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Clinical Outcome of Isolated Popliteal Artery Aneurysms Treated with a Heparin-bonded Stent Graft

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WHAT THIS PAPER ADDS

This study shows the clinical outcome of popliteal artery aneurysms treated with heparin-bonded stent grafts. The outcome of treatment with heparin-bonding technology in a large cohort of patients with a follow-up of 3 years has not been described previously, therefore this study adds new results to the existing literature.

Objective: The use of self-expanding stent grafts for treatment of popliteal artery aneurysms (PAA) is a matter of debate, although several studies have shown similar results compared with open surgery. In recent years, a new generation stent graft, with heparin-bonding technology, became available. The aim of this study is to present the results of endovascular PAA repair with heparin-bonded stent grafts.

Methods: Data on all patients with PAA treated with a heparin-bonded polytetrafluoroethylene (ePTFE) stent graft between April 2009 and March 2014 were gathered in a database and retrospectively analyzed. Data were collected from four participating hospitals. Standard follow-up consisted of clinical assessment, and duplex ultrasound at 6 weeks, 6 months, 12 months, and annually thereafter. The primary endpoint of the study was primary patency. Secondary endpoints were primary-assisted and secondary patency and limb salvage rate.

Results: A total of 72 PAA was treated in 70 patients. Mean age was 71.2 ± 8.5 years and 93% were male ($n = 65$). The majority of PAA were asymptomatic (78%). Sixteen cases (22%) had a symptomatic PAA, of which seven (44%) presented with acute ischemia. Early postoperative complications occurred in two patients (3%). Median follow-up was 13 months (range 0—63 months). Primary patency rate at 1 year was 83% and after 3 years 69%; primary assisted patency rate was 87% at 1 year and 74% after 3 years. Secondary patency rate was 88% and 76% at 1 and 3 years, respectively. There were no amputations during follow-up.

Conclusion: Endovascular treatment of PAA with heparin-bonded stent grafts is a safe treatment option with good early and mid-term patency rates comparable with open repair using the great saphenous vein.

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INTRODUCTION

Popliteal artery aneurysms (PAA) account for 70—80% of all peripheral artery aneurysms.[1—3] PAA occur more often in men than in women, and the incidence increases with age. The popliteal artery is considered aneurysmal when the diameter reaches 1.5 cm or exceeds 50% of the size of the normal artery defined by the diameter of the contralateral popliteal artery. PAA occur bilaterally in 45% of patients.[4] Approximately 40% of PAA are symptomatic and associated with a risk of amputation of 30—40%.[1,5,6] The reported incidence of thromboembolic events in asymptomatic untreated PAA is 14% per year.[7—10] The gold standard for PAA repair is still surgical treatment with venous bypass grafting in combination with either ligation or resection of the aneurysm.[11—13] If no suitable vein conduit is available, expanded polytetrafluoroethylene (ePTFE) or polyester grafts can be used, although with a 30% lower patency compared with the venous conduit at long-term follow-up.[14,15] Another treatment option for PAA is endovascular repair, which provides shorter operation time, hospital stay, and less perioperative and postoperative morbidity and therefore a faster patient recovery. Most studies have shown patency rates at 4 years varying between 64% and 88%, which is comparable with the 4-year patency rate of a surgical bypass (69—88%).[16—21]

Heparin-bonding technology has increased patency rates of surgical grafts in general, and results with heparin-

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bonded stent grafts for occlusive disease are promising.[22] Early results in a small series of 10 patients showed good results up to 1 year.[23] The purpose of the present study was to evaluate patency of PAA treated with heparin-bonded stent grafts in a larger cohort of patients.

MATERIALS AND METHODS

All patients with a PAA treated between April 2009 and March 2014 with a polytetrafluoroethylene (ePTFE) heparin-bonded stent graft (Viabahn endoprosthesis, W. L. Gore & Associates, Flagstaff, AZ, USA) were gathered in a database and retrospectively analyzed. Patient data were retrieved from four hospitals (Klinikum Nuremberg Süd, Paracelsus Medical University, Nuremberg, Germany; University Hospital, Padua, Italy; University Medical Center Groningen, Groningen; and Rijnstate Hospital, Arnhem, the Netherlands).

