Stent-Supported Reconstruction of the Aortoiliac Bifurcation With the Kissing Balloon Technique

Dierk Scheinert, MD; Malte Schröder, MD; Jörn O. Balzer, MD; Hermann Steinkamp, MD; Giancarlo Biamino, MD

Background—Bilateral iliac artery obstructions involving the aortic bifurcation or high-grade stenosis of the abdominal aorta are not usually considered an indication for percutaneous treatment. The purpose of the present study was to evaluate the initial and long-term results of primary stent implantation for reconstruction of the aortic bifurcation.

Methods and Results—In 48 patients with obstructions of the aortoiliac segment, primary stent implantation was performed with the “kissing balloon technique.” Preinterventional angiography showed bilateral stenoses (≥85%) of the proximal common iliac arteries in 25 patients, unilateral occlusions and contralateral stenosis in 22 patients, and bilateral occlusion in 1 patient. In 7 cases, stents were placed for the treatment of high-grade infrarenal aortic stenoses. After excimer laser-assisted recanalization of the common iliac artery obstructions, the aortic bifurcation was reconstructed with the bilateral simultaneous implantation of Palmaz stents (diameter, 7 to 8 mm). Stents used for the treatment of aortic stenoses (Palmaz, n=6; Gianturco, n=1) had a diameter ranging from 20 to 25 mm. In all patients, stents were placed successfully (residual stenosis <30%) and without complications. A clinical improvement of +2 to +3 according to American Heart Association criteria was observed in 41 and 7 patients, respectively. Follow-up was performed clinically (standardized treadmill testing and color-coded Doppler ultrasound) and angiographically. The primary angiographic patency rate (24-month follow-up) was 86.8%. In 3 patients, angiography revealed significant restenoses, which were successfully treated with percutaneous transluminal angioplasty.

Conclusions—Primary stent implantation with the kissing balloon technique is safe and effective for the treatment of aortoiliac obstructions involving the aortic bifurcation and represents a true endovascular alternative to surgery. (Circulation. 1999;100[suppl II]:II-295–II-300.)

Key Words: angioplasty ▪ aorta ▪ claudication ▪ peripheral vascular disease ▪ stents

Percutaneous transluminal angioplasty (PTA) has proved to be an effective technique for the treatment of focal iliac artery stenoses.1-2 The immediate technical success rate has improved significantly, up to 95%,3-6 especially with the use of adjunctive stent placement. The patency rates of 80% to 90% after 5 years that have been reported for short iliac stenoses are comparable to surgical results.7,8 Complex iliac artery obstructions, particularly bilateral stenoses or total iliac artery occlusions, are usually treated with aortofemoral or aortobifemoral graft surgery. Although highly effective, these surgical interventions are associated with a substantial procedure-related risk for the patient. In a meta-analysis of studies published after 1975, the aggregated operative mortality rate was 3.3%, and the aggregated systemic morbidity rate was 8.3%.8

Although the clinical introduction of endovascular stents has contributed to an expansion of indications for minimally invasive endovascular procedures,9 there is only limited experience with PTA for the treatment of bilateral iliac obstructions involving the aortic bifurcation. The potential of contralateral embolism or contralateral iliac artery occlusion due to dislodgement of atherosclerotic or thrombotic material during unilateral PTA has prevented the common use of interventional techniques in this vessel segment.

To avoid these complications, the “kissing balloon technique” was developed for bilateral simultaneous angioplasty of the common iliac arteries. Clinical experience with this technique has been reported only occasionally, and there are no documented series.10-13 The purposes of this study were to evaluate the clinical, hemodynamic, and angiographic changes after stent-supported reconstruction of the aortic bifurcation with the kissing balloon technique and to assess the long-term results of this procedure.

Methods

Study Population

In this study, we analyzed the data for 48 consecutive patients with bilateral common iliac artery obstruction involving the aortic bifur-
TABLE 1. Population Characteristics and Preinterventional Clinical Classification

| Age, y | Mean±SD | 59±10.2 |
| Range | 38–78 |
| Sex, n (%) | Male | 29 (60.4) |
|            | Female | 19 (39.6) |
| Cardiovascular risk factor, n (%) | Smoking | 41 (85.4) |
| Arterial hypertension | 36 (75.0) |
| Hyperlipoproteinemia | 23 (47.9) |
| Diabetes mellitus | 5 (10.4) |
| Family history | 11 (20.8) |

Preinterventional clinical categories (Rutherford classification), n (%)

1: Mild claudication | 2 (4.2)
2: Moderate claudication | 10 (20.8)
3: Severe claudication | 34 (70.8)
4: Ischemic rest pain | 2 (4.2)
5: Minor tissue loss | ...
6: Major tissue loss | ...

