Bifurcated Endograft in Aortoiliac Type C and D Lesions: Long-Term Results

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ABSTRACT

Purpose: To report long-term outcome when using a bifurcated aortic endograft for treatment of aortoiliac occlusive disease (AIOD) in Trans Atlantic Inter Society Consensus (TASC) classification C and D patients.

Materials and Methods: Between May 2001 and May 2009, 14 patients (11 men, 3 women) with aortoiliac TASC C and D type lesions and a mean age of 59 years (range 41–73 years) were treated using a bifurcated aortic endograft. Although these patients were young, all were considered at high surgical risk. Patients were followed up clinically and by computed tomography (CT) every 3 months for 1 year and yearly thereafter.

Results: Endoprosthesis placement was performed in all patients with a technical success rate of 100%. There were no amputations or deaths at 30 days after the procedure. The mean follow-up was 62 months (range 11–96 months). One patient was lost during follow-up at 11 months, and another patient died of a nonrelated cause after 49 months. A single limb occlusion of the prosthesis was seen in two patients at 2 months and 7 months; both were successfully treated by intraarterial fibrinolysis. At a mean follow-up of 62 months, primary patency was 85.7%, and secondary patency was 100%.

Conclusions: This series shows promising long-term results following the use of a bifurcated aortic endograft for treatment of AIOD TASC C and D type lesions. Bifurcated aortic endograft is a good minimally invasive alternative to open surgery in high surgical risk patients.

ABBREVIATIONS

ABI = ankle-brachial index, AIOD = aortoiliac occlusive disease, TASC = Trans Atlantic Inter Society Consensus

There is controversy regarding the ideal therapeutic approach for aortoiliac occlusive disease (AIOD). Traditional treatment consists of endarterectomy and aortobifemoral bypass, with excellent long-term results. Surgical reconstruction offers the best overall patency rates of 80%–90% at 5–10 years (1). However, this excellent long-term outcome is associated with major complication rates of 8.3% and a 3.3% perioperative mortality rate (2). As promising alternatives to open surgery, several endovascular techniques have been progressively introduced in the aortoiliac territory with the development of “kissing balloon,” “kissing stent,” and “kissing stent graft” techniques. These techniques show acceptable results with primary patency rates after bare stent deployment of 74%–89.9% at 3 years and 74%–82% at 5 years (3–7). The use of covered stents might increase patency with primary patency rates of 84%–92% at 2 years (8,9).

Angioplasty with optional stent placement in a kissing technique is not always indicated because arteriosclerotic disease might extend into the distal aorta. Excessive stent overlap and radial mismatch of aortic lumen dead space around the protruding segment of the stents have been reported with failure of kissing stents in the aortic bifurcation (10,11).

A bifurcated aortic endovascular prosthesis has been used for >10 years in the treatment of aortic aneurysmal disease. In 2005, we published our preliminary experience with the use of a bifurcated endoprosthesis as an alternative therapeutic option in the treatment of complex AIOD in selected patients with severe comorbid
conditions and critical limb ischemia (12). Our study showed that the use of a bifurcated endoprosthesis is a technically feasible and less invasive therapeutic alternative with promising good short-term results. Data for long-term follow-up were unavailable, however. The purpose of this article is to report the long-term outcome after endovascular treatment of nonaneurysmal AIOD using a bifurcated aortic endovascular prosthesis.

**MATERIALS AND METHODS**

Between May 2001 and May 2009, 14 patients (11 men and 3 women) with a mean age of 59 years ± 10 (range 41–73 years) underwent endovascular treatment for AIOD using a bifurcated aortic endovascular prosthesis. Five of these patients were already part of a preliminary report (12). Table 1 lists the patients’ demographic data. Indications for treatment were critical limb ischemia (ulceration, gangrene, or rest pain) in seven patients (50%) and a history of severe claudication (< 200 m) in the remaining seven patients (50%). According to the Trans Atlantic Inter Society Consensus (TASC II) classification on the morphologic stratification of iliac lesions, all of these patients had complex stenoocclusive lesions extending into the distal aorta and were classified as TASC C and D (13).

All patients were deemed nonsurgical candidates because of high-risk factors such as cardiac disease, hostile abdomen, or obesity. A conventional endovascular approach such as the kissing stent was not indicated in these patients because complex arteriosclerotic lesions extended into the abdominal aorta.

