Previous PTCA: 13
- Previous CABG: 1
- Left ventricular ejection fraction < 50%: 31

#### PTCA = percutaneous coronary angioplasty; CABG = coronary artery bypass grafting; MI = myocardial infarction.

### Table 2. Angiographic characteristics

| Number of diseased vessels | 1 | 38 (38%) |
| Target vessels | 2 | 45 (45%) |
| RCA | 3 | 18 (18%) |

#### Target vessels
- LAD: 54 (50%)
- LCX: 24 (21%)
- RCA: 27 (25%)
- SVG: 2 (2%)

#### Lesion morphologic features (ACC/AHA)
- A: 26 (23%)
- B1: 45 (40%)
- B2: 29 (26%)
- C: 13 (11%)

#### Lesion morphology
- Irregularity: 23 (20%)
- Angulation > 45°: 22 (20%)
- Ostium: 6 (5%)
- Bifurcation: 7 (6%)
- Thrombus: 3 (3%)
- Mild calcification: 9 (8%)

#### Stent diameter, mm
- 4: 38/3.5/3.25/2.75
- 5: 114/157/9

#### Stent length, mm
- 16.3 ± 4.3

#### Maximal pressure during stent deployment (atm)
- 14 ± 2

#### Additional balloon
- 15

#### Additional stent
- 3

#### Procedural time, min
- 45 ± 23

### Table 3. Procedural characteristics

| Transradial approach | 71 |
| Number of stents | 118 |

#### Second-generation stents
- NIR Primo/Royal/Sox: 19/24/7
- Cordis Cross Flex/LC+/BX: 6/27/9
- AVE GFX-II/S660: 13/2
- ACS Duet/Tristar: 3/7
- Others: 1

#### Stent diameter, mm
- 4/3.5/3.25/2.75
- 5/7

#### Stent length, mm
- 16.3 ± 4.3

#### Maximal pressure during stent deployment (atm)
- 14 ± 2

#### Additional balloon
- 15

#### Additional stent
- 3

#### Procedural time, min
- 45 ± 23

**Data are expressed as number or mean ± SD.**

### Table 4. Quantitative angiographic analysis results

| (n = 113) |
| Reference diameter (mm) | 3.09 ± 0.30 |
| Before intervention | 3.24 ± 0.45 |
| After stenting | 0.88 ± 0.37 |
| Minimal lumen diameter (mm) | 3.01 ± 0.31 |
| Before intervention | 71.8 ± 8.3 |
| After stenting | 7.3 ± 4.9 |
| Percent diameter stenosis (%) | 11.16 ± 5.85 |

**Data are expressed as mean ± SD or %.**
11.5% to 7.3 ± 7.5% after stenting. Additional balloons were used in 15 lesions (13%). Three lesions needed additional stenting, including two in which downward occlusive coronary dissection occurred and one in which inadequate stent-length covering was deployed. The procedural time was 43 ± 25 min. There was no incomplete stent expansion, distal embolization, stent loss, coronary artery perforation or emergency bypass surgery.

Late clinical outcome after successful direct stenting

As shown in Table 5, clinical follow-up was observed in all 101 patients (100%) at a mean of 12.8 months (range 8 to 18.9). Stress test results were available for 94 patients (94%). During the follow-up period, 23 patients (23%) had one or more events. The mean interval between procedure and first event was 6.5 months (range 1 to 17). Target vessel revascularization was performed in 14 patients (14%), of whom 13 had repeated balloon angioplasty and 1 had coronary bypass surgery. One patient had a Q wave myocardial infarction and received primary angioplasty within 6 hours. Two patients (2%) died due to refractory congestive heart failure within 4 months. Positive stress test results or recurrence of symptoms occurred in 6 patients (6%), who were treated medically.

Angiographic follow-up after direct stenting is not routinely performed at our institution and was obtained in 43 (43%) patients with 45 lesions (40%). Restenosis (defined as ≥50% diameter stenosis) was observed in 14 (31%) of lesions. The relatively high angiographic restenosis rate (31%) was due to bias in case selection (only patients with positive stress test or suspected angina were given angiographic follow-up). Fig. 1 shows event-free survival rate by Kaplan-Meier method. It demonstrates cumulative event-free rates of 80% at 8 months and 72% at 18 months, respectively.