*Category 1, treadmill exercise completed (5 min at 2 mph on a 12% incline), postexercise ankle pressure (AP) >50 mm Hg but >25 mm Hg less than normal; category 2, symptoms between categories 1 and 3; category 3, treadmill exercise cannot be completed, postexercise AP <50 mm Hg; category 4, resting AP of <40 mm Hg; category 5, nonhealing ulcer, focal gangrene; and category 6, extending above the transmetatarsal level, functional foot no longer salvageable.14,15

Recanalization Procedure and Stent Implantation

The standard approach for bilateral iliac artery stenoses was the retrograde technique. After bilateral sheath placement (8F) on each side, an 0.018-inch guidewire (High Torque; Mallinckrodt) was navigated through the lesion.

In the case of unilateral iliac artery occlusion, the wire loop technique was used.16 After retrograde puncture and sheath placement into the contralateral CFA, the occlusion was initially passed in crossover technique with a 0.035-inch hydrophilic guidewire (stiff type, angled tip; Terumo), finally placed into the superficial femoral artery. With the guidewire as a marker, the ipsilateral CFA was punctured under fluoroscopic control, and a second 8F sheath was placed. With an angled, shaped wire loop introduced through the ipsilateral sheath, the tip of the guidewire was snared and retrieved out of the sheath. This technique of initial contralateral passage of the occlusion minimizes the risk of subintimal tracking in the area of the aortic bifurcation. The additional steps of the procedure are performed similarly to those for stenotic lesion with a bilateral retrograde approach.

To achieve optimal debulking of the obstructed vessel, several retrograde passes were made with a multifiber laser catheter. Pulsed Excimer laser systems, working at a wavelength of 308 nm (LAIS DYMER 200+; pulse duration, 200 ns; calibrated fluence, 40 to 60 mJ/mm²; Spectranetics CVX 300: pulse duration, 200 ns; calibrated fluence, 45 mJ/mm²), were used for the generation of laser energy. Additional predilatations with undersized balloons (mean diameter, 6.2 mm; range, 5 to 7 mm) were performed in 16 of 48 patients (33.3%), always with the kissing balloon technique.

In all cases, primary implantation of Palmaz stents (P394; Johnson & Johnson Interventional Systems) was performed to stabilize the recanalized vessel segment. Balloon-mounted stents were bilaterally introduced and positioned at the aortic bifurcation extending 3 to 5 mm into the distal aorta; this allows optimal reconstruction of the aortic bifurcation. In all cases, stent implantation was performed simultaneously on both sides with the kissing balloon technique.

A total of 113 stents were implanted into the common iliac arteries. The mean length of the stented segment was 4.8±0.82 mm (range, 3 to 12 mm). Diameters of the implanted devices were equal to the final balloon diameter (range, 7 to 10 mm; mean, 7.8±0.61 mm). To avoid overdilatation, final balloon diameters were selected through comparison with the distal reference segment. (See Figure.)

In 7 patients with relevant aortic stenoses, stent implantation into the infrarenal aorta was performed. Stent types used in this location were Palmaz stents (P4014/PS014) in 6 patients and a Gianturco stent in 1 patient, respectively. Diameters ranged from 20 to 25 mm. Because large aortic balloons with diameters between 20 and 25 mm allow only low-pressure inflations (2 to 4 atm), in all cases, we performed simultaneous dilatations with 2 balloons (diameter, 8 to 10 mm) within the stent to achieve an optimal expansion.

Postprocedural Treatment

During intervention, all patients received 10 000 U heparin intra-arterially, followed by 1000 to 1200 U/h heparin IV for 24 hours (activated partial thromboplastin time, 60 to 80 s). Anticoagulation was continued with 0.3 mg low-molecular-weight heparin SC (Fraxiparin; Sanofi Winthrop GmbH) BID for 2 weeks. Oral anticoagulation with phenprocoumon was administered to 3 patients. All other patients received a combination of ticlopidine (250 mg BID for 4 weeks) and acetylsalicylic acid (100 mg/d).

Follow-Up Protocol

Clinical follow-up examinations, including standardized treadmill testing and color-coded duplex sonography (Sonos 1000 and Sonos 2000 7.5-MHz linear transducer; Hewlett Packard), were performed at hospital discharge; at 1, 3, 6, 12, and 18 months; and then yearly. In 43 of 48 patients (89.6%) after a mean period of 18 months (range, 4 to 51 months), follow-up angiography, including intra-arterial measurement of translesion pressure gradient, was obtained.

