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Polytetrafluoroethylene Covered Stent Placement for Focal Occlusive Disease of the Infrarenal Aorta

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WHAT THIS PAPER ADDS

The primary use of PTFE covered stents for treatment of infrarenal occlusive disease of the abdominal aorta is safe and provides a valid alternative for surgical reconstruction, as the complication and morbidity rates are very low and patency rates are excellent.

Background: Arterial insufficiency is rarely caused by isolated infrarenal aortic occlusive lesions. Endovascular treatment options include plain balloon angioplasty and bare metal stent placement. In this study the feasibility and efficacy of polytetrafluoroethylene (PTFE) covered balloon expandable stents were evaluated.

Material and methods: Consecutive patients from two centers were prospectively collected in a database and retrospectively analyzed. Results were evaluated by clinical examination, ankle-brachial indices (ABI), duplex ultrasound, and plain abdominal radiography.

Results: Thirty-six consecutive patients were treated between November 2008 and June 2013. Indication for treatment was Rutherford 3 ($n = 29$), 4 ($n = 3$), and 5 ($n = 4$). Technical success was always achieved and there were no distal embolizations or vessel wall ruptures. The median follow-up was 22 months (range 0–60). All patients improved clinically and the ABI increased significantly from 0.73 $\pm$ 0.18 to 1.01 $\pm$ 0.14 ($p < .01$). One patent covered stent was removed surgically because of infection. Primary patency rates were 100% at 1 and 2 years without stent fractures.

Conclusion: The use of PTFE covered stents for the treatment of isolated infrarenal aortic occlusive disease is safe and very effective. Patency rates are excellent and complications including distal embolization and vessel wall rupture are extremely rare.

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INTRODUCTION

Since the early 1980s endovascular treatment of aorto-iliac occlusive disease has been widely applied, mostly in the iliac arteries. Although isolated occlusive disease of the infrarenal aorta is rare, it may cause arterial insufficiency leading to (disabling) claudication or even critical limb ischemia. Surgical treatment options include aortic bypass grafting and endarterectomy that are associated with outstanding patency rates of up to 86.3% at 5 years.[1] However, surgical reconstruction is associated with a 8.3–12.2% complication rate and a 3.3–4.4% mortality rate.[2] Regardless of the improved quality of postoperative care, the mortality rate of open surgical repair has not decreased during the last decades. After surgery, late complications may also occur and include incisional hernia with an incidence of 9.8%[3] and postsurgical adhesion formation. Adhesions are known to be the most important cause of small bowel obstruction, a problem that is related to inadvertent enterotomies, a higher rate of intensive care treatment and prolonged hospital stay in case of a re-laparotomy.[4] Possible reduction in early and late complications, in combination with the persistent mortality rate, justify the search for minimally invasive alternatives.

Endovascular alternatives, including plain balloon angioplasty and primary bare metal stent placement, are described in case series only. Complications of endovascular treatment include vessel wall rupture and distal embolization with a reported incidence of up to 10.2%.[5,6] The authors' single centre initial experience with balloon-expandable polytetrafluoroethylene (PTFE) covered stents in 11 patients for this specific indication was published previously, but given the low sample size no robust conclusions could be drawn.[7]

The use of covered stents may reduce the incidence of complications and growing evidence suggests that covered