Several clinical factors (gender, age, risk factor, clinical presentations) and angiographic variables (ex-

Table 5. Follow-up results

<table>
<thead>
<tr>
<th>Follow-up, days</th>
<th>383 ± 115</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical follow-up obtained</td>
<td>101 (100%)</td>
</tr>
<tr>
<td>Stress test (exercise test or and thallium scan)</td>
<td>94 (94%)</td>
</tr>
<tr>
<td>Event-free</td>
<td>77 (77%)</td>
</tr>
<tr>
<td>Events</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Target vessel revascularization</td>
<td>14 (14%)</td>
</tr>
<tr>
<td>Cardiac death due to congestive heart failure</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Recurrence of symptoms and or positive stress test</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>Angiographic follow-up</td>
<td></td>
</tr>
<tr>
<td>≥50% diameter stenosis</td>
<td>45 (40%)</td>
</tr>
<tr>
<td>Diffuse type (≥10 mm) restenosis</td>
<td>14 (31%)</td>
</tr>
<tr>
<td>Focal type (&lt;10 mm) restenosis</td>
<td>7 (50%)</td>
</tr>
</tbody>
</table>

aData are expressed as mean ± SD or number (%) of patients.

bCanadian Cardiovascular Society class I to IV angina.

cData are expressed as number (%) of lesions (n = 113).
Discussion

Comparison with other studies

We performed direct stenting using different types of second-generation stents for various clinical presentations. We demonstrated that the technique has a high immediate success rate (90%), and a favorable long-term clinical event-free rate. These results are comparable to other studies, which achieved between 80% to 97% success rates depending on inclusion criteria or specific stent. To our knowledge, there have been three other long-term follow-up studies published. Laarman et al. designed a prospective study including 250 patients undergoing direct stenting; the 6-month follow-up showed that the overall re-intervention rate was 9.7%. Wilson et al. did a retrospective study from the Mayo Clinic Coronary Intervention database. Their analysis revealed a cumulative event rate of about 15% at 9 months. Because the data in these two studies were collected by reviewing charts and interviewing patients in person or by telephone, they may have underestimated restenotic rate. Our prospective study in cluded stress tests (treadmill or cist test, thallium scan) carried out in 94 pa tients (94%), so it may better reflect the actual restenotic rate. In the third study, Danzi et al. evaluated angiographic follow-up for direct stenting in pa tients with a de novo lesion and 1-vessel coronary artery disease. The restenosis rate was 22.8%, similar to that of the group of patients who were treated with conventional stenting. Our group in cluded patients with more multiple-vessel disease, older age, and more complex lesions than that of Danzi et al. However, the fact that intravascular ultrasound (IVUS) was not performed in our study as a guide for direct stenting, may have affected our restenosis rate results. We adopted de la Torre Hernandez et al.’s suggestion that balloon/artery ratio of 1.1 to 1.2 be used in combination with implantation pressures of 12 to 16 atm. Their study showed that the results of direct stenting in selected lesions could be compared with conventional stenting. More research is needed to provide insights into the exact impact of direct stenting with out IVUS guide.

Rationale for direct stenting without predilation

Given the excellent immediate and long-term results recently demonstrated by standard stenting techniques, stent deployment has become a primary therapy. Five clinical trials were performed to compare routine vs provisional use of stents (OCBAS, FROST, DESTINI, DE BATE-II and OPUS-1). Meta-analysis revealed that provisional stenting needed more procedural time and repeat procedures, and that the stenting rate was more than 50%. Routine stenting technique not only reduced adverse clinical events, but it was also more cost-effective than provisional stenting.

Furthermore, the advantages of direct stenting include faster procedures with less radiation and contrast medium, reduced ischemic times, less myocardial ischemia, less major coronary artery embolization and lower costs, as compared with the routine stenting technique. So far, direct stenting with new-generation stent has been selected for patients with simple lesions, as described in the Belgium Netherlands Stent Study and the Stent Restenosis Study. 

However, the approach could also be very useful for treating patients with acute coronary syndromes, and for lesions of old saphenous vein grafts, in which the risk of distal embolization may be exacerbated by predilatation. With increased experience in sizing of stents and exact positioning of stents, selected complex lesions (type B2-C) are also candidates for direct stenting. In daily practice, 33% to 50% of lesions were considered candidates for direct stenting. In the present study, 37% of all lesions were complex lesions (B2-C); these had the equiv-
lent event-free sur vival rate of the sim plex le sion.

**Study limitations**

The major lim i ta tion of the pres ent study is that it did not in clude com par i son with con trol sub jects who under went stent im plan ta tion af ter pre di lat ation. There fore, the clin i cal out come can only be com pared to those of sim ilar pa tient groups. Use of intra coronary ul tra sound would have pro vided in sights into the ex act im pact on the arte rial lu men and stent ex pan sion. Finally, re peat an gi ography was not rou tinely un der taken, be cause it is not part of our usual clin i cal prac tice. De spite these lim i ta tions, this study rep re sents our ex pe ri ence based on a sin gle med i cal cen ter and pro vided ade quate in for ma tion through thorough clin i cal fol low-up.

**Conclusions**

With the avail abil ity of new-gen eration stents, our study de mon strates that direct stenting with out pre di latation can be per formed in a wide range of clin i cal pres en tations and types of cor o nary le sions. Di rect stenting is not only safe and fea si ble, with high fi nal suc cess rate, it is also an ef fec tive method in terms of low long-term clin i cal fol low-up.

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**References**