Definitions

“Technical success” was defined as restored patency of the vessel with an angiographic residual diameter stenosis of <30% and a residual translesion pressure gradient of <5 mm Hg.
“Cumulative clinical patency rates” were calculated according to the Rutherford criteria on the basis of findings of the most recent available investigation. Angiographic patency at follow-up was defined as ≤50% diameter restenosis and a translesion pressure gradient of <5 mm Hg. “Cumulative angiographic patency rates” were calculated based on the angiographic findings, including intra-arterial pressure measurements for 43 patients who underwent follow-up angiography.

“Primary patency” refers to uninterrupted patency with no procedures performed on or at the margins of the treated segment. “Secondary patency” was defined as patency of the target vessel regardless of secondary interventions performed to restore blood flow.

Statistical Analysis
Continuous variables are presented as mean±SD values, if appropriate. In the case of a non-gaussian distribution, median and range values are given. Patency rates were calculated with the use of the Kaplan-Meyer life-table method. The paired t test was used to analyze continuous data from paired samples.

Results
Primary Technical and Clinical Results
In all patients, stents were placed successfully, with restoration of the patency of the vessel segments; consequently, the technical success rate was 100%. There were no major procedure-related complications. In particular, no thromboembolic events were observed. Minor puncture site complications occurred in 3 cases (6.2%), including 2 hematomas and 1 false aneurysm, which could be successfully treated with ultrasound-guided compression.

A marked clinical improvement of +3 or +2 grades according to the limb status grading system was achieved in 7 and 41 patients, respectively (Table 2). Changes in the ABI and the Doppler peak flow velocity (transcutaneous color-coded Doppler ultrasound) before and after the intervention, as well as the values at the most recent available follow-up, are given in Table 3.

Follow-Up Results
During the mean clinical follow-up of 24 months (median, 22 months; range, 6 to 56 months), a deterioration in the initial clinical improvement according to American Heart Association classification was observed in only 5 patients. Accordingly, the mean ABI before and after treadmill exercise, as well as the Doppler peak flow velocities in the CFA, remained almost stable during the follow-up period (Table 3).

In 3 of 5 symptomatic patients, the control angiography revealed significant restenoses within the stented segment. In the remaining 2 cases, de novo atherosclerotic lesions at other vessel segments (external iliac artery, n=1; superficial femoral artery, n=1) were demonstrated. All lesions could be successfully treated with secondary interventions, leading to a secondary patency rate of 100%.

Cumulative primary clinical and angiographic patency rates were calculated on an intention-to-treat basis using the Kaplan-Meyer life-table method and are given in Table 4.

Discussion
PTA of atherosclerotic iliac artery stenosis is an effective and established method of recanalization with low complication rates and long-term results that approach those of surgical bypass procedures. Because the success of iliac angioplasty is related to factors such as length, eccentricity, calcification of the lesion, and the presence of occlusions or stenoses, obstructions of the pelvic arteries are classified into 4 categories. Generally, the best results, with technical success rates of 95% and 5-year patency rates of 80% to 90%, have been reported for short segment stenosis.

TABLE 2. Short- and Long-term Clinical Improvement According to Limb Status Grading System

<table>
<thead>
<tr>
<th>Grade*</th>
<th>Postinterventional, n (%)</th>
<th>Most Recent Available Clinical Follow-Up,† n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: No change</td>
<td>…</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>+1: Minimally improved</td>
<td>…</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>+2: Moderately improved</td>
<td>41 (85.4)</td>
<td>38 (79.2)</td>
</tr>
<tr>
<td>+3: Markedly improved</td>
<td>7 (14.6)</td>
<td>6 (12.5)</td>
</tr>
</tbody>
</table>

