CLINICAL RESEARCH STUDIES

Endovascular treatment of popliteal artery aneurysms: Results of a prospective cohort study

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Objective: **Popliteal artery aneurysms can be treated endovascularly with less perioperative morbidity compared with open repair. To evaluate suitability of the endovascular technique and the clinical results of this treatment, we analyzed a prospective cohort of consecutive popliteal aneurysms referred to a tertiary university vascular center.**

Methods: **All popliteal artery aneurysms between June 1998 and June 2004 that measured >20 mm in diameter were analyzed for endovascular repair. Anatomic suitability was based largely on quality of the proximal and distal landing zone as determined by angiography. Endovascular treatment was performed by using a nitinol-supported expanded polytetrafluoroethylene lined stent graft introduced through the common femoral artery.**

Results: **We analyzed 67 aneurysms in 57 patients. Ten aneurysms (15%) were excluded from endovascular repair, or from any repair at all, for various reasons. The remaining 57 (85%) were treated endovascularly, of which 5 were treated emergently for acute ischemia. During a mean 24-month follow-up, 12 stent grafts (21%) occluded. Primary and secondary patency rates were 80% and 90% at 1 year, and 77% and 87% at 2 years of follow-up. Postoperative treatment with clopidogrel proved to be the only significant predictor for success.**

Conclusions: **Endovascular repair of a popliteal artery aneurysm is feasible. Changes in the material used and the addition of clopidogrel may improve patency rates. (J Vasc Surg 2005;41:561-7.)**

Popliteal artery aneurysms (PAA) account for most peripheral aneurysms. They are potentially dangerous, with a 5-year cumulative risk for complications ≤68%.[1] The most common complications are acute thrombosis, with occlusion of the aneurysm, and distal embolization. As a result, acute ischemia may occur and will lead to limb loss in ≤40% of patients.[2] In addition, chronic distal embolization of small mural thrombi can lead to progressive occlusion of tibial and peroneal arteries, resulting in chronic or acute limb ischemia.

To prevent these severe complications, elective treatment is advocated.[2-4] Whether small and asymptomatic aneurysms should be treated is still a point of debate.[5,6] Nevertheless, most authors consider a cutoff point diameter of 20 mm a criterion for treatment, and some treat even smaller aneurysms when mural thrombus is present.[1,4,6,7]

Open surgical treatment with a venous bypass graft is still the treatment of choice for most surgeons. Patency rates of these reconstructions depend mainly on the quality of the peroneal and tibial arteries, the type of bypass material, and whether the reconstruction was performed for acute ischemia or in the elective setting.[2,3,8,9]

The first endovascular repair of a PAA, performed with a homemade device, was reported in 1994 by Marin.[10] Thereafter, several case reports and relatively small series have been published describing the endovascular treatment of PAA (Table I).

Advantages of the endovascular treatment include the minimally invasive character of the procedure, with only a small incision in the groin, minimal morbidity, and a shorter operation time and hospital stay.[11] A particular problem associated with this technique is that the stent graft crosses the knee joint. Repetitive stress on the device in this bending zone may lead to complications, including kinking, fracture of the stent-graft material, and occlusion.[11]

This study describes the results of the largest worldwide series of PAA treated with a single type of endovascular stent graft and analyses the predictive value of different variables on stent-graft occlusion.

METHODS

Between June 1998 and June 2004, all consecutive PAAs referred to University Medical Center Groningen, a tertiary center, that measured more than 20 mm in diameter on duplex ultrasound scanning were analyzed for endovascular treatment. Two types of aneurysms were included:

1. Aneurysms in patients who did not present with acute limb ischemia. In these patients, angiography was performed to determine anatomic suitability, including the presence of a

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Table I. Literature overview of popliteal artery aneurysms treated with commercially available stent-grafts*

