Treatment of Iliac Artery Aneurysms by Percutaneous Implantation of Stent Grafts

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Background—Iliac artery aneurysms have traditionally been treated by direct surgical reconstruction. Endovascular stent grafts have been developed to provide an effective but less invasive treatment option for patients with peripheral arterial aneurysms.

Methods and Results—In 48 patients, a total of 53 endoprostheses (mean length 7.3 cm, mean diameter 8.1 mm) were implanted into the iliac arteries (common iliac artery n=29, external iliac artery n=19) for percutaneous exclusion of aneurysmal lesions. The technical success of complete exclusion of the aneurysm was achieved in 47 of 48 cases (97.9%). In 1 case, persistent perfusion through a collateral branch was detected; however, this aneurysm thrombosed spontaneously within 2 weeks. In all patients, graft patency was monitored by clinical examination, which included the standardized treadmill test with calculation of the ankle-brachial Doppler index and color-coded duplex ultrasound. Forty-two of the 48 patients (87.5%) underwent follow-up angiography. According to Kaplan-Meier life-table calculations, primary patency rates were 100% after 1 year, 97.9% after 2 years, 94.9% after 3 years, and 87.6% after 4 years. Serial contrast-enhanced spiral CT scans were performed to rule out late procedural failures and to assess growth progression of the lesions. No secondary leaks were observed. Furthermore, the aneurysm diameter had reduced from 24.8±8.0 mm to 23.1±6.6 mm at the last follow-up (P=NS).

Conclusions—Stent grafts are a safe and effective treatment option for iliac artery aneurysms and provide good long-term patency of the graft. (Circulation. 2000;102[suppl III]:III-253-III-258.)

Key Words: aneurysm ■ arteries ■ stents ■ peripheral vascular disease ■ surgery

Isolated aneurysms of the iliac arteries are relatively uncommon and represent ≈2% to 7% of all intra-abdominal aneurysms.1–3 Most of the aneurysms remain asymptomatic, and specific symptoms caused by local compression, thrombosis, or atheromatous embolization are rarely observed. Consequently, diagnosis of iliac artery aneurysms is usually made incidentally during ultrasound, CT scanning, or angiography.

Although data on the natural history of iliac artery aneurysms are limited because of their rare occurrence, expansive growth and subsequent rupture has been well documented in several series.2,4 Therefore, elective surgical reconstruction is considered to be the treatment of choice.

Similar to surgical reconstruction of abdominal aortic aneurysms, open surgical graft placement for iliac aneurysm repair is a major procedure, which is associated with considerable procedure-related morbidity and mortality rates. The development of transliminally placed endovascular stent grafts, which have been extensively studied for aneurysm exclusion in the abdominal and thoracic aorta, offers a less invasive approach for exclusion of iliac artery aneurysms.

The purpose of this article is to evaluate the acute and follow-up results of percutaneous endovascular stent-graft exclusion of isolated iliac artery aneurysms.

Methods

Patients

Between January 1994 and March 1998, a total of 57 patients were referred to our institution for percutaneous treatment of isolated unilateral iliac artery aneurysms. In this study, patients with complex aneurysmatic lesions including bilateral or multilevel aneurysmal disease or aneurysms of the internal iliac artery were not considered appropriate candidates for percutaneous treatment. In a further 6 cases with unilateral common or external iliac artery aneurysms, the vascular pathology was not suitable for endovascular treatment because the aneurysm extended into the aortic bifurcation that provided an inadequate proximal neck (<1.5 cm). In another 3 cases, large collateral branches from the hypogastric artery were present that communicated with the aneurysm sac. Although coil embolization before endovascular grafting may have resulted in aneurysm exclusion, these patients were excluded from the study. All patients who were not considered for percutaneous treatment were referred for surgical reconstruction. In the remaining 48 patients, percutaneous implantation of stent grafts was performed for aneurysm exclusion.

