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Evaluation of the usefulness of primary stenting of the iliac artery with Palmaz stent in patients with arteriosclerosis obliterans

Hitoshi Sakuda, Moriyasu Nakaema, Noboru Higa, Shinobu Matsubara, Thoru Uezu, Mitsuyoshi Shimoji, Kazufumi Miyagi, Yoshihiko Kamada, Yukio Kuniyoshi and Kageharu Koja

Second Department of Surgery, Faculty of Medicine, University of the Ryukyus, Okinawa, Japan

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ABSTRACT

We evaluated the clinical usefulness of primary stenting of the iliac arteries with Palmaz stent in patients with arteriosclerosis obliterans by analysis of early and midterm postoperative results. Between December 1997 and December 2000, we treated 16 patients of 18 ischemic lower limbs (16 stenoses and 2 occlusions) including 15 men and 1 woman between 48 and 76 years of age (average 63.4 years). Primary stenting was indicated for patients with apparent ischemic symptoms (Fontaine stage of II, III and IV) and reduced ankle pressure index (API, 0.9 or less). Morphological indication was segmental lesions of the iliac artery: an occlusive lesion was 3 cm or less in length, and a stenotic lesion 60% or more in degree and 6 cm or less in length. The stented lesions were located in the common iliac artery in 6 limbs, in the external iliac artery in 7 limbs, and in both arteries in 5 limbs. The 5 patients with multiple arterial occlusive disease underwent simultaneous iliac stent placement and infrainguinal open surgery. Initial technical and clinical success of zero or less than 10% residual stenosis was achieved in all patients (100% initial success rate). A minor complication was noted in 1 patient (5.6%), a small pseudoaneurysm at the punctured site of the common femoral artery that was treated successfully by compression therapy. No major complication requiring open surgery, blood transfusion or perioperative death occurred in any of our patients. Mean API increased significantly from 0.59 ±0.23 preoperatively to 0.95 ±0.17 postoperatively ($p<0.01$). Clinical symptoms improved in all patients except 1. During the follow-up period of 2 to 46 months (average 21 months), 2 high-risk patients died from cerebral hemorrhage, 1 at 5 months and the other at 22 months after stenting. A stented artery in the primary thrombocytosis patient, who received stents for distal anastomotic stenosis of an aortobi-iliac synthetic bypass, occluded after 2 months and was treated by axillofemoral bypass. In a patient with diffuse atherosclerosis of the iliac artery, a severe 75% stenosis recurred within the stent and its distal artery, which was successfully treated by re-stenting. The 3-year primary cumulative patency rate in total patient series was 88.5%, and secondary rate was 94.4%. Although further follow-up studies are needed to evaluate long-term efficacy, our current results indicated that primary stenting for segmental iliac lesions is safe, minimally invasive, and as functional as conventional open surgery. *Ryukyu Med. J., 21(1) 29～33, 2002*

Key words: primary stenting, Palmaz stent, arteriosclerosis obliterans, iliac artery

INTRODUCTION

In treatments of iliac occlusive disease in patients with arteriosclerosis obliterans (ASO), aortofemoral bypass has been established as one of the standard surgical treatments due to excellent results, an operative mortality of 2% or less and a primary cumulative patency rate of 86.8% at 10 years[1].

Bypass surgery is extremely invasive, however, it requires a large skin incision and a wide exposure of the retroperitoneum to approach the artery, resulting in loss of large amounts of blood and a long hospital stay. Conventional endovascular interventions such as percutaneous transluminal angioplasty (PTA), atherectomy, and laser angioplasty are less invasive than open surgery. Indications for such treatments have been limited to short solitary stenosis or to patients at high operative risk because of the frequent occurrence of late restenosis[2-4]. A new device, the metallic stent, has the potential to prevent restenosis because of its mechanical structure[5] and it is

anticipated to improve short- and long-term results of endovascular treatment. Several studies have reported satisfactory clinical results with metallic stenting in the iliac arteries[6-9].