Author	*Publication Year*	*No. of aneurysms*	*Type of stent-graft (No. per type)*	*No. treated emergently for acute ischemia (%)*	*Follow-up period (mo; mean)*	*Occlusions (No. per type) (%)*
Marcadé[13]	1996	6	CES	0	6	1
Kudelko[14]	1998	1	WG	0	10	0
Bürger[15]	1998	1	HB	1	6	0
Beregi[16]	1999	3	CES	0	24	0
Müller-Hülsbeck[17]	1999	6	CES(4); P(1); WS(1)	6 (100)	4	4 (3CES; 1P) (67)
Henry[18]	2000	10	P(7); CORV(3)	—‡	—‡	5 (3CORV; 2P) (50)
Ihlberg[19]	2000	1	HB	0	5	0
Howell[20]	2002	13	WG	0	12	4
Gerasimidis[21]	2003	9	HB(6); WG(2); P(1)	0	14	4 (3HB; 1WG) (44)
This study	2005	57	HB; VB†	5 (9)	24	12 (21)

CES, Cragg Endopro system 1; *WG,* Wallgraft; *HB,* Hemobahn; *P,* Passager; *WS,* Wallstent; *CORV,* Corvita; *VB,* Viabahn.
*Reports on homemade devices were not included.
†In some patients both the Hemobahn and Viabahn stent-graft were used to treat the popliteal aneurysm according to the diameters and availability of according stent-grafts.
‡Not stated in the article.

landing zone in the proximal and distal popliteal artery of at least 3 cm in length, the absence of extensive aneurysmal or stenotic disease at the level of the iliac and femoral arteries, and the presence of at least one good tibial or peroneal artery serving as a run-off vessel.

2. Some patients with aneurysms presented with acute limb ischemia. These patients with an acute occlusion of a PAA but with a viable limb (Rutherford category I and IIa acute limb ischemia)[12] were usually treated by thrombolysis. After successful recanalization, they were evaluated for endovascular repair as in an elective setting.

This study was approved by the institutional medical ethics committee, and each patient provided informed consent.

Endovascular procedure. On admission, duplex ultrasound scanning was performed to determine intima-to-intima diameters of landing zones and length of the aneurysm. In addition, the proximal and distal margins of the aneurysm were marked with a pencil on the patient's leg. In the presence of mural thrombus, this proved to be a reliable indication of the exact localization of the aneurysm.

All procedures were performed in an operating theater by an endovascular team that included a vascular surgeon and a radiologist. Access to the ipsilateral common femoral artery was achieved by open dissection of the groin. A 30-cm-long 12F sheath was introduced and continuously flushed with heparinized saline (500 IU/500 mL). Heparin (5,000 IU) was also administered intravenously. A calibrated straight angiocatheter was positioned just proximal to the trifurcation of the popliteal artery, after which angiography was performed by hand injection through the sheath.

The selection of the appropriate stent graft was based upon measurements of landing zone diameters and lengths. Both preoperative duplex ultrasound scanning and intraoperative calibrated angiography were used in the decision-making. Self-expanding nitinol-supported stent grafts with an inner lining of ultrathin expanded polytetrafluoroethylene (PTFE) were used. Up to June 2003, only the Hemobahn stent graft (W.L. Gore & Associates, Inc, Flagstaff, Ariz) was used. After June 2003, the Viabahn stent graft (W.L. Gore) also became available and was used instead of the Hemobahn for the available diameters of 6, 7, and 8 mm. Technical improvements of the Viabahn included the deployment over a 0.035-inch instead of a 0.025-inch guide wire, concentric deployment instead of unfolding, and deployment starting at the distal end instead of the proximal end in the Hemobahn, providing an easier and more accurate deployment distally.

Follow-up. In an effort to avoid kinking of the stent graft, our patients were advised to avoid >90° knee flexion. Ankle brachial pressure index (ABI), duplex ultrasound scanning, and plain radiographs of the knee were made at discharge, after 6 weeks, and every 6 months thereafter. Radiographs of the knee were made in extension, including both anteroposterior and lateral views, and in 90° flexion. All patients received antiplatelet or anticoagulation therapy. Up to April 2003, antiplatelet therapy consisted of 80 mg/day acetylsalicylic acid (ASA). After April 2003, this protocol was changed and 75 mg clopidogrel was added for 6 weeks after the operation. Patients who were taking anticoagulants before the intervention, mostly for cardiac indications, continued this therapy after the operation. These patients were also given clopidogrel for 6 weeks.