Indication for intervention included asymptomatic isolated PAA with a diameter of more than 20 mm.[24] Endovascular PAA treatment was chosen if the lesion was anatomically suitable with at least one patent outflow artery to the foot. Medical history, patient demographics, and clinical state were noted. Patients with an untreated inflow stenosis (>50% diameter reduction) of the iliac or common femoral artery and patients with untreated atherosclerotic disease with a stenosis of the superficial femoral artery (>50%) were excluded from endovascular treatment. Other exclusion criteria were compression syndrome of the popliteal artery (lumen <4.0 mm), degenerative connective tissue disease, contraindications to anticoagulation or antiplatelet therapy, hypersensitivity to heparin, septicemia, thrombophilic disease, and severe untreated medical comorbidities (such as coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, metastatic malignancy, and dementia).

Cardiovascular risk factors were scored according to the Society for Vascular Surgery (SVS) and American Association for Vascular Surgery (AAVS) medical comorbidity grading systems. Procedural aspects and post-procedural data were retrieved from the patients' case files. Standard follow-up consisted of clinical assessment, duplex ultrasound examination at 6 weeks, 6 months, 12 months, and annually thereafter and yearly biplane x-rays of the knee in two directions.

Retrospective "patient's files" research is not subject to German, Italian, and Dutch law for human bound research, and therefore investigational review board approval was not required. As a consequence, patient informed consent was not obtained. Patients' data were analyzed anonymously.

Treatment protocol

In all patients a pre-operative CT-angiography (1 mm cut) was performed to accurately plan the procedure. A proximal and distal landing zone of ±1.5 cm in length was required; the endograft oversizing never exceeded 15%. A below the knee popliteal artery of <4.5 mm in diameter was not considered for treatment.

Before operation, antibiotic prophylaxis was administered. Access to the common femoral artery was performed either percutaneously or surgically, as preferred by the treating surgeon. After introduction of the sheath and administration of 5000 IU heparin intravenously, the PAA was passed with a Terumo wire (Terumo Medical Corporation, Elkton, MD, USA). A calibrated straight angiocatheter was positioned just proximal to the trifurcation of the popliteal artery. Angiography was performed to determine the proximal and distal landing zones. An Amplatz wire (Amplatz Super Stiff guide wire, Boston Scientific Corporation, Marlborough, MA, USA) was used for insertion and deployment of the stent graft. All PAA were excluded with one or multiple Viabahn endoprostheses. The stent grafts were post-dilated with an angioplasty balloon of the same size as the stent graft. Completion angiography of the stent graft and outflow vessels was performed routinely including a lateral projection with forced leg flexion to identify any bending between the artery and the endograft. All patients received dual antiplatelet inhibitors for at least 6 months, unless oral anticoagulation was indicated for other reasons. After 6 months patients received single antiplatelet inhibitors, usually acetylsalicylic acid, unless oral coagulation was indicated.

Definitions

Patency definitions were applied as recommended in the guidelines of Rutherford et al.[25] Primary patency was defined as blood flow maintained through the device after implant without an intervention. Primary-assisted patency was defined as blood flow maintained through the device after implant regardless of re-interventions performed. Secondary patency was defined as blood flow through the device regardless of re-interventions performed following total occlusion. An occlusion was defined as absence of flow in the treated segment. A failure of the stent graft was defined as an occlusion, with or without clinical symptoms, not responding to therapy. Limb salvage was defined as the absence of major amputation. Exclusion of the PAA from the blood circulation was defined as the absence of flow in the PAA and without any PAA sac enlargement.

Endpoints

The primary endpoint of this study was the primary patency rate of the stent graft. Secondary endpoints included primary-assisted and secondary patency rates as well as the limb salvage rate.