Recently, the usefulness of primary stenting for complex atherosclerotic lesions[10] and occlusion[11] have been reported. However, the indications for and efficacy of primary stenting are still controversial, and there have been no reports on long-term results of primary stenting in Japan. Thus, we evaluated the clinical usefulness of primary stenting in the iliac arteries of patients with ASO by analysis of early and midterm postoperative results.

PATIENTS AND METHODS

Between December 1997 and December 2000, we treated 16 ASO patients by primary stenting of 18 ischemic lower limbs due to iliac occlusive disease. The patients included 15 men and 1 woman between 48 and 76 years of age (average 63.4 years). Accompanying disorders included endstage chronic renal failure (3 patients), coronary arterial disease (CAD, 6 patients), insulin-dependent diabetes (3 patients), malignant tumor (2 patients), liver cirrhosis (1 patient), cerebrovascular disease (2 patients), and primary thrombocytosis (1 patient).

Primary stenting was indicated for patients with apparent ischemic symptoms (Fontaine stage of II, III and IV) and reduced ankle pressure index (API, 0.9 or less). Morphological indication was segmental lesions of the iliac artery: an occlusive lesion was 3 cm or less in length, and a stenotic lesion 60% or more in degree and 6 cm or less in length. The lesions with severe eccentric plaques and heavy calcifications in the strongly distorted artery were excluded.

Ischemic symptoms comprised gangrene/ulcer (6 limbs), severe claudication (the maximum walking distances less than 100 m) (4 limbs), and moderate claudication (8 limbs). API values ranged from 0 to 0.87 (average 0.59) excluding 2 limbs in which ankle pressure was impossible to measure by Doppler flowmeter because of severe calcification of the tibial arteries associated with diabetes mellitus.

The iliac arteries were occluded in 2 limbs, and stenotic in 16 limbs including moderate degree (60%) in 2 and severe (75% or more) in 14, and concentric lesion in 8 and eccentric in the other 8. Calcified plaques, ulcerated plaques and multiple lesions were noted in 11, 2 and 4 limbs, respectively. Infrainguinal arterial occlusive disease was associated with 8 limbs.

Primary stenting was done with 1 to 3, average 1.6, Palmaz™ stents (Johnson & Johnson Medical Co., Tokyo, Japan). The procedure comprised three steps: predilation of the lesion with 5-7-Fr balloon catheters (Johnson & Johnson Medical Co., Tokyo, Japan), delivery and deployment of the stent within the artery and follow-up postdilation with 7-8-Fr balloon catheters to shape the artery. Final stent diameters were 7.2-8.0 mm. In the 2 cases of occlusion, urokinase (240,000-480,000 U) was infused intraarterially immediately before passing a guidewire for subsequent PTA. The stented lesions were located in the common iliac artery (CIA) in 6 limbs, in the external iliac artery (EIA) in 7 limbs, and in both arteries in 5 limbs.

The 5 patients underwent simultaneous iliac stent placement and infrainguinal open surgery, which included femoropopliteal bypass in 4 limbs and femoropopliteal-tibial sequential bypass in 1.

During the procedures, systemic heparinization was carried out via intravenous injection. All patients had received oral antiplatelet drugs such as aspirin (80 mg/day), ticlopidine (200 mg/day), or cilostazol (200 mg/day) before stenting, and continued these same drugs during follow-up.

The patients were followed up at our outpatient clinic and evaluated on the basis of femoral pulses and measurement of API once every month for the first 3 months after the procedure, and then every 3 months. We performed transbrachial arteriography to evaluate the patency of the stented iliac artery when there was reduction of the femoral arterial pulses or the API decreased by 0.1 or more compared with the immediate post stenting value. The iliac artery was defined to be patent when it was free of occlusion or when stenosis did not exceed 20 percent.

Changes in API were analyzed statistically for each patients by a paired t test. Values are shown as mean $\pm$ SD. A p value of 0.05 or less was considered statistically significant. Patency rate was calculated by a life table method.