**Definitions**

Technical success was defined as restored patency with a residual stenosis of < 30%. Clinical success was defined as at least a twofold improvement according to the Limb Status Grading System (14). A complication was defined as any untoward event after the procedure with a lasting unfavorable effect or an event requiring a change in management. Primary patency referred to uninterrupted patency with no procedures performed on or at the margins of the treated segment. Only procedures performed proximal or distal to the initially treated segment to treat progression of disease in an adjacent native vessel were exempted. Secondary patency was defined as any procedure that restored patency after thrombosis (15). Limb occlusion was defined as absence of flow through the device with or without intraluminal thrombosis (16).

**Follow-Up Protocol**

Clinical follow-up examination including palpable common femoral artery pulses, the presence or absence of claudication, and ankle-brachial index (ABI) measurement was performed at discharge; at 3, 6, 9, and 12 months; and every 6 months thereafter. Computed tomography (CT) angiography (nonenhanced images, 10-mm slice thickness; arterial-phase contrast-enhanced images, 2.5-mm slice thickness) was performed at each follow-up. After 2005, our internal protocol changed to the following: During the first year, follow-up and CT angiography were performed as mentioned previously (at 3, 6, 9, and 12 months); however, after the patient concluded the 12-month follow-up, control CT angiography was performed annually only.

**Endovascular Procedure**

All consecutive patients with AIOD received endovascular treatment according to the protocol approved by our local institutional review board. After giving written informed consent, all patients with an occlusion of at least one access vessel underwent a two-step procedure; otherwise, the endograft was placed directly after balloon dilation in the same session.

First, standard digital subtraction angiography was performed through a 5-F brachial (in cases of Leriche syndrome) or contralateral femoral access (side of one patent iliac axis) to delineate the extent and severity of AIOD (Fig 1a and b). In cases of total aortic or iliac occlusion, the occlusive segment was crossed using either a straight or an angled 0.035-inch wire (Radifocus Guide Wire M; Terumo, Europe N.V., Leuven, Belgium). Reentry devices were not needed in any patient in this series.

If the occlusive lesion was crossed in an intraluminal way, a 24-hour catheter-directed intraarterial fibrinolysis session was initiated using an open-ended perfusion wire (Medtronic Vascular, Danvers, Massachusetts). Technical details have been described previously (17,18). Control angiography after 24 hours was performed to confirm lumen restoration. The underlying stenotic lesions were dilated with angioplasty balloons (OPTA; Cordis, Miami, Florida) ranging from 6 × 40 mm to 8 × 40 mm in size depending on the original artery diameter. If the lesion was crossed in a subintimal way, initial angioplasty was performed using balloon catheters (OPTA) ranging from 4–6 mm in diameter to open a channel and enable later recanalization.

**Table 1. Demographic Data, Symptoms, and Risk Factors**

<table>
<thead>
<tr>
<th>Risk Factors and Clinical Setting</th>
<th>No. Cases</th>
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</thead>
<tbody>
<tr>
<td>Sex (male/female)</td>
<td>11/3</td>
</tr>
<tr>
<td>Age (y)</td>
<td>59 ± 10</td>
</tr>
<tr>
<td>Hypertension</td>
<td>10</td>
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<tr>
<td>Diabetes mellitus</td>
<td>4</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>8</td>
</tr>
<tr>
<td>Current smoking</td>
<td>12</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>6</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>3</td>
</tr>
<tr>
<td>Chronic renal failure</td>
<td>2</td>
</tr>
<tr>
<td>Claudication</td>
<td>7</td>
</tr>
<tr>
<td>Chronic critical limb ischemia</td>
<td>7</td>
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</tbody>
</table>
In the second step, a bifurcated aortic endovascular prosthesis was placed to restore the aortoiliac bifurcation. In all cases, the Excluder prosthesis (W.L. Gore Associates, Flagstaff, Arizona) was used. The procedures were performed in a standard operating room equipped with a digital C-arm angiographic unit (Integris V2000; Philips Medical Systems, Best, The Netherlands). Under general anesthesia, the common femoral artery on the side with more favorable anatomy was exposed through a surgical cutdown. There was no need for a conduit. Technical details of endograft placement were described in a previous report (12).

