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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