Definitions. *Quality of arterial outflow* was assessed on preoperative angiography and reported by the number of peroneal and tibial arteries that were patent up to the ankle. The *total stented length* was defined as the total length of the popliteal artery covered by the stent graft, measured on plain radiograph of the knee. This equals the sum of the length of the stent grafts used, minus the sum of the length of the overlap zones. The available stent graft lengths were 5, 10, and 15 cm; therefore, more than one stent-graft was needed in some cases. The *overlap zone* was defined as the extent of insertion of one stent-graft into the other. The *landing zone* was defined as the site of healthy popliteal artery where the stent-grafts ended proximally and distally to the PAA. A

Table II. Details of patients excluded for endovascular repair

Exclusion criteria	*n*	*Treatment*
Elective cases		
Inflow disease	2	Below-knee bypass
Outflow disease*	3	Below-knee bypass
Combination of in/outflow disease	1	Below-knee bypass
Thrombosis of the aneurysm	2	No treatment†
Acute cases		
Thrombosis of the aneurysm	2	Below knee bypass (1) / No treatment‡ (1)
Total	10	

*One patient had a high anterior tibial artery origin; two patients had a too-short distal landing zone.
†Thrombosis diagnosed on day of planned endovascular treatment; no treatment because asymptomatic.
‡Patient presented with marginally threatened acute limb ischemia (Rutherford category II.a)[12] with evolution to moderate claudication in a few days time. He was not treated because of extensive comorbidity, including impaired renal function.

procedure was *technically successful* when the PAA was excluded with preservation of the outflow vessels.

Statistical analysis. Data for continuous variables were expressed as mean ± standard deviation. Data were prospectively collected and analyzed in a retrospective manner. Primary outcome measures were graft patency, limb survival, and patient survival. Time-to-event variables were studied with Kaplan-Meier survival analysis using the Statistical Package for the Social Sciences (SPSS) version 11.0 software (SPSS, Chicago, Ill). The predictive value of the different variables on occlusion of the stent graft was assessed in univariate analyses. Categorical variables were analyzed with χ^2 test and continuous variables were analyzed with the Student *t* test (normal distribution) or Mann-Whitney *U* test (skewed distribution). Significant factors of the univariate analyses were entered in a logistic regression model. $P < .05$ was considered statistically significant.

RESULTS

A total of 67 PAA in 57 patients were evaluated for endovascular repair. Ten PAA were excluded from endovascular repair by the selection criteria (Table II). The remaining 57 PAAs (85%) in 48 patients were treated endovascularly. The mean age of these patients was 66 ± 9 years (range, 52 to 85 years), and 91% were men. Twelve (21%) of the 57 PAAs were symptomatic and presented with acute ischemia (n = 5), venous compression (n = 3), claudication (n = 2), pain in the popliteal fossa (n = 1), or rupture (n = 1). Six patients were treated in an acute setting, of whom five presented with acute limb ischemia. They were treated with thrombolytic therapy (urokinase) and subsequent stent grafting. The other patient had a ruptured aneurysm. The mean PAA diameter was 29 ± 8 mm (range, 16 to 65 mm). Two smaller aneurysms (16 and 18 mm) occurred in two of the patients who presented with acute limb ischemia. All repairs were technically successful. Details of the operative procedures are listed in Table III.

Table III. Details of operative procedures

	n	%
Preoperative		
Grade of outflow quality (number of infrapopliteal vessels)		
1	4	7
2	14	25
3	39	68
Thrombolytic therapy	5	9
Intraoperative		
Approach		
EIA*	1	2
CFA	56	98
No. of stent grafts per aneurysm		
1	18	32
2	32	56
3	6	10
4	1	2
Patients treated bilaterally in one session	6	10
Ancillary procedures:		
Aortic bifurcation graft	1	
Interposition graft CFA	5	
PTA SFA	1	
Total	7	12
Postoperative		
Antiplatelet therapy with/without clopidogrel	17/33	
Anticoagulation with/without clopidogrel	1/6	
Antiplatelet therapy or anticoagulation with/without clopidogrel	18/39	32/68

CFA, Common femoral artery; *EIA,:* external iliac artery; *SFA,* superficial femoral artery; *PTA,* percutaneous transluminal angioplasty.
*Treated with an aortobiiliac prosthesis for abdominal aortic aneurysm in the same session.