Statistical analysis

Distribution was tested using the Shapiro-Wilk test. Categorical variables are presented as numbers followed by percentages; continuous variables are presented as mean ± standard deviation or as median with range when appropriate. Patency rates were determined using the Kaplan-Meier life-table method. Cox-regression analyses were generated to analyze possible risk factors. A *p*-value <.05 was considered statistically significant. All analyses were performed with SPSS 22.0 (Statistical Package for the Social Sciences Inc., Chicago, IL, USA).

RESULTS

A total of 72 PAA were treated with a heparin-bonded stent graft in 70 patients. During the study period 97 other PAA were treated with open surgery. Sixty-five patients were male (93%), and mean age was 71.2 ± 8.5 years. The majority of PAA were asymptomatic (78%). Sixteen PAA (22%) were symptomatic, of which seven (44%) presented with acute limb ischemia. Patient characteristics are shown in Table 1. Forty-six patients (66%) had a unilateral PAA and 24 patients (34%) bilateral PAA. Only two patients were treated bilaterally. In the remaining patients the PAA had not reached the cut-off diameter for treatment. Thirty-two patients (44%) had a concomitant aneurysm (abdominal, $n = 24$ [75%], iliac, $n = 6$ [19%], femoral, $n = 2$ [6%]). Mean preoperative ankle brachial index (ABI) was 0.89 ± 0.20. Lesion characteristics are shown in Table 2. The majority of PAA had a diameter >25 mm (83%), while 12 PAA had a diameter between 21 mm and 25 mm (16.7%).

Procedural aspects

Twenty-three procedures (32%) were accomplished with local anesthesia for the intervention, 12 patients (17%) with spinal anesthesia, and the remaining 37 procedures (51%) with general anesthesia. Heparin was administered during all procedures. Four cases (6%) underwent thrombolysis before stent graft placement. In 33 procedures (46%) one stent graft was used, 31 procedures (43%) two stent grafts, seven procedures (10%) were accomplished using three stent grafts, and in one procedure four stent grafts were used (1%). The median length of the covered segment of the femoropopliteal artery was 17 cm (range 10–36 cm) with a median overlap zone of 3 cm (range 3–10 cm). Median contrast volume administered was 45 mL (range 25–135 mL). The median duration of only the stent graft placement was 45 minutes (range 23–120 minutes). A concomitant procedure was performed in 13 patients (19%). Two patients (3%) underwent endovascular repair of an abdominal aortic aneurysm, two patients (3%) had an interposition graft to treat a common femoral artery aneurysm, three patients (4%) had an angioplasty of the superficial femoral artery to treat a <50% stenosis and prohibit inflow problems, one patient underwent an embolization of a popliteal artery side branch, and the remaining five patients (8%) underwent angioplasty of crural vessels. The technical success rate was 100%.

Table 1. Patients' baseline characteristics.

	$N = 70$
Tobacco use	28 (40%)
Hyperlipidemia	55 (79%)
Diabetes mellitus	3 (4%)
Hypertension	51 (73%)
Renal failure	26 (37%)
Coronary artery disease	24 (34%)

Table 2. Lesion characteristics.

	$N = 72$
Right/left leg	40/32 (56%/44%)
Median diameter PAA, mm	31 (21–86)
Median distal neck length, mm	54 (20–133)
Median PAA length, mm	78 (23–200)
Number of distal run-off vessels	
1 vessel	16 (22%)
2 vessels	17 (24%)
3 vessels	39 (54%)

