

Open repair versus endovascular treatment for asymptomatic popliteal artery aneurysm: Results of a prospective randomized study

Michele Antonello, MD, Paolo Frigatti, MD, Piero Battocchio, MD, Sandro Lepidi, MD, Diego Cognolato, MD, Alberto Dall'Antonia, MD, Rudi Stramanà, MD, Giovanni P. Deriu, MD, and Franco Grego, MD, *Padua, Italy*

Purpose: The aim of this prospective randomized study was to evaluate the relative risks and advantages of using the Hemobahn graft for popliteal artery aneurysm (PAA) treatment compared with open repair (OR). The primary end point was patency rate; secondary end points were hospital stay and length of surgical procedure.

Methods: The study was a prospective, randomized clinical trial carried out at a single center from January 1999 to December 2003. Inclusion criteria were an aneurysmal lesion in the popliteal artery with a diameter ≥ 2 cm at the angio-computed tomography (CT) scan, and proximal and distal neck of the aneurysm with a length of >1 cm to offer a secure site of fixation of the stent graft. Exclusion criteria were age <50 years old, poor distal runoff, contraindication to antiplatelet, anticoagulant, or thrombolytic therapy, and symptoms of nerve and vein compression. The enrolled patients were thereafter prospectively randomized in a 1-to-1 ratio between OR (group A) or endovascular therapy (ET) (group B). The follow-up protocol consisted of duplex ultrasound scan and ankle-brachial index (ABI) measured during a force leg flexion at 1, 3, and 6 months. Group B patients underwent an angio-CT scan and plain radiography of the knee with leg flexion ($>120^\circ$) at 6 and 12 months, and then yearly.

Results: Between January 1999 and December 2003, 30 PAAs were performed: 15 OR (group A) and 15 ET (group B). Bypass and exclusion of the PAA was the preferred method of OR; no perioperative graft failure was observed. Twenty stent grafts were placed in 15 PAAs. Endograft thrombosis occurred in one patient (6.7%) in the postoperative period. The mean follow-up period was 46.1 months (range, 12 to 72 months) for group A and 45.9 months (range, 12 to 65 months) for group B. Kaplan-Meier analysis showed a primary patency rate of 100% at 12 months for OR and 86.7% at 12 months with a secondary patency rate of 100% at 12 and 36 months for ET. No statistical differences were observed at the log-rank test. The mean operation time (OR, 155.3 minutes; ET, 75.4 minutes) and hospital stay (OR, 7.7 days; ET, 4.3 days) were statistically longer for OR compared with ET ($P < .01$).

Conclusion: We can conclude, with the power limitation of the study, that PAA treatment can be safely performed by using either OR or ET. ET has several advantages, such as quicker recovery and shorter hospital stay. (J Vasc Surg 2005;42:185-93.)

Popliteal artery aneurysms (PAAs), despite their rarity, account for 70% to 80% of all peripheral artery aneurysms.¹⁻⁵ They occur more frequently in men, and about half are bilateral and are accompanied by aortic or femoral aneurysms.⁶⁻⁹ A PAA can be asymptomatic and is often discovered by coincidence, or is symptomatic with acute thrombosis or distal embolization; rupture is uncommon.⁶⁻⁹ Asymptomatic and symptomatic aneurysms of ≥ 2 cm in diameter are considered candidates for elective surgery.¹⁰

The goals of surgical treatment for PAA are to isolate and exclude the aneurysm, prevent distal embolization, and allow effective revascularization. Limb salvage is low in patients with symptomatic PAAs, particularly in those with acute ischemia; it is higher for asymptomatic patients.¹¹⁻¹³ Moreover, it is also argued that although long-term graft patency may not be good, limb salvage is achieved if the graft remains patent for >1 year.¹⁴

During recent years, endovascular surgery has become a valid alternative to open repair. Particularly significant progress has occurred in the endovascular treatment of arterial aneurysms, especially of the abdominal aorta. Potentially, PAAs are also treatable by an endovascular procedure. The endovascular exclusion of PAAs, a less invasive procedure compared with conventional surgery, offers some advantages: lower blood loss, quicker recovery, and shorter hospital stay; moreover, it permits

From the Department of Vascular Surgery, University of Padua.