RESULTS

Initial technical and clinical success of zero or less than 10% residual stenosis was achieved in all patients (100% initial success rate). A minor complication was noted in 1 patient (5.6%), a small pseudoaneurysm at the punctured site of the common femoral artery that was treated successfully by compression therapy. No major complication requiring open surgery, blood transfusion or perioperative death occurred in any of our patients. Acute renal failure, heart attack, or hepatic failure did not worsen postoperatively in any patient with any of these accompanying disorders. Mean API increased significantly from 0.59 ± 0.23 preoperatively to 0.95 ± 0.17 immediately after stenting ($p<0.01$) (Fig. 1). Clinical symptoms improved in all patients except 1. In patients with intermittent claudication, pain-free and maximum walking distances increased 100 m or more than that before stenting. Ischemic ulcers and gangrene healed immediately except 1 limb in which multiple digital artery occlusions were associated with primary thrombocytosis.

During the follow-up period of 2 to 46 months (average 21 months), 2 patients with severe systemic arteriosclerosis

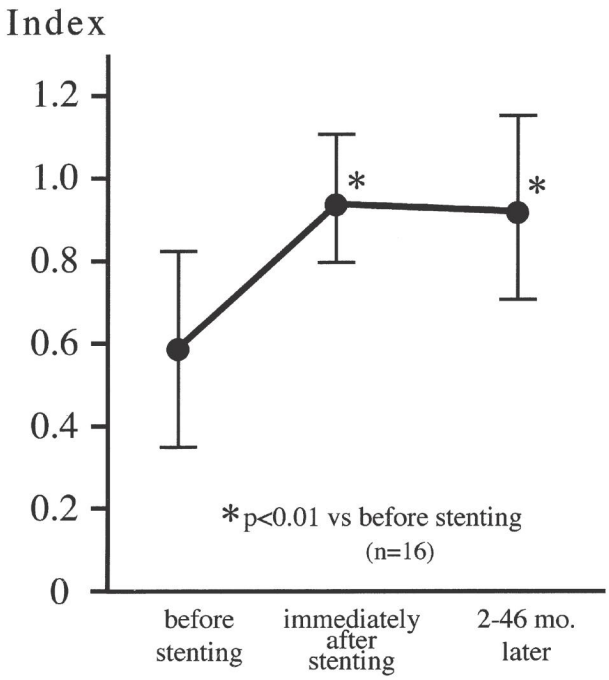

Fig. 1 Change in ankle pressure index after primary iliac artery stenting.
The mean ankle pressure index significantly increased from 0.59 ±0.23 before stenting to 0.95 ±0.17 immediately after stenting ($p<0.01$), and 0.92 ±0.24 at 2-46 months after stenting ($p<0.01$). In 2 of 18 limbs, ankle pressure could not be measured because of severe calcification of the tibial arteries.

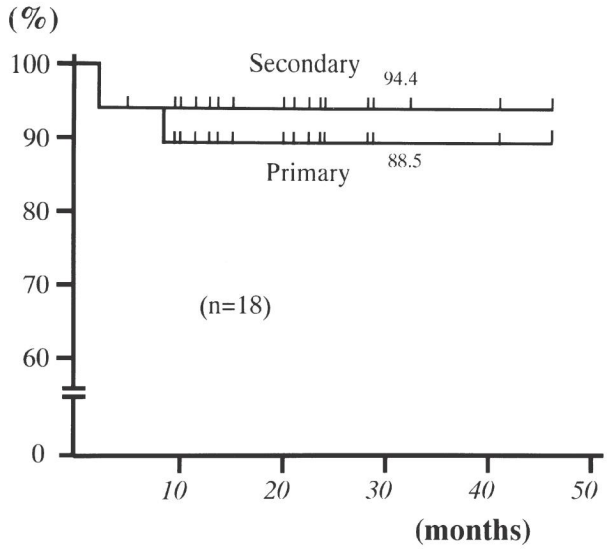

Fig. 2 Cumulative patency rate of the stented arteries.
The patency rate of iliac arteries treated by primary stenting was calculated by a life table method.