*Grade 0, no shift in clinical category and <0.10 change in ABI; grade +1, >0.10 increase in ABI but no category improvement, or vice versa; grade +2, at least single category improvement, ABI increased by >0.10 but not normalized; and grade +3, symptoms gone or markedly improved, ABI increased to >0.90.†Clinical follow-up, mean 24 mo; median, 22 mo; range, 6–56 mo.
In contrast, the experience with PTA for complex bilateral aortoiliac obstructions is limited and has been reported only sporadically and for small numbers of patients.10–12,17 Technical difficulties, such as the unavailability of suitable-sized high-pressure aortic balloons, and the relatively frequent occurrence of severe procedure-related complications, such as contralateral peripheral embolism in the case of conventional unilateral PTA, have been major drawbacks in the widespread use of interventional techniques in this location. Indeed, inflation of a single balloon in 1 common iliac artery close to the aortic bifurcation can cause compression of the contralateral artery, resulting in relatively poor dilatation and risking contralateral embolization. To overcome these problems, the kissing balloon technique was developed. In the performance of a simultaneous bilateral inflation of similar-sized balloons, the aortic bifurcation can be optimally dilated, minimizing the risk of plaque displacement and embolization. Insall et al18 reported a series of 86 kissing balloon procedures performed in 79 patients; technically successful dilatation was achieved in 94%, and symptomatic relief was obtained in 87%.

In the past decade, the implantation of endovascular stents has become a widely used adjunctive interventional technique. Especially in the iliac location, the use of these devices in the case of relevant residual stenosis yields excellent results and limits the complications of angioplasty.2–6 The potential of endovascular stents to improve the results of angioplasty at the aortic bifurcation has not yet been systematically analyzed.13 However, implantation of stents in this location may be particularly beneficial because ostia of major arterial branches such as the aortic bifurcation are prone to severe atherosclerotic changes of the vessel wall combined with extensive calcification. Several mechanisms have been proposed to account for this phenomenon. The markedly reduced cross-sectional area of the iliac vessels compared with the aorta causes an increase in blood pressure–induced arterial wall stress. Mediated by endothelial cells, smooth muscle cells, and the penetration of LDL, this may subsequently promote atherosclerosis.19 Furthermore, hemodynamic phenomena such as non-Newtonian fluid rheology at the aortic bifurcation cause increased wall shear stress, which shows a positive correlation with intimal thickness.20

In the present study, 48 patients with obstructions of the aortoiliac bifurcation underwent excimer laser-assisted angioplasty, followed by primary stent implantation with the kissing balloon technique. All stents were placed, with successful restoration of the vessel patency. Because the use of conventional diagnostic angiography may underestimate hemodynamically significant residual luminal narrowing in iliac arteries, intra-arterial measurement of translesion pressure gradient was performed.21 With this hemodynamic criterion, successful stent deployment was confirmed in all cases, leading to a 100% technical success rate.

Several technical aspects should be considered to achieve an optimal technical result. In the common iliac arteries, stent and balloon diameter should be chosen through comparison with the normal distal reference segment, providing an optimal luminal gain and full expansion of the stent. The techniques of intra-aortic stent placement are more demanding than those in iliac procedures. For heavily calcified infrarenal aortic stenoses, an optimal circumferential apposition of the stent is sometimes difficult to achieve because large aortic balloons permit only a limited inflation pressure. A double-balloon technique with 2 simultaneously inflated smaller balloons (diameter, 8 to 10 mm) can be used to solve

### TABLE 3. Preinterventional and Postinterventional Hemodynamic Characteristics

<table>
<thead>
<tr>
<th>Follow-Up, mo</th>
<th>Patients, n</th>
<th>Lost to Follow-Up, n</th>
<th>ABI at rest</th>
<th>Right</th>
<th>Left</th>
<th>ABI after treadmill test</th>
<th>Right</th>
<th>Left</th>
<th>Doppler peak flow velocity in the CFAs, m/s</th>
<th>Right</th>
<th>Left</th>
<th>Most Recent Available Clinical Follow-Up*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>48</td>
<td>...</td>
<td>0.51±0.16</td>
<td>0.53±0.14</td>
<td>0.91±0.13</td>
<td>0.92±0.15</td>
<td>0.89±0.17</td>
<td>0.88±0.016</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>48</td>
<td>...</td>
<td>0.41±0.14</td>
<td>0.44±0.15</td>
<td>0.84±0.16</td>
<td>0.84±0.14</td>
<td>0.80±0.16</td>
<td>0.79±0.16</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>40</td>
<td>7</td>
<td>0.31±0.16</td>
<td>0.35±0.18</td>
<td>1.05±0.29</td>
<td>0.99±0.31</td>
<td>1.01±0.25</td>
<td>0.98±0.36</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Clinical follow-up, mean 24 mo; median, 22 mo; range, 6–56 mo.
†P<0.001 compared with preinterventional value.
this problem. However, we always avoided overdistalatation to prevent the risk of hazardous aortoiliac rupture.