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Reprint requests: Michele Antonello, MD, Department of Vascular Surgery, University of Padua, School of Medicine, Via Giustiniani 2, 35125 Padua, Italy (e-mail: michele.antonello.1@unipd.it).

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Table I. Demographic and clinical data

	Group A (OR)*	Group B (ET)*
Male/female	12/3	14/1
Mean age (range)	64.7 (51-84)	62.7 (51-81)
Smoking (%)	10 (66.7)	9 (60)
Diabetes mellitus (%)	2 (13.3)	2 (13.3)
Hypertension† (%)	10 (66.7)	7 (46.7)
CAD‡ (%)	4 (26.7)	5 (33.3)
Hypercholesterolemia (%)	4 (26.7)	4 (26.7)
COPD§ (%)	3 (20)	2 (13.3)

OR, Open repair; ET, endovascular treatment; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease.

*P values for all data are not significant.

†History of hypertension; patient taking at least one antihypertensive medication.

‡History of myocardial infarction, angina or electrocardiographic sign of myocardial ischemia.

§Defined as forced expiratory volume in 1 second (FEV₁) <1 or FEV₁/FVC (forced vital capacity) <75.

the endograft to be deployed through a percutaneous access.

The main problem with PAA endovascular reconstruction is the availability of an endograft with the good flexibility that is required for the close relation of the aneurysm with the knee joint. The Hemobahn graft (W.L. Gore & Assoc, Flagstaff, Ariz) is a self-expanding nitinol stent, internally covered by an ultra-thin polytetrafluoroethylene (PTFE) graft. As a result of a special nitinol stent design, the Hemobahn offers good flexibility and radial stiffness. Endovascular repairs for PAAs have been described by several authors, but few reports have showed the safety and efficacy of the Hemobahn endograft in the treatment of this type of aneurysm.¹⁵⁻¹⁷

The aim of this prospective randomized study was to evaluate the relative risks and advantages of using the Hemobahn graft for PAA treatment compared with surgical repair. The primary end points were primary and secondary patency rates; the secondary end points were hospital stay, length of surgical procedure, and any other local complication. Our hypothesis was that ET of PAAs would obtain better results compared with OR.

MATERIALS AND METHODS

Study design. The study, which was approved by the ethics committee of our institution, was a prospective, randomized clinical trial carried out at a single center from January 1999 to December 2003. During the study period, all patients with a diagnosis of PAA at the duplex scan underwent an angio-computed tomography (CT) scan and digital subtraction angiography (DSA) to define the aneurysm extension and diameter, proximal and distal necks, significant collateral vessels originating from the aneurysm, and distal outflow.

Inclusion criteria were:

1. an aneurysmal lesion in the popliteal artery with a diameter of ≥ 2 cm at the angio-CT scan, and

2. proximal and distal neck of the aneurysm with a length of >1 cm to offer a secure site of fixation of the stent graft.

Exclusion criteria were:

1. age <50 years old;
2. poor distal runoff, defined as a runoff score of <8 according to the system recommended by the Joint Council of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery in which a value of 1 represents optimal runoff and a value of 10 absent runoff¹⁸;
3. a contraindication to antiplatelet, anticoagulant, or thrombolytic therapy, and
4. symptoms of nerve and vein compression.

The enrolled patients were thereafter prospectively randomized in a 1-to-1 ratio between open repair (OR) (group A) or endovascular treatment (ET) (group B). Patients with bilateral PAAs were enrolled in the study; the second randomization was performed after a minimum of 3 months.

The randomization scheme was obtained by using sealed opaque envelopes containing the indication to OR or ET, that were put into a container in blocks of 10 (5 OR, 5 ET). The envelopes were extracted by the study controller the day before the procedure was planned. Patients were excluded from this study and therefore from randomization if they declined to participate.