The baseline clinical characteristics of the study population are given in Table 1. Twenty-eight patients had coexistent coronary artery disease and 7 patients had renal insufficiency with an elevated mean baseline serum creatinine level of 1.7 mg/dL. In 37 cases, symptomatic peripheral arterial occlusive disease was present. According to the Rutherford classification,4 6 patients were graded as category 1, 13 as category 2, 17 as category 3, and 1 as category 4.
Obstructive lesions were localized in the iliac level in 21 cases and in the femoropopliteal or infrapopliteal arteries in 16 patients. In 13 cases, coexistent stenoses of the ipsilateral iliac artery were treated before or after exclusion of the iliac artery aneurysm during the same procedure. In 11 patients, recanalization procedures at other target vessels were carried out before hospital discharge.

The aneurysms were localized in the common iliac artery in 29 and in the external iliac artery in 19 cases. Aneurysm size was calculated by means of intra-arterial angiography and contrast-enhanced spiral CT. Lesions were considered aneurysmatic if the diameter had at least twice the size of the reference vessel. According to the preinterventional spiral CT scans, the maximum aneurysm diameter varied between 16 and 55 mm (median 28 mm), with a mean diameter of $24.8 \pm 8.0$ mm. Mean aneurysm length calculated from the preinterventional angiography was $3.8 \pm 1.6$ mm. Only 4 patients (8.3%) were symptomatic, with lower abdominal discomfort and a palpable pulsatile mass. Three patients (6.2%) with symptomatic peripheral arterial occlusive disease (Rutherford category 3, n=2; category 4, n=1) exhibited an occlusion of the distal popliteal artery and the tibioperoneal trunk, which was presumably the result of thromboembolic embolization from ipsilateral iliac artery aneurysms.

Endovascular Stent Graft Devices and Implantation Technique

In total, 53 endovascular stent grafts were implanted. The mean total length of the stent graft was $73 \pm 22$ mm, with an average diameter of $8.1 \pm 0.8$ mm.

In 37 cases, Dacron-covered self-expanding nitinol endoprostheses (Cragg EndoPro System 1, Mintec) were used. In a further 6 patients, a second-generation device with a similar construction (Passager, Boston Scientific) was implanted. The Wallgraft endoprosthesis (Boston Scientific), which is a recently developed, fully supported stent graft system covered with medium-porosity PET-graft material, was implanted in 5 cases (Figure 1).

In all cases, the endoprostheses were implanted percutaneously after local anesthesia of the puncture site. Implantation of stent grafts was performed retrogradely by the use of access through the ipsilateral common femoral artery (F8-10 hemostatic sheath). Sheaths were removed immediately after the procedure. In 18 patients, a percutaneous vascular suture system (Prostar, Perclose) was used. In the remaining cases, hemostasis was achieved by manual compression.

Peri-interventional heparin (10,000 IU) was given intra-arterially. Postinterventional anticoagulation was continued with heparin (1000 to 1200 IU/h IV, activated partial thromboplastin time 60 to 80 seconds) for 24 to 48 hours, which was followed by low-molecular-weight heparin (Fraxiparin, Sanofi Winthrop GmbH) twice daily for 2 weeks. All patients received a combination of 100 mg OD ASA and 250 mg BID ticlopidine for 6 weeks.

Definition of Procedural Success

The result of stent graft implantation was documented angiographically by the use of at least 2 different projections. Procedural success was defined as accurate positioning of the endoprosthesis that achieved complete exclusion of the aneurysm, and in cases of coexistent obstructive lesions, a residual diameter stenosis of <30%.

Follow-Up

All patients were included in a follow-up protocol that used clinical examination, a standardized treadmill test (5 minutes at 2 mph, 12% incline) with calculation of the ankle-brachial Doppler index (ABI) before and after exercise, and color-coded Doppler studies on hospital discharge, after 3, 6, 12, 18, and 24 months and then yearly. Follow-up angiograms were obtained in 42 of 48 patients (87.5%) at 17±7 months of follow-up. Six asymptomatic patients refused consent for follow-up angiography.

To rule out late procedural failures, including secondary leaks or reperfusion of the aneurysm through collateral branches, patients were scheduled for sequential contrast-enhanced spiral CT scanning at 6, 12, and 24 months after intervention. Furthermore, the postinterventional development of the aneurysm size was evaluated in comparison with the preinterventional value.

Definitions of Patency

Primary patency refers to uninterrupted patency of the endoprosthesis with no procedures performed on or at the margins of the treated vessel segment. Secondary patency was defined as patency of the target vessel including cases in which blood flow could be restored by successful repeat interventions for restenoses or reocclusions.