Contralateral limb collapse of the prosthesis body was found in most cases because the diameter of the prosthesis exceeded the width of the distal aortic lumen. Recanalization of the contralateral leg orifice was performed through an antegrade access using a brachial (5-F) approach or through the ipsilateral prosthesis leg. The guide wire was snared from the contralateral common femoral artery, and a balloon catheter was inflated to expand the contralateral leg orifice using the “through and through” technique (Fig 2a and b). Finally, the contralateral limb component was introduced (12-F) through the contralateral common femoral artery and was attached with a 3-cm overlap to the body of the bifurcated aortic endovascular prosthesis (Fig 2c). Both limb components were dilated using the kissing technique with 12-mm diameter balloon catheters (OPTA) at each site (Fig 2d). If the limb length of the bifurcated aortic endovascular prosthesis was inadequate to cover lesions in the external iliac artery, additional endovascular prostheses were used as extenders to restore the luminal diameter.

After completion of the procedure, angiography was performed to document the postgrafting status, the patency of the hypogastric arteries, and distal runoff (Fig 3). The surgical cutdown was repaired surgically; meanwhile, the puncture of the contralateral limb component was closed by manual compression to minimize risk of potential complications produced by percutaneous closure devices.

**Statistical Analysis**

Time-to-failure curves for patency were calculated using the Kaplan-Meier analysis method. The specific failure event was defined as thrombosis of one or both prosthesis legs. Variables are presented as mean ± standard deviation, with maximal and minimal values, when indicated.

**RESULTS**

All 14 patients included in this study underwent preprocedural angiography that revealed diffuse occlusive lesions in the aortoiliac region, and all lesions were classified as TASC C (n = 3) or D (n = 11) lesions. Of these patients, three presented with bilateral common iliac artery occlusion and distal aortic lesions; unilateral occlusion of the common and external iliac arteries combined with complex aortic lesions were found in four patients, six patients had diffuse disease involving the aorta and both iliac arteries with hemodynamically significant stenosis, and one patient was treated for chronic occlusion of the infrarenal aorta. Intraluminal recanalization and fibrinolysis were performed in five (36%) patients. Subintimal recanalization before endoprosthesis placement was necessary in three (21%) patients. In the remaining six (43%) patients, percutaneous
transluminal angioplasty was necessary to position the endoprosthesis; this was carried out in the same session. Endoprosthesis placement was performed in all patients with a technical success rate of 100%. Mean aortic lumen diameter was 8 mm ± 4.7. There were no amputations or deaths at 30 days after the procedure. Immediate hemodynamic success was achieved in all patients. ABI improved from 0.69 ± 0.14 before aortoiliac reconstruction to 0.94 ± 0.07 at hospital discharge (P = .01). The ABI at the latest follow-up was 0.91 ± 0.12.

The duration of the endovascular procedure was 175 minutes ± 45 (minimum 90 minutes, maximum 222 minutes). The mean hospital stay was 7 days ± 1 (minimum 6 days, maximum 8 days), with only 1 day of intensive care unit admission for each patient. Endovascular prosthesis patency was confirmed by CT angiography (Fig 4) and duplex sonography at discharge.

Additional outflow endovascular procedures were required directly after endoprosthesis placement. Additional extenders were placed to cover longer occlusive lesions in the external iliac arteries in four (29%) patients. Self-expanding Smart stents (Cordis) were necessary in five (36%) patients to manage either residual stenosis or arterial dissections compromising the iliac arteries and to adapt distal prosthesis limb diameter to iliac artery diameter.

In one (7%) patient, a renal artery ostium stenosis was treated with the placement of a balloon-expandable Hercu-link stent (Guidant Europe NV, Diegem, Belgium) in the same session as the endograft placement. However, a thrombus in the left renal artery was detected after stent placement. This thrombus was thought to be due to juxtarenal aortic mural thrombus migration. The patient was successfully treated with intraarterial administration of 500,000 urokinase units (Uroquidan; UCB Pharma S.A., Barcelona, Spain), and patency was confirmed by an angiogram obtained 45 minutes later.

The mean follow-up was 62 months (minimum 11 months).

**Figure 2.** (a) The collapsed contralateral leg was recanalized through the prosthesis body, then the wire was snared from an ipsilateral femoral access, and a balloon catheter was introduced. (b) The balloon was inflated to dilate the contralateral prosthesis leg orifice. (c) The contralateral leg component was introduced with a 3-cm overlap to the body of the bifurcated endoprosthesis. (d) Both limbs were dilated using a progressive kissing technique to achieve full expansion of the prosthesis.