During a mean follow-up of 24 months (1 to 72), 12 stent grafts occluded (21%). Thrombolytic therapy was used to recanalize these occluded vessels in 7 patients, open thrombectomy was performed in 1 patient, and the other 4 were managed conservatively (Table IV). Thrombolytic therapy failed in two of the seven patients, and additional thrombectomy was then performed. No patient required amputation or bypass surgery.

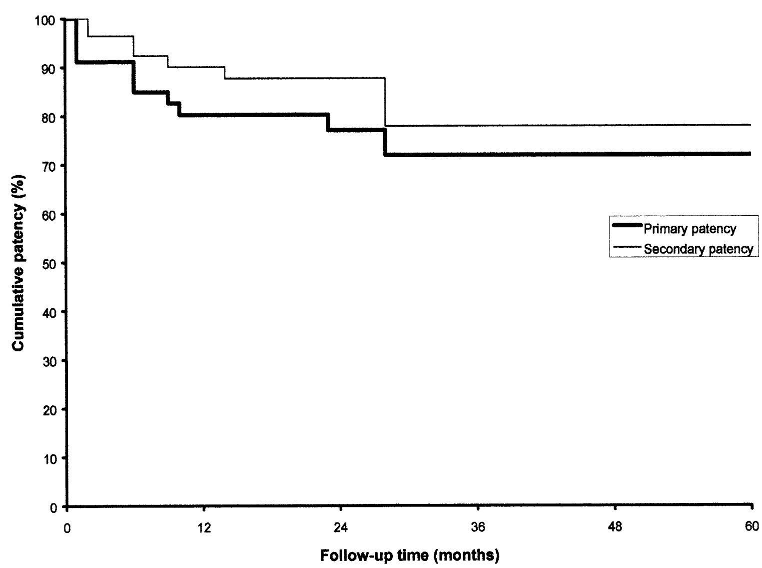
Primary and secondary patency rates were 80% and 90% at 1 year, and 77% and 87% at 2 years follow-up, respectively (Figure 1). None of the stent grafts occluded in the emergent group.

At univariate analysis, treatment with clopidogrel was the only significant predictor for success (n = 18, patency 100%) ($P = .008$). Age of the patient, diameter of the aneurysm, type of stent graft, number and length of endoprostheses, length of overlap zone, number of run-off vessels (one vs two or three), and type of surgery (elective vs emergent), were not. In a multivariate logistic regression, the effect of clopidogrel intake was again found to be the only significant predictor for success ($\chi^2[1] = 10.526$, $P < .01$).

Table IV. Details of 12 occlusions

Patient Number	*Age (y)*	*Time to occlusion (months)*	*Symptoms** (Rutherford)[12]	*Treatment*	*Reocclusion*	*Treatment*	*Residual symptoms** (Rutherford)[12]	*Status*	*Follow-up (months)*
1	82	6	Claudication (2)	–	–	–	Claudication (1)	Occluded	65
2	82	6	Acute ischemia (IIb)	–†	–	–	Claudication (2)	Occluded	56
3	72	6	Acute ischemia (IIa)	Thrombectomy	Yes	No	Claudication (3)	Occluded	51
4	78	1	Acute ischemia (IIa)	Thrombolysis‡	Yes	No	Claudication (3)	Occluded	45
5	55	9	Claudication (2)	–	–	–	Claudication (2)	Occluded	45
6	59	1	Acute ischemia (IIa)	Thrombolysis§	No	–	Asymptomatic (0)	Open	41
7	68	28	Claudication (2)	–	–	–	Claudication (2)	Occluded	55
8	53	1	Acute ischemia (IIa)	Thrombolysis	Yes	No	Claudication (3)	Occluded	24
9	75	1	Acute ischemia (IIa)	Thrombolysis	No	–	Asymptomatic (0)	Open	20
10	66	23	Claudication (3)	Thrombolysis	Yes	Thrombectomy	Claudication (1)	Open	40
11	61	10	Claudication (3)	Thrombolysis**	No	–	Claudication (1)	Open	20
12	63	1	Acute ischemia (IIa)	Thrombolysis††	Yes	No	Claudication (3)	Occluded	2