Postoperative period

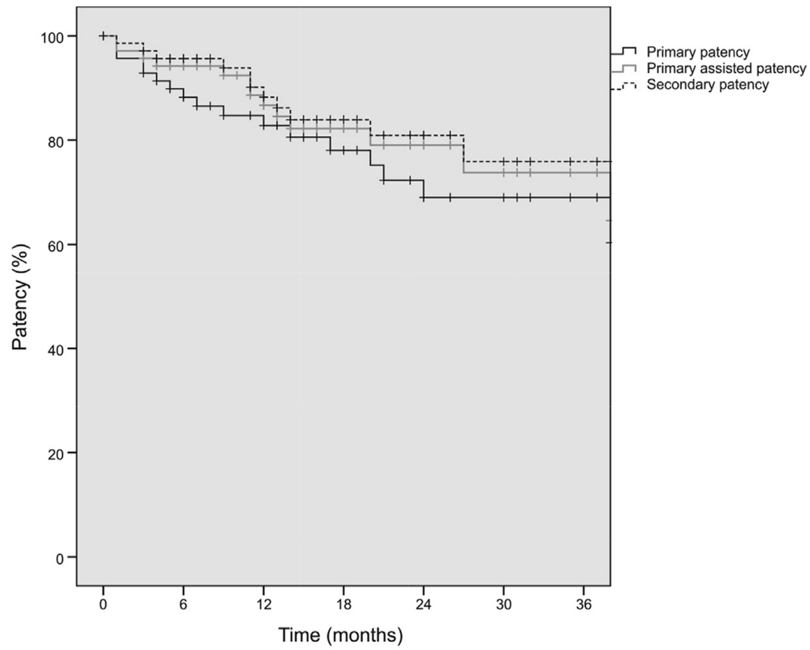
The median length of hospital stay was 4 days (range 1–12 days). In the early postoperative period, two complications occurred (3%). One patient had a groin hematoma, which was treated conservatively. The other patient developed a pseudoaneurysm of the common femoral artery, which was successfully treated with thrombin injection. The mean postoperative ABI was 0.98 ± 0.20 ($p = .03$ versus preoperative). Sixty-three cases (88%) were prescribed acetylsalicylic acid 80 mg in combination with clopidogrel 75 mg daily. Two cases (3%) were treated with coumarin derivates only, three cases (4%) with acetylsalicylic acid 80 mg in combination with coumarin derivates, and the remaining four cases (6%) with a combination of clopidogrel 75 mg and coumarin derivates.

Follow-up

The median follow-up was 13 months (range 0–63 months). During follow-up, seven patients (10%) died. In all cases the cause of death was unrelated to the aneurysm or its treatment. Three patients (4%) were lost to follow-up. One patient had an edge stenosis of the distal edge which was treated with balloon angioplasty. During follow-up, four endoleaks (6%) were detected, including one type 1 endoleak, and three type 2 endoleaks. Duplex ultrasound examination in all four patients showed a decrease of the aneurysm size and therefore all were treated conservatively. Primary patency rates at 1, 2, and 3 years were 83%, 69%, and 69%, respectively (Fig. 1). Primary-assisted patency rates were 87%, 79%, and 74%, and secondary patency rates were 88%, 81%, and 76% at 1, 2, and 3 years, respectively. No stent fractures were reported during follow-up. Analysis of possible risk factors, including number of stent grafts ($p = .94$), number of run-off vessels ($p = .95$), sex ($p = .51$), age ($p = .13$), use of clopidogrel ($p = .73$), and asymptomatic versus symptomatic ($p = .06$) did not show any significant predictor for loss of patency.

Occlusions

During follow up, 13 stent grafts (18%) occluded. Four cases (31%) presented with acute lower limb ischemia and were treated with a surgical bypass ($n = 3$) or thrombolysis ($n = 1$). Six cases (46%) presented with Rutherford 4 lower limb ischemia and were treated with a surgical bypass ($n = 4$) or conservative therapy (walking exercise) ($n = 2$).



Limbs at risk							
Primary patency	72	56	44	30	22	14	9
Primary assisted patency	72	59	45	28	22	14	9
Secondary patency	72	60	47	31	23	15	9
Patency (%)							
Primary patency	100	88.3	82.8	78.1	69.0	69.0	69.0
Primary assisted patency	100	94.2	86.7	82.2	79.1	73.8	73.8
Secondary patency	100	95.7	88.3	83.9	80.9	75.9	75.9
SE (%)							
Primary patency	0	3.9	4.8	5.6	7.0	7.0	7.0
Primary assisted patency	0	2.8	4.4	5.2	5.9	7.5	7.5
Secondary patency	0	2.4	4.2	5.0	5.6	7.2	7.2

Figure 1. Patency rates at 1, 2, and 3 years follow-up.