died from cerebral hemorrhage; 1 patient with endstage chronic renal failure, CAD and insulin-dependent diabetes at 5 months, and the other with primary thrombocytosis and CAD at 22 months after stenting. A stented artery in the primary thrombocytosis patient, who received stents for distal anastomotic stenosis of an aortobi-iliac synthetic bypass, occluded after 2 months and was treated by axillofemoral bypass. In a patient with diffuse atherosclerosis of the iliac artery, a severe 75% stenosis due to intimal hyperplasia recurred within the stent and its distal artery. It was successfully treated by re-stenting with 2 Palmaz™ stents, which broadly covered the original stent and the distal artery. This patient's API increased from 0.55 to 0.90 after re-stenting. The other 16 patients had kept good femoral pulsations without decrease in API values (Fig. 1). The latest API was 0.92 ±0.24. The 3-year primary cumulative patency rate in total patient series was 88.5%, and secondary rate was 94.4% (Fig. 2).

CASE PRESENTATION

A 76-year-old man had intermittent claudication of the right lower extremity with maximum walking distance of about 50 m. He had mild right hemiplegia due to prior cerebrovascular event. Angiography revealed a 12 mm segmental occlusion of the right CIA (Fig. 3, left). A 5-Fr catheter was introduced into the proximal region of the right CIA via contralateral femoral approach. Thrombolysis was carried out with intraarterial infusion of urokinase (240,000 U). A thin guidewire was successfully passed through the lesion, and the lesion was dilated first with a 4 mm balloon catheter and then with a 6 mm balloon catheter. A 7 mm diameter Palmaz™ stent was deployed, and PTA was performed with an 8 mm balloon catheter (Fig. 3, right). The API in this patient increased from 0.56 to 1.19. He has been symptom-free for 2 years since the procedure.

DISCUSSION

In the present series of patients, the initial success rate was 100% without serious complications. The API values increased statistically and clinical symptoms im proved markedly. Excellent midterm results were achieved; the primary stent patency rate was 88.5% and the secondary patency rate was 94.4% at 3 years. These results support the safety and usefulness of primary stenting with Palmaz™ stent.

Stent placement in the peripheral arteries began in 1969 when Dotter[12] inserted a coil spring into the popliteal artery of a dog. Since Wright *et al.*[13] reported on the Zigzag stent (Z stent) in 1985, various stents have been developed in Europe and America and are now implanted in coronary arteries, iliac arteries, and lower limb arteries. Coronary artery stenting has been used extensively in Japan. The Palmaz™ stent became the first iliac artery stent to be covered by health insurance in Japan; this occurred at the end of 1997. Since then, iliac artery stenting has gradually become more widely used.

