Primary balloon expandable polytetrafluoroethylene-covered stenting of focal infrarenal aortic occlusive disease

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Background: Focal infrarenal aortic occlusive disease requiring treatment is an uncommon condition. Short lesions may be treated endovascularly, while long lesions are traditionally treated by surgery. Advances in endovascular devices, including development of covered stents, may expand endovascular options. This study evaluates the feasibility, safety, and midterm results of primary polytetrafluoroethylene (PTFE)-covered stenting of isolated atherosclerotic lesions of the infrarenal aorta.

Material and Methods: Between November 2008 and March 2011, 12 patients, aged 59 (42 to 78) years, were treated with a balloon-expandable PTFE-covered stent for a focal infrarenal aortic stenosis (n = 11) or occlusion (n = 1). Indications included disabling claudication (n = 9), rest pain (n = 1), or minor tissue loss (n = 2) Follow-up consisted of clinical examination, ankle-brachial indexes, plain abdominal radiography and duplex ultrasonography.

Results: Eleven procedures were performed percutaneously and one in combination with an endarterectomy of the right common femoral artery. Technical success was 100%, and clinical improvement was achieved in all but one patient, who needed additional femoropopliteal bypass surgery. The median follow-up was 18 months (range 2-30 months). During follow-up, all patients remained asymptomatic and ankle-brachial indexes had normalized. Duplex ultrasonography showed no re-stenosis, and there were no stent fractures on abdominal radiographs.

Conclusions: The primary use of PTFE-covered stents is a feasible, effective, and safe treatment for focal atherosclerotic lesions in the infrarenal aorta. Comparative studies with traditional treatment modalities, however, are indicated before considering the use of covered stents as standard treatment. (J Vasc Surg 2012;55:674-8.)
with a friable thrombus, in order to prevent embolization. The primary use of balloon expandable covered stents for isolated aortic occlusive disease has not been described, to date.

The aim of the present study was to assess the safety, feasibility and outcome of polytetrafluoroethylene (PTFE)-covered balloon-expandable stents in the treatment of isolated infrarenal aortic lesions.

METHODS

Study population. Case files of all patients that were treated in the Rijnstate Hospital for isolated infrarenal aortic occlusive disease from November 2008 and March 2011 were studied. Demographics, medical history, and ankle-brachial indexes (ABI) were noted. Preprocedural imaging studies (Fig 1), procedural findings, and clinical status were studied. Patients with involvement of the aortic bifurcation and iliac arteries requiring kissing stents were excluded, since the aim of the study focused on isolated infrarenal aortic lesions. Patients with isolated aortic lesions were preferably treated endovascularly in our center. Patients with extensive aortic lesions extending into one or both common iliac arteries were treated surgically during the study period.

On duplex scan, a stenosis with a peak systolic velocity (PSV) ratio of $>2.5$ was considered to be significant. Technical success was defined as a successful vascular access, completion of the endovascular procedure, as well as immediate morphologic success, with $<30\%$ residual diameter reduction and exact deployment of the stent graft on postprocedural angiography. Clinical success was defined as either the absence of symptoms or improvement by at least one category according to the Rutherford classification. Primary patency was defined as a patent stent graft after endovascular reintervention but without occlusion at any time. Secondary patency was defined as a patent stent graft after occlusion, with patency ending with an untreated or surgically treated occlusion.

Treatment protocol. Patients were preferably treated using local anesthesia in the interventional angio suite. When patients required an additional surgical intervention, the procedure was performed in the operating theater. A retrograde percutaneous access to the common femoral artery was obtained using the Seldinger technique and an 8F introducer sheath was placed. Patient received 5000 IU heparin. The lesions were crossed using a 0.035 Terumo wire (Terumo Medical Corporation, Elkton, Md) and a 5F flush catheter (VCF; Cook Medical Inc, Bloomington, Ind). Subsequently, a diagnostic digital subtraction angiogram (DSA) was performed (Fig 2, A). After removing the catheter, the delivery system was positioned and a balloon-expandable PTFE-covered stent (Advanta V12 LD; Atrium Medical, Hudson, NH) was deployed. If indicated, the stent grafts were postdilated using a 14-mm percutaneous transluminal angioplasty balloon (Wanda; Boston Scientific, Natick, Mass). The delivery system was then replaced by the flush catheter and angiography was performed to ensure proper location and deployment (Fig 2, B). Postprocedural, the distal runoff was assessed. Hemostasis was achieved using an 8F femoral closure device (Angioseal, St. Jude Medical, St. Paul, Minn). Patients were treated with acetylsalicylic acid 80 mg daily, unless oral anticoagulation was indicated for other pathology, and statin medication. Follow-up consisted of clinical assessment, duplex ultrasonography, and ankle-brachial indexes at 3, 6, 12, and 24 months. Plain abdominal X-ray was performed at 12 and 24 months.

Statistical analysis. Two-tailed statistical analysis of differences between groups was performed using the non-
parametric Mann-Whitney U test using the StatView software version 5.0.1 (SAS Institute Inc., Cary, NC). A P value <.05 was considered statistically significant.