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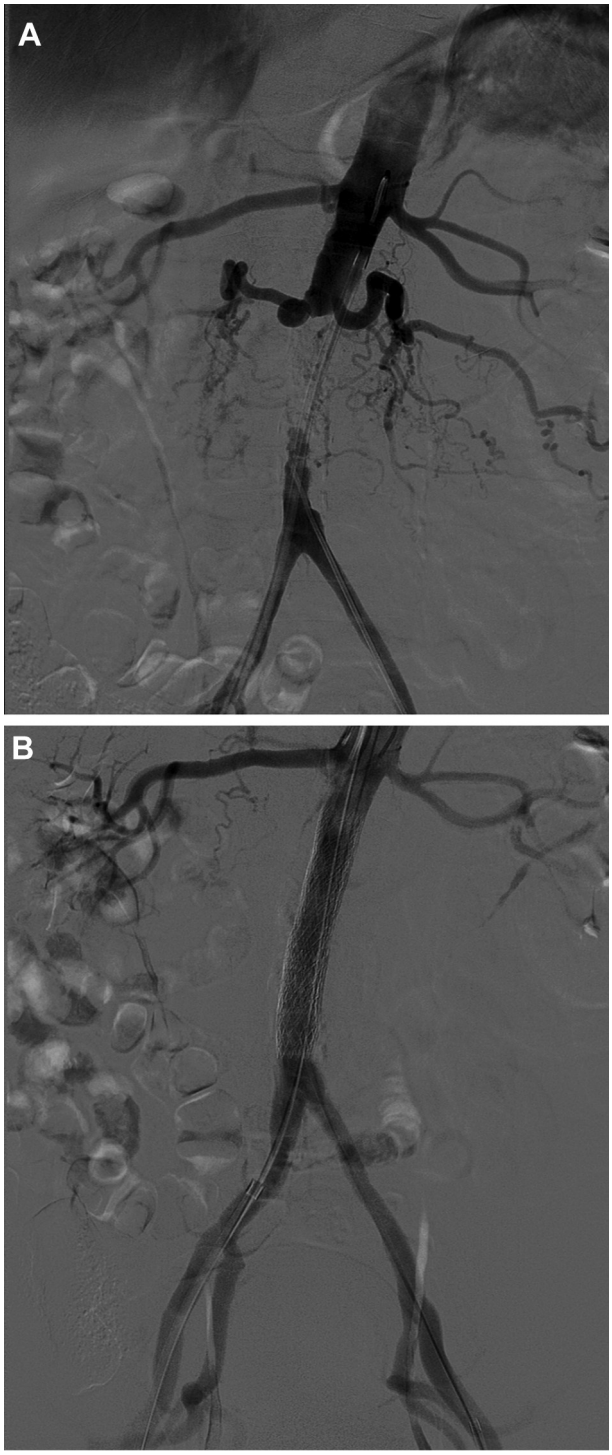

Figure 1. (A) Angiography of an occlusion of the infrarenal aorta in a 65 year old male patient, suffering from disabling intermittent claudication. Bifemoral access was obtained in this case as bilateral involvement of the iliac ostia was expected based on preoperative imaging. (B) Completion angiography after placement of PTFE covered stents showing a complete recanalization of the infrarenal aorta without residual stenosis.

stents have better patency rates in extensive occlusive disease, possibly because of prevention of tissue ingrowth.[8]

In this study, the safety, feasibility, and efficacy of PTFE covered balloon-expandable stents is evaluated for isolated focal infrarenal occlusive disease in an extended two center cohort of patients with a prolonged follow-up.

PATIENTS AND METHODS

Patients

In two clinics, the University Hospital of Regensburg, Germany and the Rijnstate Hospital, Arnhem, The Netherlands, patients treated for isolated occlusive lesions of the infrarenal aorta were prospectively collected in a database and retrospectively analyzed. Pre-treatment lesion morphology was analyzed using CT angiography and scored according to the TASC-2 guidelines.[9] Clinical symptoms were graded according the Rutherford classification for chronic ischemia.[10] Demographic data, medical history, and co-morbidity were retrieved from the medical files and scored according to the Society for Vascular Surgery (SVS) and American Association for Vascular Surgery (AAVS) medical co-morbidity scoring system.[11] Cardiovascular risk management is standard practice in both clinics, including the use of antiplatelet agents and statins when indicated.

Technique

Details of the procedure have been described previously by Bruijnen et al.[7] Briefly, patients are treated in a (hybrid) operating theater or at the catheter laboratory of the radiology department. Patients in the operating theater receive standard antibiotic prophylaxis in contrast to the patients treated at the department of radiology. One of the common femoral arteries is accessed either percutaneously or by surgical cut down under heparin prophylaxis, and a 9-French sheath is introduced. After passing the lesion with regular wires and catheters, a diagnostic digital subtraction angiogram is performed (Fig. 1A). Thereafter, a 12-mm Advanta V12 LD balloon expandable ePTFE covered stent (Atrium Medical, Maquet Getinge Group, Hudson, NH, USA) is expanded at the diseased segment, without predilatation. If required, the expanded stent is post-dilated to adapt to the aortic diameter with a 14 mm or 16 mm PTA balloon. A completion angiogram is performed to assess for proper deployment and outflow (Fig. 1B). Hemostasis is achieved using a closure device following percutaneous access.

Post intervention, patients continue their acetylsalicylic acid daily, unless oral anticoagulation with coumarines is indicated for other pathology.