Statistical Analysis

Data are presented as mean value±SD where appropriate. In case of a non-gaussian distribution, median and range are given. Continuous variables are compared by paired Student’s t test (baseline and follow-up). A value of P<0.05 was considered statistically significant. Cumulative patency rates were calculated by means of the Kaplan-Meier life-table method.
Results

Acute Procedural Results
A primary technical success with an instant exclusion of the aneurysmal lesion was achieved in 47 of 48 cases (97.9%). In 1 case, a residual perfusion of the iliac artery aneurysm through a collateral branch from the contralateral hypogastric artery was present; however, the residual perfusion resolved spontaneously within several days. At the next follow-up examination 2 weeks after the initial procedure, a completely thrombosed aneurysm with no residual flow outside the endoprosthesis was found during color-coded ultrasound and contrast-enhanced spiral CT scanning.

Twenty-three of the 37 patients (62.2%) with claudication or rest pain showed a marked clinical improvement of at least +2 in limb status grading, according to the American Heart Association guidelines, immediately after the interventional procedure. The ABI increased at rest from 0.71 ± 0.19 to 0.93 ± 0.15 (P<0.01) and after the treadmill test from 0.51 ± 0.18 to 0.89 ± 0.16 (P<0.01).

Complications
There were no serious procedural or postprocedural complications. Minor puncture site complications were observed in 2 cases (4.2%), which included 1 groin hematoma (2.1%) without the need for transfusion and 1 false aneurysm (2.1%) that was treated by ultrasound-guided compression. In 8 patients (16.7%), on the first or second postintervention day after implantation of the EndoPro System1, a significant rise in body temperature (mean 38.8°C) occurred. Concomitantly, the white blood cell counts were also elevated up to a mean of 15.6/nL in 7 patients (14.6%), and the C-reactive protein levels were increased (mean 13.6 mg/dL) in 11 cases (22.9%). Repeated blood cultures did not reveal any bacterial growth. Because the clinical course was always self-limiting, the fever and laboratory findings are most likely attributable to a foreign body–type of reaction against the implant. With an average of 6.4 versus 3.1 days, the time of in-hospital stay was markedly prolonged in the group of patients who had fever and elevated inflammatory markers.

Follow-Up

Patency of Stent Grafts
Clinical follow-up examinations, which included the treadmill test, calculation of ABI values, and color-coded Doppler ultrasound, were undertaken within a mean of 35 ± 10.6 months (range 16 to 55 months). During this period, there were no cases of graft occlusion.

In 4 cases, clinical failure with a recurrence of claudication and decreased ABI values were observed. These 4 patients belonged to the group with coexistent peripheral arterial occlusion disease, 2 of whom had undergone balloon dilatation for iliac artery stenoses. In 3 of these 4 symptomatic cases, the follow-up angiography revealed significant restenoses of the endoprosthesis. In 2 cases, a marked intimal hyperplasia with a 70% diameter stenoses was found at the outlet of the endoprosthesis. In 1 case, the restenoses was localized at the entrance of the stent graft. In the remaining patient with clinical recurrence, angiography confirmed the patency of the endoprosthesis in the iliac location. However, a de novo stenosis in the ipsilateral superficial femoral artery was present, which was recanalyzed by PTCA during the same intervention.

A Kaplan-Meier life-table calculation of the primary angiographic patency rate is given in Table 2. Because all restenotic lesions were successfully treated by PTCA, the secondary patency rate during follow-up was 100%.

Contrast-Enhanced Spiral CT Findings
Serial contrast-enhanced spiral CT scans were performed in all patients (Figure 2). In none of the cases was there evidence of secondary procedural failures, which included secondary perigraft leaks, graft displacement, or reperfusion of the aneurysmal lesion. Maximum aneurysm diameters calculated from the CT images obtained before and after implantation of the stent graft as well as the value from the last available follow-up scan (mean 32 ± 11.3 months after intervention) are shown in Figure 3. Overall, there was no statistically significant change in aneurysm size. Minimal progression of the aneurysm diameter by 3 and 4 mm, respectively, was detected in 2 cases at 6 months. Repeated follow-up scans confirmed that no further progressive growth occurred.