*Rutherford classification for acute limb ischemia (I, IIa, Iib, and III) and for chronic limb ischemia (0 to 6).
†Occlusion of Hemobahn following occlusion of iliac inflow tract (Vanguard contralateral limb), treated with crossover bypass to the deep femoral artery without additional treatment to recanalize the occluded Hemobahn.
‡Thrombolysis followed by iliac artery and superficial femoral artery PTA and stent.
§Thrombolysis followed by Wallstent to cover a fold in the proximal end of the Hemobahn.
**Thrombolysis failed and was followed by open thrombectomy and proximal and distal patch plasty.
††Thrombolysis followed by stent at the proximal border of the stent for stenosis.



Numbers at risk:						
Primary patency:	57	33	21	10	7	3
Secondary patency:	57	38	24	11	7	3

Fig 1. Cumulative primary and secondary patency rates. Standard errors ranged from 1.7% to 7.7% and from 1.8% to 7.8% for primary and secondary patency, respectively.

Other complications occurred, including migration of the prosthesis, stenosis at the border of the stent graft, continuous sac enlargement, and breakage of the stent material (Table V). Early migration led to the disconnection of two overlapping stent grafts and a type III endoleak in one patient. Diagnosis was made on the first postoperative day with radiograph, and repair with a bridging stent graft was successful. In two other patients, the sealing zone initially chosen was short, and a slight late migration occurred that led to a type I endoleak. Repair with an extension was successful. Stenosis at the border of the stent graft occurred in two patients. One of these patients presented with claudication after 12 months and was successfully treated with percutaneous transluminal angioplasty (PTA).

Table V. Complications other than occlusions

Complication	*n*	*Treatment*	*Status*
Migration			
Without endoleak	5	—	Patent
With type 1 endoleak	2	Extension	Patent
With type 3 endoleak*	1	Bridging stent-graft	Patent
Sac enlargement	1	—	Patent
Stenosis†	2	PTA	Patent
Stent breakage	2	Thrombectomy‡(1)	Patent
		No treatment§ (1)	Occlusion
Total	13 in 9 patients		

PTA, Percutaneous transluminal angioplasty.
*Type 3 endoleak was diagnosed on the duplex scan on the first postoperative day; radiograph showed disconnection.
†One of these two patients had an extension proximally and a PTA distally, and is the patient with sac enlargement.
‡This patient had an occlusion (patient 11; Table IV).
§This patient had an occlusion (patient 7; Table IV); no treatment because of only mild claudication.

The other patient was asymptomatic, but the distal stenosis was diagnosed on angiography during repair for a proximal endoleak. Treatment with PTA was successful. Breakage of the stent material was observed in two patients, which led to occlusion in both cases.

During follow-up, five patients died of unrelated causes after a mean of 40 ± 20 months after the procedure. The 1-year and 2-year patient survival was 100% and 97%.

DISCUSSION

This prospective cohort study shows that the results of endovascular treatment of PAA are slightly inferior to those of open repair. The primary patency rate was 77% at 2 years of follow-up. Complications occurred in 21 (37%) of the 57 treated aneurysms and included occlusions, stenoses, migrations, endoleaks, and continuous sac enlargement. Twelve stent grafts (21%) occluded, but no patient with an occluded stent-graft needed a femoropopliteal bypass or an amputation.

We believe this is the largest series of PAA treated with one type of endovascular stent graft. The Hemobahn and the Viabahn, which were used in this series, are made of a nitinol stent with an inner lining of ultrathin (100 μm) expanded PTFE. The advantages of these stent grafts over other designs may be that they have a high flexibility, which is necessary to cross the knee joint, and that the luminal surface is made of smooth graft material instead of irregular stent material.

A literature search of reports on endovascular treatment for PAA with commercial devices only reveals case reports and small series (Table I).[13-21] Some of these devices, including the Cragg Endopro System 1 (Mintec, Freeport, Bahamas) which became later the Passager stent graft (Boston Scientific, Watertown, Mass), and the Corvita stent graft (Boston Scientific, Bülach, Switzerland), were relatively stiff. Therefore, they were not ideally designed to be used in a relatively small artery such as the popliteal artery, which is subject to repetitive flexion and extension. Other devices such as the Wallgraft (Boston Scientific, Natick, Mass) and the Hemobahn/Viabahn are more flexible.