RESULTS

Demographic data. During the study period, a total of 12 patients were treated with PTFE-covered stents for focal infrarenal aortic occlusive disease. The median age was 59 (range 42-78) years and the male-to-female ratio was 1:3. Patients presented with Rutherford category 2 (n = 1), 3 (n = 8), 4 (n = 1), and 5 (n = 2). All patients were smokers. Nine patients had dyslipidemia, two suffered from diabetes mellitus, seven patients had hypertension, and two patients had a cardiac history. The median preprocedural ABI was 0.75 (range 0.31-0.93) on the right side and 0.74 (range 0.28-0.90) on the left side. One patient had previously been treated with an aortobifurcation prosthesis and presented with a stenosis of the proximal anastomosis.

Preprocedural imaging. All patients were evaluated using duplex ultrasound scanning and all but one underwent computed tomography (CT) scanning. In the remaining patient, the intervention was scheduled on duplex only. A focal aortic stenosis was found in 11 patients and one patient had a total occlusion. The median grade of stenoses was 75% (range 67%-91%) The median lesion length was 35 mm (range 10-58 mm). Ten of 12 (83%) stenosis were eccentric and two (17%) were concentric. In nine out of 12 (75%) patients, the lesion was heavily calcified and six patients (50%) had an ulcerative plaque.

Procedure. Eleven procedures were performed percutaneously using local anesthesia only. One patient underwent a concomitant endarterectomy of the right common femoral artery under general anesthesia. Technical success was achieved in all patients, and all stent grafts were placed without predilatation. The median duration of the procedure was 45 minutes (range 20-90 minutes), with a median fluoroscopy time of 4.26 minutes (range 3.20-13.56 minutes), and a median of 75 mL (range 50-190 mL) contrast media was used. The used diameters of stent grafts were 12 mm (n = 11) and 10 mm (n = 1) with a length of 4 cm (n = 9) and 6 cm (n = 3). Lesion characteristics of each patient have been described in the Table.

There were no vessel wall ruptures, dissections, or signs of distal embolization. One patient developed pain and impaired coordination of her right leg during the procedure, most likely caused by a femoral nerve neuropathy. Repeated magnetic resonance scanning of the myelum showed no signs of ischemia or infarction. The symptoms resolved spontaneously within months after treatment. Other complications included two conservatively treated access-site hematomas. Most patients were discharged from the hospital on the first postprocedural day (range 0-6 days).

Follow-up. Postoperatively, all but one patient showed clinical improvement. This patient was known to have an occluded femoropopliteal artery and underwent additional successful femoropopliteal bypass surgery. It was decided to perform the central reconstruction first, to improve inflow. After the femoropopliteal bypass surgery, the patient improved to Rutherford 0. The median Rutherford classification improved from 3 (range 2-5) to 0 (range 0-2). After a median follow up of 18 months (range 2-30), no patient had clinical signs of re-stenosis. Postoperatively, the median ankle-brachial indexes had increased to 1.09 (range 0.79-1.21, P < .01) on the right side and 1.02 (range 0.76-1.32, P < .01) at the left side, respectively, and did not decrease during follow-up. Duplex ultrasonography at 3 (n = 11), 6 (n = 10), 12 (n = 9), and 24 (n = 4) months showed no re-stenosis or edge stenosis. There were no secondary interventions during follow-up. Abdominal radiographs at 12 and 24 months follow-up demonstrated no stent migration or stent fracture.

Fig 2. A and B, Procedural angiogram confirming the subtotal stenosis in the 48-year-old male patient. C, Postprocedural angiogram showing a good deployment of a 6 cm long 12 mm Advanta V12 LD stent graft (Atrium Medical, Hudson, NH) without residual stenosis. Patient had improved to Rutherford 0 and the ankle-brachial index (ABI) had normalized.
DISCUSSION

Data from the present study have shown that the use of PTFE-covered stents for isolated atherosclerotic lesions in the infrarenal aorta is safe, feasible, and associated with an excellent outcome. During follow-up, all stents remained patent, which indicates that covered stents may be a valid alternative for surgery.

The high patency rate observed in our study is in accordance with the recent studies that showed that covered stents are associated with a significantly increased patency rate in complex iliac occlusive disease. Unfortunately, we were able to include only 12 patients, rendering the series too small to make any reliable comparison with previous publications on bare metal stents or a historic control group due to underpower. Sabri et al\textsuperscript{14} have compared 26 patients who were treated with kissing covered stents with a historical control group and showed that the use of covered stents increased the primary patency from 62\% to 92\%. Additionally, the multicenter randomized Covered Versus Balloon-Expandable Stent (COBEST) trial, which compared the use of covered stents to bare metal stents in iliac occlusive disease, has shown that covered stents significantly improve patency rates in TASC-II C and D lesions.\textsuperscript{15} This may be related to the fact that covering of the diseased segment will reduce the risk on in-stent re-stenosis, thereby increasing patency rates. It must be noted, however, that isolated aortic disease is likely to be different from bifurcation and isolated iliac disease from a hemodynamic standpoint. Our results on focal aortic lesions are limited by the small sample size and study design. Comparative studies are required to assess the exact role of covered stents in the treatment algorithm of isolated aortic occlusive disease. The relative rareness of this pathology, however, might complicate the design of comparative studies.