Three cases (23%) presented with Rutherford 3 symptoms and were treated with thrombolysis ($n = 1$) or conservative therapy ($n = 2$). Both thrombolysis procedures were successful and uncomplicated. No major amputations were performed during follow-up.

DISCUSSION

This study has shown that treating PAA with heparin-bonded stent grafts has similar results compared with surgery and is associated with a low complication rate, a short hospital stay, and without amputations during follow-up. The 1-year primary patency of 84% is in range with published results of open surgery (76–90%).[12,13,26]

Eslami et al. compared endovascular repair of PAA with open surgery and stated that surgery is associated with lower major adverse limb events and a better primary patency.[27] Nonetheless, that study was retrospective, the two groups were not equally divided as the surgery group was larger, and the endovascular group had a higher rate of congestive heart failure and chronic obstructive pulmonary disease. Analysis of primary-assisted and secondary patency rates between surgery and endovascular therapy shows that they are in the same range. At 1 year, Cervin et al. found a secondary patency rate after endovascular treatment of 86%, and Serrano Hernando et al. of 89%, while earlier studies have also shown similar outcomes after endovascular treatment of a PAA.[13,28–33] In a recent meta-analysis, von Stumm et al. described comparable mid-term results of open versus endovascular repair of PAA.[28] The complication rate in the present study population was low (3%) compared with the reported complication rate of surgical therapy (11–25%).[34,35]

Previous studies have described stent fracture as one of the main limits of endovascular treatment of the PAA.[36] In the present study population no stent fractures occurred during follow-up, although follow-up may have been too short for fractures to occur. The stent graft used in the present study has a heparin-bonded ePTFE surface, which lowers platelet deposition and reduces thrombogenicity. In addition, the stent graft has a laser-cut contoured proximal edge, which may improve apposition of the device to the vessel wall. This contoured proximal edge and the addition of heparin could explain the better results compared with studies in which older generation stent grafts were used. In a previous study by Tielliu et al. with only non-heparin-bonded stent grafts, stent fractures often occurred at the borders of the overlap zone.[36] With the availability of longer stent grafts the number of required stent grafts is likely to decrease. In the present study 46% of patients were treated with a single stent graft. In the study by Tielliu et al. a single stent graft was used in only 27% of cases and the remaining patients (73%) were treated with multiple stent grafts.[36]

There are certain assets of stent grafts in the treatment of PAA. Endovascular treatment has a minimal invasive character and is associated with a shorter operating time, a shorter length of hospital stay, and lower morbidity, complication, and amputation rates.[37] Therefore, treatment of PAA with a stent graft should be considered an alternative treatment option. However, long-term results of endovascular therapy are still scarce. As also stated in a recent Cochrane review by Joshi et al., future research such as randomized controlled trials with large groups comparing endovascular approach with heparin-bonded stent grafts versus surgical approach is necessary to define the best treatment option.[37]

The present study has limitations. First, this study has a retrospective design. Selection bias cannot be excluded as patients were treated according to the institutional standards and at the discretion of the surgeon. Patient selection, obviously, may explain the satisfying success rate in the present series as selection is likely to be a key factor for loss of patency. The diameter at which a PAA requires treatment is still matter of debate.[23] In the present study only a minority with a smaller diameter between 21 and 25 mm were treated. These smaller PAAs seem to be easier to treat and could positively affect the results. The large variation in follow-up between the subjects prohibits analysis of long-term results. In an earlier study by Tielliu et al. the use of clopidogrel significantly determined the patency of the stent graft.[29] In this study most patients received clopidogrel postoperatively. No possible risk factors were found that could influence the patency of the stent graft, although sample sizes are small. Because of the limitations of the present study, the lack of significant risk factors should be handled with care. Therefore future research is essential to analyze possible risk factors concerning patency of the stent graft placed for PAA.

In conclusion, treating PAA with heparin-bonded stent grafts is a safe and feasible treatment option with low morbidity and amputation rates. The patency rates show promising results and no stent fractures at short-term follow-up. Nonetheless, long-term outcomes and randomized controlled trials are necessary to determine the position of the endovascular treatment option in the treatment algorithm of the PAA.

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CONFLICT OF INTEREST

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