Follow-up consists of clinical assessment, duplex ultrasound, and ankle-brachial indices at 3, 6, and 12 months, and annually thereafter. Plain abdominal X-ray is performed at 12 and 24 months to assess for material breakdown or migration.

Definitions and statistics

The primary outcome measure was primary patency, defined as an uninterrupted patency in the absence of occlusion, with no procedures performed on the vessel or stent to prevent occlusion. A re-stenosis was defined as a lesion with a peak systolic value (PSV) ratio >2.5 as

Table 1. The incidence of cardiovascular risk factors of patients treated with an ePTFE covered stent graft for isolated lesions in the infrarenal aorta.

	n	%
ASA		
1	0	0
2	15	42
3	18	50
4	3	8
Tobacco use		
Never, >10 years ago	6	17
No, but <10 years ago	0	0
Yes <20/day	21	58
Yes >20/day	9	25
Diabetes mellitus		
No	31	86
Adult, dietary or oral medication controlled	3	8
Adult, insulin-dependent	2	6
Juvenile diabetes	0	0
Hypertension		
No	17	47
Treated by single drug	10	28
Treated by two drugs	3	8
Treated by three drugs	6	17
Hyperlipidemia		
Normal lipids	10	28
Mildly elevated, dietary control	2	6
Treated with drugs	22	61
Unknown	2	6
Cardiac disease		
Asymptomatic	24	67
Non recent myocardial infarction (MI) (>6 m), asymptomatic MI on EKG (electrocardiogram)	2	6
Stable angina pectoris, arrhythmias, treatable heart failure	4	11
Unstable angina pectoris, recent MI(<6 m)	6	17
Pulmonary disease		
Asymptomatic	27	75
Mild dyspnea	3	8
Moderate dyspnea	2	6
O_2-dependent, pulmonary hypertension	0	0
Unknown	4	11
Carotid disease		
No disease	36	100
Asymptomatic, but sign of disease	0	
TIA/stroke without temporary deficit	0	
TIA/stroke with permanent deficit	0	
Renal disease		
No	27	75
GFR (glomerular filtration rate)30—50 mL/min	8	22
GFR 15—30 mL/min	1	3
GFR <15 mL/min or renal transplant	0	0

measured in the stent and directly proximal or distal to the stent, or an angiographic diameter reduction of >50%.[12]

Secondary outcomes were assisted primary patency, secondary patency, limb salvage rate, technical success, clinical improvement, and complications. Terms and classifications were defined according to the reporting standards of Rutherford et al.[10]

Technical success was defined as stent placement restoring blood flow with <30% residual stenosis. Clinical improvement was defined as a symptomatic improvement of at least one Rutherford category.

Statistical analysis

Statistical analysis was performed using SPSS version 19.0 (Statistical Package for the Social Sciences, Inc., Chicago, IL, USA). Variables were expressed as mean ± standard deviation (SD) in the case of normal distribution, or median and range in other distributions. In all patients the mean ABI of both legs was calculated to compare pre- and post-procedural ABI with paired *t* tests. Also, the highest ABI before the procedure was compared with the post-procedural ABI at the same leg with paired *t* tests. Patency rates and limb salvage rates were estimated using the Kaplan—Meier survival analysis. Probability values given are based on two-sided analyses of test results. A significance level of 5% was used.

RESULTS

In the period of November 2008 to June 2013, 36 consecutive patients, 13 males and 23 females, with isolated infrarenal aortic occlusive disease were treated with a balloon expandable covered stent in the two clinics. During the same period no other patients were treated with either plain balloon angioplasty or bare metal stent placement for this specific indication. The mean age was 58 years (range 37—78 years). The co-morbidities of the study group are listed in Table 1. Patients were classified as Rutherford 3 ($n = 29$), 4 ($n = 3$), or 5 ($n = 4$).

Twenty-one procedures (58%) were performed percutaneously. In 15 procedures access was obtained by surgical cut down. In 10 cases the procedure was combined with other treatment modalities, including endarterectomy of the common femoral artery ($n = 9$), balloon angioplasty or stenting of the iliac artery ($n = 4$) or femoro-femoral crossover bypass ($n = 2$). Technical success was achieved in all patients. In one patient the procedure was complicated by a stent dislocation from the balloon. In this case the stent was successfully replaced and deployed. Flow limiting dissections occurred in two procedures (one proximal, one in the iliac tract) and both were treated with balloon angioplasty, followed by covered stent placement. Post-procedural complications included two groin hematomas, both treated conservatively. The 30-day complication rate was 6% and there was no 30-day mortality.