In the present study, 83\% of patients had a heavily calcified eccentric lesion. Although rarely described, eccentric heavily calcified lesions are likely to carry increased risk of vessel wall rupture during dilation. It, therefore, seems reasonable to assume that endovascular treatment in these patients is often refused. In two recently published series of bare metal stenting, the incidence of vessel wall rupture was approximately 2\%.\textsuperscript{11,16} A potential advantage of the use of bare stents could be that one may oversize the stent, balloon the area with a smaller balloon enough to crack it, and allow the stent to expand over time to avoid rupture. In the present series, we did not observe any vessel wall rupture. Theoretically, the PTFE would have immediately covered the rupture, when occurred. A rupture of the PTFE covering material, due to dilatation of a heavily calcified lesion, has never been described to our knowledge.

Covered stents might also reduce the incidence of embolization, by covering the vulnerable ulcerative plaque, as was present in half of our patients. This strategy has recently been proposed in another retrospective series, using self-expandable stents in two patients.\textsuperscript{16} In our patients, there were no clinical signs of emboli, which is in accordance with previous case series of patients treated with covered stents for iliac occlusive disease.\textsuperscript{14,15} In the COBEST trial, the incidence of thromboemboli, using with either covered or bare metal stents, was 1.2\%.\textsuperscript{15}

In our study group, seven patients suffered from a TASC-II type B lesion. These include stenosis <3 cm in length, and an endovascular procedure is recommended unless an open revascularization procedure is required for other lesions in the same anatomic area. To our surprise, we were unable to adequately categorize the remaining five lesions properly into TASC-II categories.\textsuperscript{2} One patient suffered from an isolated aortic occlusion and the remaining four patients had a stenosis longer than 3 cm. Isolated infrarenal aortic lesions are not described in types A and C, while a type D lesion is defined as an infrarenal aortoiliac occlusion, which was not the case in our patients. The observation that five out of 12 patients may not be categorized indicates that the current version of the TASC-II

<table>
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<th>Patient</th>
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<th>Lesion length (mm)</th>
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<th>Distance of the lesion to renal arteries (mm)</th>
<th>Aortic bifurcation (mm)</th>
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IMA, Inferior mesenteric artery.

Table. Anatomical characteristics of the treated lesions
classification is inadequate for isolated infrarenal aortic lesions.

The use of covered stents may increase procedural costs. A proper cost-benefit analysis has not been published to date. An increased patency rate, as is shown in extensive iliac disease, combined with a possible decrease in complications might render the procedure cost effective. Without randomized studies, however, it might be more cost effective to reserve covered stenting for cases in which rupture is suspected. Studies focusing on the use of various techniques in relation to quality adjusted life years are therefore required.

In conclusion, we have shown that the use of covered stents for isolated aortic occlusive disease is safe, and related to low morbidity and excellent patency rates. Comparative studies with traditional treatment modalities are indicated to assess the role of covered stents in the treatment strategy of these lesions.

AUTHOR CONTRIBUTIONS
Conception and design: RB, AH, MR
Analysis and interpretation: RB, MR
Data collection: RB
Writing the article: RB, FG, MR
Critical revision of the article: CZ, AH, JO, CZ
Final approval of the article: MR
Statistical analysis: MR
Obtained funding: Not applicable
Overall responsibility: MR

REFERENCES

INVITED COMMENTARY

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The authors report a series of patients with focal infrarenal aortoiliac occlusive disease that was treated with polytetrafluoroethylene-covered stenting. Although this is a small series, it provides valuable information on a problem encountered frequently enough in clinical practice and shows that primary use of polytetrafluoroethylene-covered stents is a feasible, effective, and safe treatment for focal atherosclerotic lesions in the infrarenal aorta. With a median follow-up of 18 months, there were no instances of restenosis and no need for any secondary interventions.

It should be particularly noted that all patients were treated with a balloon-expandable stent, with no reported adverse events of aortic rupture. In addition, 67% of the patients had a patent inferior mesenteric artery, and 33% had aortic mural thrombus, with no reported cases of bowel ischemia or embolization.

The reader is correct to be somewhat skeptical of drawing broad conclusions from a small series that lacks a control group undergoing angioplasty or bare-metal stenting, but the results will expand our knowledge, inform future study, and impact the clinical care of patients with focal infrarenal aortoiliac occlusive disease. The results of this series, albeit limited, also seem to dismiss some of the concerns associated with the endovascular treatment of aortic occlusive disease such as a high recurrence rate, risk of intrageneric rupture, risk of colonic ischemia, and the presence of heavily calcified lesions that would be resistant to angioplasty and stenting.

Stenting for focal infrarenal aortoiliac occlusive disease appears to be an attractive alternative treatment option for such patients. However, longer follow-up, and as the authors rightfully conclude, additional comparative studies with traditional treatment modalities, are needed before considering the use of covered stents as the first-line standard treatment.