Discussion

Occurrence and Natural History of Isolated Iliac Artery Aneurysms
Aneurysmal lesions of the iliac arteries are most commonly associated with aneurysms of the abdominal aorta. In patients with abdominal aortic aneurysms, an involvement of the iliac arteries has been reported, with a frequency of up to 50%. In contrast, isolated iliac artery aneurysms represent a rare entity. According to autopsy studies from both North America and Europe, the incidence of isolated iliac aneurysms varies between 0.03% and 0.1%, as compared with 3.8% for abdominal aortic aneurysms. Iliac artery aneurysms are

### TABLE 2. Cumulative Patency Rates (Kaplan-Meier Life-Table Method)

<table>
<thead>
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<th>Follow-Up, mo</th>
<th>No. of Patients</th>
<th>Lost to Follow-Up</th>
<th>Local Events</th>
<th>Patency, %</th>
<th>SD</th>
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<td>5</td>
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<td>97.9</td>
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<tr>
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<td>17</td>
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<td>94.9</td>
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<tr>
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<td>14</td>
<td>1</td>
<td>87.6</td>
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...
also rare in a vascular surgeon’s clinical practice, with a reported frequency of <2%.2

Despite their rarity, several reports have suggested that isolated iliac artery aneurysms have a high risk of rupture, with an associated high mortality rate of up to 80%.4,10 Aneurysm expansion occurs in 36% of patients at a rate of 4 mm/y11; however, the critical size at which an aneurysm might rupture is unclear.

**Surgical Treatment**

Although definitive guidelines for the treatment of this relatively uncommon vascular pathology are not available, elective surgical treatment is indicated in the majority of patients. Surgical reconstruction with aneurysm resection and graft interposition is a relatively complex procedure. Mortality rates of 11% and 13% have been reported for elective procedures in 2 recent studies.4,12 Furthermore, significant operative morbidity has been seen, which includes ischemia of the lower extremities, hemorrhage, sepsis, ureter injury, renal failure, and graft infection. However, these data on morbidity and mortality are derived from unselected surgical cohorts with a high percentage of complex aneurysmatic lesions, including multiple aneurysms and large aneurysms of the internal iliac artery. Furthermore, the average diameter was relatively high (mean 5.5 cm in Reference 7). Therefore, a direct comparison with the complication rate observed in our study, which included uncomplicated aneurysmatic lesions of the iliac arteries, is not possible.

**Percutaneous Treatment: Previous Results**

The feasibility of placing endovascular stent grafts for percutaneous exclusion of aneurysmal lesions has been demonstrated in animals and human beings.13,14 The first clinical experiences, particularly with stent graft placement for exclusion of abdominal aortic aneurysms, were promising.15 Experience with the percutaneous placement of endovascular stent grafts for repair of iliac artery aneurysms is limited to case reports and small series of patients with limited follow-up.

Marin et al16 described in 1995 the transfemoral endovascular repair of 14 iliac aneurysms in 11 patients by means of stent grafting and achieved a 100% technical success rate with no procedural deaths and no acute or late graft occlusions during a mean follow-up of 11 months. Similar results were achieved by Razavi et al.17 They successfully treated 9 isolated iliac aneurysms in 8 patients, but the median follow-up was only 8.5 months.17 The most extensive experience of endovascular repair of iliac artery aneurysms comes from a multicenter French study.18 Twenty-seven iliac aneurysms in 26 patients were percutaneously treated by stent graft implantation. The immediate failure rate in this study was 18.5%: 1 patient died of bleeding from an arterial puncture site, 2 patients had failure of device insertion, and 2
patients had persistent flow within the aneurysm. The follow-up time was again limited to a mean of 12 months, with 1 graft occlusion and 1 restenosis.

Percutaneous Treatment: Technical Considerations

In a considerably large group of patients, we achieved a technical success rate of 97.9% with only 1 patient, who exhibited residual flow in the aneurysm through a collateral branch.