Clinical improvement with at least one Rutherford category occurred in all patients. The mean ABI improved significantly from 0.73 ± 0.18 before the procedure to 1.01 ± 0.14 after the procedure ($p < .01$). The highest measured ABI before the procedure also improved significantly from 0.76 ± 0.19 to 1.03 ± 0.14 ($p < .01$). During follow-up, two patients died, both 11 months after the procedure, one as a result of pulmonary causes, and one following a cardiac event.

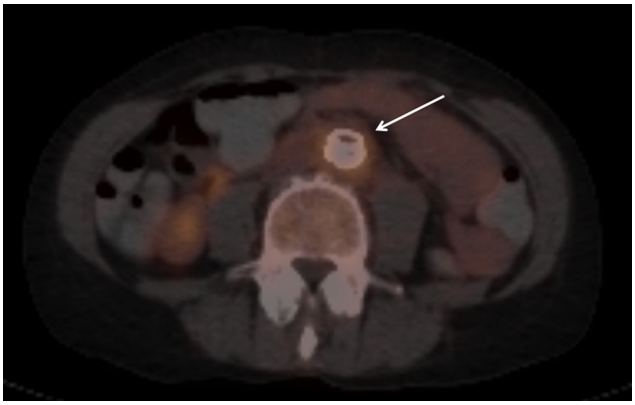

Figure 2. FDG-PET/CT scan of a 55-year-old female patient with a *Streptococcus pyogenes* infection of a covered stent in the infrarenal aorta, showing increased focal FDG uptake and thickened aortic wall, suggesting edema.

The median follow up was 22 months with a range of 1 week-60 months. A follow up of 6 months was available for 32 patients, 12 months for 27 patients, and 2 years for 17 patients. During follow up all stents remained patent, making the primary patency rate 100% during the first 2 years. One re-intervention was performed. In this patient, an infection of the stentgraft occurred 11 months after the procedure, while the stent itself remained patent. The procedure was not combined with other interventions and was performed percutaneously. Clinical symptoms included abdominal pain, fever, and increased infection parameters. Blood cultures were positive for *Streptococcus pyogenes*. FDG-PET/computed tomography (CT) scanning revealed an infection at the site of the stent (Fig. 2). The stent was surgically removed, there were no signs of re-stenosis or occlusion, and after an endarterectomy the aorta could be primarily closed, without patching.

Abdominal X-rays during follow-up did not show any stent fractures, kinking, or migration in the study cohort. There was no limb-loss during the follow up period.

DISCUSSION

This two center cohort study shows that the use of PTFE covered stents for the treatment of isolated infrarenal aortic occlusive disease is both safe and very effective. Patency rates are excellent and only one major complication, a stent infection, occurred during follow up. In this series no signs of distal embolization or vessel wall rupture were found.

The largest cohort study on endovascular treatment of isolated infrarenal occlusive lesions to date was published by Kim et al.[6] In that study both balloon-expandable and self-expandable bare metal stents were used to treat 49 lesions. Complications were reported in 16.3% of the patients and distal embolization occurred in 10.2%. A possible advantage of PTFE covered stents includes the immediate covering of ulcerated plaques and vessel wall thrombus, thereby possibly preventing distal embolization. Moreover, the "dog-bone" shape inflation of the balloon may catch emboli behind the covering material, thus further reducing the chances of embolization. In this cohort no distal embolization occurred, although the occurrence of subclinical microemboli cannot be excluded. However, two dissections were seen during the procedures. In one case a dissection in the common iliac artery was treated primarily with PTA alone, with no residual stenosis. Five weeks later this patient presented with an occlusion of the common iliac artery, which was treated by a self-expandable covered stent. In the other case a flow limiting dissection occurred proximal to the stenosis in the aorta, which was treated with an additive PTFE covered balloon expandable stent, with overlap, without residual stenosis.

Table 2. Lesion characteristics of patients treated with an ePTFE covered balloon expandable stent for isolated lesions in the infrarenal aorta.