**Figure 3.** Final angiogram shows a patent bifurcated aortic endovascular prosthesis with remodeling of the aortoiliac bifurcation.
months, maximum 94 months). Only one patient was lost during this period (11 months), and another patient died of a nonrelated cause (lung cancer) after 49 months. Two major complications occurred in the follow-up period: Two patients presented with acute limb ischemia at 7 months and 2 months. After performing angiography, a diagnosis was made in both cases of acute single leg prosthesis occlusion (left leg in one patient and right leg in the other patient); this was successfully treated with intraarterial fibrinolysis through a percutaneous approach. An aortoiliac outflow impairment was detected in both cases. One patient presented with a stenosis in the overlapping segments of the bifurcated prosthesis in the left leg and a stent that had been placed in the external iliac artery 2 years earlier. In this patient, the prosthesis remained patent up to the most recent follow-up. In the other case, natural evolution of atherosclerotic disease was detected. This patient (left limb occlusion after 7 months) was lost to follow-up after 11 months.

Only one patient experienced intermittent claudication, which appeared 5 months after the procedure. Diagnostic angiography showed a 75% stenosis in the left distal superficial femoral artery that was successfully treated with balloon angioplasty, and the patient has remained asymptomatic up to the most recent follow-up. The stenosis was related to the evolution of atherosclerotic disease in this patient and was not considered as a treatment failure. Kaplan-Meier survival analysis showed an 85.7% cumulative patency rate at 8 years (Fig 5), with a secondary patency rate of 100%.

**DISCUSSION**

For many years, the traditional treatment for complex AIOD has been an aortobifemoral bypass graft. With the progressive development of minimally invasive techniques, different series have been published applying endovascular techniques in the treatment of patients with AIOD, most of them with very good results (3,19,20).

However, patency of conventional endovascular procedures is influenced by geometric variables related to individual aortic anatomy and disease pattern (11). Stent configuration in the aortoiliac confluence has an impact on
gated systemic morbidity risk of 13.1% in older studies and compared with 3.3% in more recent studies with an aggregate review of data regarding morbidity and mortality. The most extensive review of data regarding morbidity and mortality (21) showed an operative mortality risk of 4.6% in older studies and 8.3% in more recent studies (1,2). The benefit of a bifurcated endoprosthesis for the management of abdominal aortic aneurysms has been shown, with a reduced rate of perioperative complications and adverse events (22). In our series, one thromboembolic event occurred, which was treated successfully by intraarterial fibrinolysis in the same procedure.

There are two important limitations related to using a bifurcated prosthesis in patients with complex AIOD. The first is the ability to achieve recanalization of the occluded segments. We do not consider any occluded artery to be a lost artery. Occluded artery recanalization can be accomplished in most cases with catheter-directed intraarterial fibrinolysis (18).

The second important limitation is the aortic lumen diameter. A normal or decreased diameter of the aorta or iliac arteries might introduce a technical problem to the procedure. The Excluder endoprosthesis has a low profile and flexible delivery system for access and navigation, which are particularly appealing for a distal aortoiliac application when severe stenotic lesions are present. Its flexible design and its conformability also allow perfect adaptation to the arterial wall in the reduced intravascular space. Use of the Excluder endoprosthesis in this condition is supported by published series in which bifurcated prostheses were placed in cases of isolated iliac aneurysmal disease in which the aorta was not aneurysmal (23–25). Because the mean aortic diameter in this series was 8 mm ± 4.7, optimal deployment of the bifurcated aortic endovascular prosthesis with a 23-mm diameter required a complex procedure (see Materials and Methods). After the correct placement of the contralateral limb, both limbs were dilated in a progressive kissing technique to their final diameter, and iliac extenders or Smart stents were used to adapt the limb diameter to the iliac artery diameter. The diameter of the aortic lumen is not an absolute limitation, but technical skills are required.

A major limitation of this series is the absence of a randomized control group. In addition, the series comprised a small number of patients reporting results from a single group. However, we believe that this approach could be a good alternative in the treatment of aortoiliac TASC C and D type lesions. Our results show patency rates that compare favorably with results in the literature for open surgery combined with the benefits of a minimally invasive procedure. However, these results must be reproduced and tested by other operators.

Although controversial, to date, the consensus treatment for AIOD in TASC C and D lesions is still aortoiliac bypass surgery. We believe that the use of a bifurcated aortic endovascular prosthesis for the treatment of complex AIOD would be an excellent treatment choice in expert hands because it combines excellent long-standing patency with low perioperative morbidity and mortality rates.
REFERENCES