The length of the stent should be chosen to completely encompass the entire lesion. This is especially critical for ostial lesions of the common iliac artery, because atherosclerotic disease usually extends into the distal aorta. To ensure optimal reconstruction of the aortic bifurcation, stents were deliberately placed in the aortic lumen somewhat beyond the assumed bifurcation. Furthermore, this technique may contribute to a reduction in embolic complications, because dislodgment of thrombotic material or plaque displacement may be prevented with the stent struts.

With regard to stent types, we almost exclusively used the Palmaz stent for implantation at the aortic bifurcation. This stent has some favorable mechanical properties for application in ostial lesions and in the relatively straight common iliac arteries, where flexibility of the stent seems to be of relatively little importance. Constructed as a plastically deformable latticework, it can particularly well resist the relatively high reconfiguration forces of fibrotic, calcified, or highly eccentric iliac stenoses. Furthermore, because the stent opens out with only minimal shortening, extremely exact placement in the aortoiliac orifice is ensured.

Early series of percutaneous recanalization procedures for chronic iliac artery occlusions demonstrated poor results and excessively high complication rates of up to 20%. More recently, larger studies have produced encouraging results. Johnston et al achieved a considerable primary recanalization rate of 82% (67 of 82 patients were treated successfully), but the cumulative patency rate after a mean follow-up of 36 months was only 58%. Vorwerk et al demonstrated that endovascular stents significantly contribute to an improvement in the long-term results. In a series of 103 patients with chronic iliac artery occlusions, the authors performed primary stent placement and achieved a primary 2-year patency rate of 83% and a 4-year patency rate of 78%. Vorwerk et al reported that one major reason for technical failure of retrograde iliac recanalization was subintimal passage of the occlusion with an eccentric reentry through the aortic wall. To avoid this complication, we performed all recanalization procedures of iliac occlusions in crossover technique using the “wire loop technique.” By using this approach, we were successful in crossing all 22 common iliac occlusions without complications.

After the initial guidewire passage of an iliac artery occlusion, effective removal of obstructing atherosclerotic and thrombotic material must be achieved. Local thrombolytic therapy before PTA has been advocated, especially for fresh iliac artery thromboses; however, it has not been proved to be universally effective for chronic occlusions. In our study, photoablation of atherosclerotic material through the performance of several passes with an excimer laser multifiber catheter (diameter, 2.2 to 2.5 mm) has been used to create a primary laser canal of 2 to 3 mm in diameter. In this way, subsequent balloon dilatation and stent implantation have been facilitated, substantially reducing the risk of distal embolization.

Long-term results are based on clinical, angiographic, and hemodynamic findings. Clinical patency was evaluated indirectly through the retention of clinical benefits, measured with the limb status grading system. Of 48 patients, 43 showed no deterioration in the initial clinical improvement, accounting for a 85.3% clinical patency rate after 24 months. However, these clinical criteria reflect the state of vessel patency for the entire extremity. To evaluate the long-term results of the aortoiliac reconstruction, angiography combined with intra-arterial measurement of the translesion pressure gradient was obtained in 43 of 48 patients (89.6%), including all cases with recurrent clinical symptoms. In only 3 patients was there evidence of relevant in-stent restenosis, accounting for a cumulative primary angiographic patency rate of 97.2% after 12 months and of 86.8% after 24 months. Because all restenotic lesions could be successfully retreated with balloon angioplasty, a secondary angiographic and clinical patency rate of 100% could be achieved.

In summary, the results of the present study demonstrate that stent-supported reconstruction of the aortoiliac bifurcation is a safe and highly effective interventional technique. Even very complex obstructions with unilateral iliac occlusion, contralateral high-grade stenosis, and coexistent infrarenal aortic stenosis can be treated, achieving a high technical success rate. The long-term results with the use of primary stent implantation at the aortic bifurcation are similar to the data reported for the use of short segment iliac artery stents. According to the low complication rate and the excellent technical and follow-up results, this technique may be considered as a first-line treatment for patients with symptomatic atherosclerotic occlusive disease at the aortic bifurcation. However, further investigation should be focused on the 5- and 10-year patency rates in comparison with the surgical results.

References

Stent-Supported Reconstruction of the Aortoiliac Bifurcation With the Kissing Balloon Technique
Dierk Scheinert, Malte Schröder, Jörn O. Balzer, Hermann Steinkamp and Giancarlo Biamino

Circulation. 1999;100:II-295-II-300
doi: 10.1161/01.CIR.100.suppl_2.II-295
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1999 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/100/suppl_2/II-295