Length stenosis (mm)	26 (5—58)
Percentage stenosis (percentage)	80 (50—100)
Eccentric lesion/concentric lesion	13/21[a]
TASC-II[b]	
B	17
D	19
Stent diameter (mm)	12 (10—14)
Stent length (mm)	41 (38—143)
Number of stents used	
1	35
3	1

Data are presented as median and range.
[a] In two occlusions the lesion configuration could not be classified.
[b] TASC-II B: stenosis <3 cm. TASC-II D: aortoiliac occlusion or involvement that needs treatment, stenosis >3 cm was considered TASC-II D.

The overall 30-day complication rate in this cohort was only 6%, which is very low compared with the other studies (0—28.5%).[5,6,13—19] Post-procedural complications included two groin hematomas, which were treated conservatively and did not cause any clinical impairment. Furthermore, there were no major complications or mortality in the first 30 days, proving the safety of the technique.

The TASC-2 guidelines provide treatment strategies based on lesion characteristics (Table 2). However, there is no TASC-2 classification available for stenotic lesions in the infrarenal aorta beyond 3 cm. In the current study these lesions were classified as TASC-2 D lesions. These lesions, however, could also be classified as TASC-2 "C" lesions. This would render the majority of lesions TASC-2 C and D. In theory, eccentric and heavily calcified lesions are more prone to rupture during intervention. A possible advantage of the use of covered stents is that they would treat any rupture instantly.

The diameter of the infrarenal aorta should be taken into account when planning the stent diameter. A 12-mm LD Advanta V12 is inserted through a 9-Fr sheath and can subsequently be flared to 20 mm, or not flared at all. Therefore, there are no limits to the possibilities of adjusting stent diameters to the aortic wall.

In theory, other possible complications of the use of covered stents are the occlusion of collateral arteries, or the inferior mesenteric artery (IMA). In stenotic lesions, however, collateral arteries and the IMA are commonly occluded. In this series, no visceral or spinal cord ischemic events occurred.

A drawback of this study is its retrospective character, and not all data were complete. During follow up, no restenosis or occlusions occurred. However, a 2-year follow up was available for only 17 patients, which is still a relatively small sample size. Given the low prevalence of these lesions, however, larger series may be hard to collect. Obviously, the study results should be established by a randomized study, but again this low incidence of the pathology will limit the feasibility of such a trial. One of the procedural complications was a stent dislocation from the balloon in one of the early patients. Thereafter, adjustments to the device have been made by the manufacturer aimed at reducing the risk of dislocation.

In this cohort one patient had an infected stent that had to be surgically removed. During the initial procedure, antibiotic prophylaxis was used and the procedure was performed percutaneously. The necessity for antibiotic prophylaxis in percutaneous procedures has never been shown, to the authors' knowledge, but seems to be indicated as foreign material is implanted and the consequences of an infection may be devastating. Covered stents may be more susceptible to infection than bare metal stents, and, therefore, the authors advocate implantation of the devices in a sterile environment such as a hybrid operating theater. However, in this cohort the patients treated at the radiology department did not receive standard antibiotic prophylaxis.

The cost effectiveness of covered stents for aorto-iliac occlusive disease is unclear, as these devices are usually more expensive than the vascular grafts used in open surgery or bare metal stents. However, recent analysis showed a significantly lower complication rate for endovascular procedures and shorter hospital stay.[20] The authors found a significantly lower inpatient cost for endovascular repair compared with open repair in aorto-iliac occlusive disease. With improving patency rates and the possible advantage of lower long term morbidity, endovascular techniques are becoming an attractive alternative to open repair. As experience grows, the need for follow up imaging may be reduced, further reducing costs for endovascular repair. Isolated stenotic and occlusive lesions of the infrarenal aorta can be treated well with single PTFE covered balloon expandable stents, as described in this paper. When the bifurcation or common iliac arteries are involved in the lesion, the authors recommend use of the recently described CERAB technique (Covered Endovascular Reconstruction of the Aortic Bifurcation).[21] In this technique, the bifurcation is reconstructed with the use of three PTFE covered stents that are placed inside each other as if they were molded together. The first clinical results of this technique are awaited.

Conclusion

The primary use of PTFE covered stents for the treatment of infrarenal occlusive disease of the abdominal aorta is safe and provides a valid alternative to surgical reconstruction, as the complication and morbidity rates are very low and patency rates are excellent.

FUNDING

None.

CONFLICT OF INTEREST

None.

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