An advantage of the Hemobahn/Viabahn, in our view, is that the graft—not the stent—is situated at the luminal surface. In addition, greater lengths are available. The mean covered length in our series was 20 ± 6 cm (range, 10 to 34). In 70% of the cases, we used more than one stent-graft to cover the length of the aneurysm and the two landing zones, with landing and overlap zones that are each preferably 3 cm long. These long overlap and landing zones are chosen to overcome the complications of migration, which may lead to either endoleak at the landing zone or disconnection at the overlap zone. A diameter mismatch between proximal and distal landing zone is another reason to use more than one stent graft.

Several recent studies have been published showing results of open reconstruction with a femoropopliteal bypass. In these studies, including both emergent and elective cases and treated with either venous bypasses or prostheses, 5-year primary patency and limb salvage rates were 69% to 86% and 87% to 98%, respectively.[3,4,6,8,9,22-24] The 30-day mortality was 0% to 7.7%. In some of these studies, primary patency rates were 82% to 92% for the subgroup of elective cases.[4,6,23,24] All studies, however, were retrospective and may have suffered from selection bias.

Our prospective series of endovascular repair had a 2-year primary patency rate of 77% and a limb savage rate of 100% after a mean follow-up of 24 months. The estimated 5-year primary patency rate was 72%; however, with only 3 patients at risk, comparison with open results at this time interval is unreliable. Persistent enlargement of the aneurysm sac has been diagnosed after open repair in ≤33% of the cases.[22,25,26] In some, enlargement was caused by within sac flow from feeding branches. No type II endoleak was found in our endovascular series and only one aneurysm increased in diameter during follow-up. No good explanation for this difference between open and endovascular repair could be found.

Forty-two percent of occlusions (5 of 12) occurred within the first month and 75% (8 of 12) within 6 months after the operation. This may suggest an influence of the postoperative antiplatelet therapy. Therefore, in analogy with the use in coronary artery bypass stenting and femoropopliteal stenting,[27] we changed the follow-up protocol after April 2003 and added clopidogrel for 6 weeks after the operation. No occlusion occurred since then in 18 PAAs treated. In our study, the additional use of clopidogrel proved to be the only significant predicting factor of success at univariate analysis.

Endovascular treatment of a PAA with stent grafts is a relatively easy, minimally invasive procedure that takes about 1 hour to complete.[11] A critical point leading to success, however, is the meticulous measuring of the landing zone diameters. In our practice, this was best done by a dedicated vascular technician and controlled by means of preoperative and intraoperative calibrated angiography. Another point of attention is to avoid placing the end of an overlap zone in the bending zone of the knee, situated at the level of the upper margin of the patella. This is especially true when the distal margin of the aneurysm ends at the same level as the end of the overlap zone. In two patients, this led to a stent fracture and eventually to occlusion of the stent-graft (Table V).

In our view, the minimally invasive character of the endovascular procedure is an advantage, especially in patients with bilateral aneurysms where operation time can be saved, which is important in a country where long waiting lists for operations exist. This minimally invasive approach may be an advantage in acute cases with critical ischemia because it avoids incisions in an ischemic leg. Moreover, in cases where occlusion of the stent-graft leads to invalidating claudication or critical ischemia, a below-knee femoropopliteal bypass is still possible. Therefore, in our hospital the endovascular procedure is the first treatment option, irrespective of the availability of saphenous vein.

CONCLUSIONS

Endovascular repair of a popliteal artery aneurysm is feasible. Patency appears slightly inferior to open repair, although most open series were retrospective studies. Recent changes to the material used and the additional use of clopidogrel may improve patency rates, however. To better understand the potential role of this minimally invasive technique, further studies are necessary to define the ideal indications, anatomic and prosthetic graft limitations, and the effect of anticoagulant and antiplatelet treatment. A randomized controlled trial should be undertaken to fully evaluate the endovascular exclusion of PAAs compared with the standard open femoropopliteal bypass procedure and with regard to patency and postoperative complications.

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