Potential problems during the stent-graft implantation can be avoided in the majority of the cases, provided a critical selection of patients is undertaken with regard to their suitability for a percutaneous aneurysm exclusion procedure. In our study, only patients with a sufficient proximal and distal neck of ≥1.5 cm as assessed by preintervention angiography were considered candidates for stent graft treatment. For patients with iliac artery aneurysms that extended into the aortic bifurcation, which could potentially be excluded by bifurcated stent grafts, elective surgical reconstruction was considered to be the better treatment option. In all patients, preintervention contrast-enhanced spiral CT scanning was performed to measure the size of the aneurysm and the proximal and distal neck. Furthermore, CT scanning provided information about the presence and extent of thrombotic material within the aneurysmal sack. Thrombotic material adherent to the vessel wall in the area of the proximal or distal fixation zone of the endoprostheses may be a cause of secondary leaks and subsequent late procedural failure. Thus, preintervention angiography and CT scanning helped to obtain information that was essential for the choice of the optimum length and diameter of the endoprostheses.

Selective coil embolization has been described for the percutaneous treatment of iliac artery aneurysms. Furthermore, this technique has been used as an adjunctive treatment combined with stent graft implantation for aneurysms with significant perfusion through collateral branches. Although this method may be of potential value in selected cases, experience with this technique as an adjunct to percutaneous aneurysm exclusion is limited. In this study, 3 patients were finally referred for surgery because of large collateral branches from the hypogastric artery.

Complications

Major procedure-related complications, such death, major bleeding, distal embolization, and transient bowel ischemia, which have been reported in single cases by Marin et al and Cardon et al, were not observed in our study. Again, optimum preintervention imaging of the vascular pathology by the use of angiography and routine contrast-enhanced spiral CT scanning may have contributed to the avoidance of complications.

After implantation of the Cragg EndoPro System 1, a considerable number of the patients had a rise in body temperature as well as elevations of the white blood cell counts and the C-reactive protein levels. Repeated blood cultures were taken, but in none of the cases was bacterial growth observed. Similar findings after implantation of Dacron-covered Nitinol stents have been reported by other authors. As the course was always self-limiting, this “post-implantation syndrome” is most likely attributable to a foreign body type of reaction against the implant. Using helical CT scans Sapoval et al demonstrated an edematous reaction adjacent to the endoprostheses. Kellner et al confirmed this finding by the use of magnetic resonance tomography. In 79% of the cases, they could find perivascular inflammatory reactions after implantation of Dacron-covered endoprostheses.

The relevance of this phenomenon is difficult to determine. The in-hospital stay was markedly prolonged in patients with postintervention inflammatory reactions. In consequence, the treatment-related costs were significantly increased. Furthermore, there is some evidence that the postintervention inflammation may lead to an accelerated proliferative response that subsequently promotes restenotic processes. As a result, it seems reasonable to focus future research on the development of alternative covering material.

Long-Term Follow-Up

Limited follow-up time of up to a maximum of 12 months has been the major limitation of all previous studies that dealt with percutaneous stent graft treatment of iliac artery aneurysms. To obtain data concerning the long-term patency of the endoprostheses, all of the patients of our study were enrolled in a follow-up protocol that included treadmill testing, color-coded Doppler sonography, and angiography. Primary patency rates of 97.9% after 2 years and 87.6% after 4 years are within the range reported for stent-supported angioplasty of iliac artery stenosis and are comparable to surgical results.

To assess the long-term durability of the procedure and to obtain data about the development of the aneurysm size after successful treatment, serial contrast-enhanced spiral CT scans were performed in all patients. No late procedural failures, such as rupture, progressive aneurysm growth, or reperfusion of the aneurysm through perigraft leaks or collateral branches were found. With regard to aneurysm size, there was no statistically significant change in maximum aneurysm diameter.

Conclusions

Percutaneous exclusion of iliac artery aneurysms by implantation of endovascular stent grafts is a feasible and safe method, which is associated with a very low procedure-related morbidity and mortality rates. The critical selection of the patients with regard to their suitability for a percutaneous aneurysm exclusion procedure should be performed and based on the preintervention angiography and routine contrast-enhanced spiral CT scans. Excellent long-term patency of the graft and the durability of the aneurysm exclusion have been demonstrated in this study. Thus, for selected patients, this minimally invasive procedure may be the primary alternative to open surgical repair.

References


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