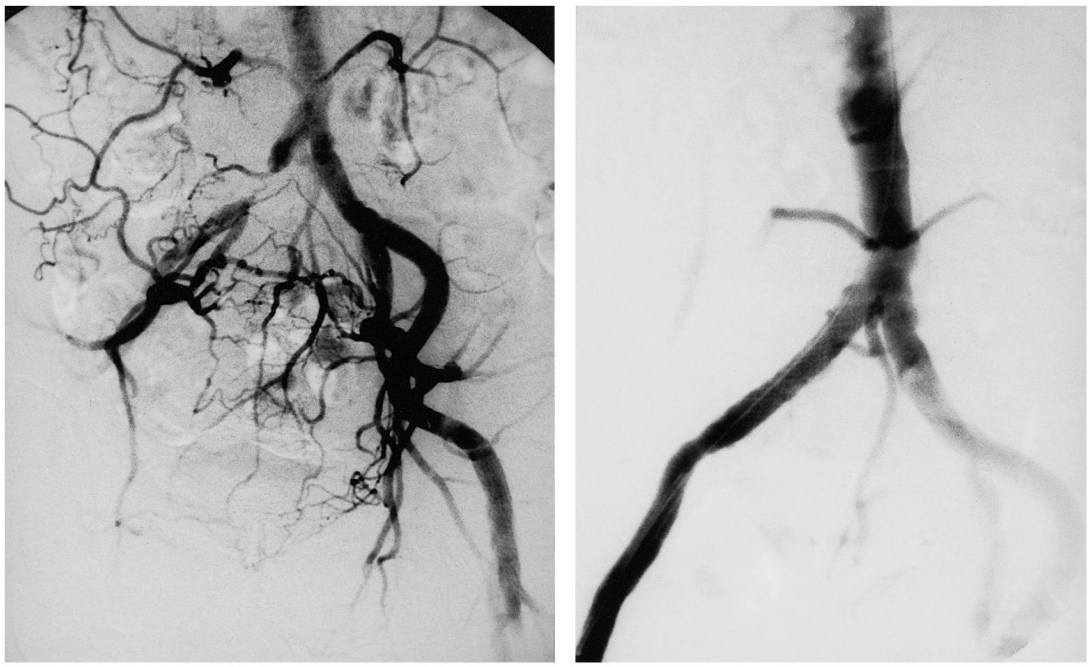

Fig. 3 Patient angiograms.
A 76-year-old man with intermittent claudication of the right lower extremity. Preoperative angiogram reveals segmental occlusion of the right common iliac artery (left). The lesion after treatment by PTA and primary stenting with a Palmaz™ stent (right).

In the past, indications for metallic stenting were limited to recurrent post-PTA lesions, arterial dissections, and elastic recoil. Although primary stenting remains controversial, particularly from the standpoint of costs, we consider primary stenting to be applicable of segmental stenotic and occlusive lesions in addition to cases matching the original indications. Recurrent high-level lesions can advance rapidly to cause critical ischemia in a lower limb, and the long-term results of PTA associated with stent placement are more favorable than the results of PTA alone[14].

Our experience indicates that practitioners must exercise care when the iliac artery is diffusely involved by atherosclerosis, and when thrombocytic hypercoagulability and hyperfunction exist because the stenting itself can act as a stimulant for restenosis and occlusion[15]. We believe careful stenting may be appropriate for treating segmental occlusive lesions that previously could not be treated except by bypass surgery or open thromboendarterectomy. The endovascular maneuvering necessary to treat such occlusions is difficult, and there is an increased possibility of causing serious complications. In particular, the initial success and long-term patency rates of stenting in long segmental occlusions are inferior to those in discreet stenotic lesions, so thoughtful consideration is necessary before deciding a stent placement for long segment occlusion.

Until now, endovascular treatment of the iliac artery was not considered appropriate in cases of ASO complicated by broad occlusions of the infrainguinal arteries. We have expanded the indications for stenting by combining infrainguinal bypass surgery with iliac artery stenting, and by attempting complete revascularization with minimal invasion. We have, thus far obtained good results. Morikei *et al.*[16] carried out iliac artery PTA or stenting associated with femoropopliteal bypass surgery in 6 cases and reported that intraoperative hemorrhage in the 6 limbs was significantly less than that in 31 limbs treated by aortofemoro-popliteal bypass. The patients were discharged more quickly after surgery.

The number of patients with ASO and critical limb ischemia due to multiple occlusive lesions who are willing to undergo complete revascularization for limb salvage has increased recently. However, these patients are usually older people who often have many complications such as ischemic heart disease, renal dysfunction, or chronic obstructive pulmonary disease. Before considering revascularization in such patients, it is necessary to attempt efficient and less invasive treatments. Therefore, we feel that combined endovascular treatment and infrainguinal open surgery will increase in the future.

Stenting can incur serious complications that require emergency surgery. Such complication include perforation, wide-ranging dissection of the artery, stent migration[17] acute arterial occlusion, and minor complications include hemorrhage from the puncture site, hematoma, pseudoaneurysm, arteriovenous fistula, local artery dissociation, and distal embolism. Oshiro *et al.*[18] reported that 4 of 25 patients (16%) required some kind of surgery after stenting, so

complications are not rare. There were no serious complications in our patients; however, we experienced localized dissection that occurred in 5 patients (27.8%) during the pre-PTA stage or guidewire manipulation. In addition, we had an unexpected insufficient stent expansion due to rupture of the balloon inside the stent. Fortunately, stent migration did not occur in this case, so we were able to handle this by PTA.

Although further follow-up studies are needed to evaluate long-term efficacy, our current results indicated that primary stenting for segmental iliac lesions is safe, minimally invasive, and as functional as conventional open surgery. We expect primary stenting to be of great benefit to patients in the future as the use of this technique increases.

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