Before starting this study, we calculated the sample size for each of the two randomized cohorts. A retrospective review of our data concerning the results of 23 consecutive PAAs treated with OR from January 1995 to December 1998 revealed a primary patency rate estimated with the Kaplan-Mayer analysis of approximately 90%. From this data, 302 patients (151 for each group) needed to be enrolled to reveal a statistical difference at 1-year follow-up. The main assumptions for this calculation were (1) the 1-year postoperative primary patency rate for the endovascular repair was expected to be 95% and (2) the power of the study was 80% at the .05 significance level by log-rank-test. To enroll 302 patients, we estimated, on the basis of our previous data, a period of 50 years would have been necessary to project this study. Nevertheless, we decided to do it with a lower number of patients and the consequent power limitation to test the safety and efficacy of ET for PAA repair.

Patients. A total of 36 patients with a diagnosis of PAA at the duplex ultrasound scan between January 1999 and December 2003 were considered for inclusion. Ten (27.8%) were excluded because of age <50 years old in two, poor distal run-off in four, proximal or distal neck with a length of <1 cm in another three, and symptoms of nerve and vein compression in one. Twenty-six patients (4 with bilateral PAAs) were randomized and assigned to the two groups: group A, 15 patients for OR; and group B, 15 patients for ET. Two patients with bilateral PAAs were assigned twice to group A and twice to both groups. The

demographic data and the preoperative risk factors for the two groups are reported in Table I. The mean aneurysm diameters and lengths were 35.8 ± 12.3 mm and 10.3 ± 2.5 cm in group A, and 36.9 ± 14.6 mm and 9.8 ± 2.1 cm in group B; they were saccular in 25 patients (83.3%) (13 in group A, 12 in group B) and fusiform in five patients (16.7%) (2 in group A, 3 in group B).

Stent-graft design.

Knee joint movements should be taken into account in the endovascular treatment of PAAs. The ideal graft should have good flexibility and resistance to external compression so that occlusion and dislodgment are avoided. The Hemobahn endoprosthesis was used for PAA treatment. The Hemobahn is a self-expanding nitinol stent, internally covered by an ultra-thin PTFE graft; therefore, it is a biocompatible graft with a smooth, blood contact surface. In addition, the special nitinol stent design, with a reduced number of net junctions, allows the combination of flexibility and radial stiffness, and the risk of kinking is minimized. Hemobahn graft sizes range from 6 to 13 mm in diameter and from 5 to 15 cm in length. Two clear linear radiopaque markers along the graft allow an easy and exact deployment in the target vessels. The stent graft is released from the catheter as the containing lacing fibre is withdrawn.

Endovascular technique. To permit a conversion to OR in case of failure of ET, the endovascular procedure was always performed in the operating room equipped with a 12-inch digital C-arm fluoroscopy unit (Series Eurocolumbus, Milano, Italy). Under locoregional anesthesia, an open exposure of the femoral artery was performed to minimize the risk of postoperative pseudoaneurysms only when the device required a sheath $>9F$. Otherwise, the antegrade percutaneous transfemoral puncture (18-gauge needle, 9F sheath, and 150-cm \times 0.025-in Terumo guidewire) was used.

The final choice of the stent length was confirmed by the intraoperative angiography. Stent diameters must take into consideration 20% to 25% oversizing. In choosing the graft length, it is necessary to consider that the stent extremity should not land at the knee joint region or very proximal to it (2 to 3 cm). Indeed, in this anatomic area, the popliteal artery shows the maximal flexibility. For this reason the endograft is always landed 2 to 3 cm over the knee joint region.

Deployment begins with a steady, continuous pull of the deployment knob. The stent graft is released from the catheter as the lacing fibre is withdrawn, beginning from the proximal end. Deployment is complete when the expanded PTFE (ePTFE) lacing fiber is fully withdrawn from the catheter. When significant sural branches are present, coil embolization is required before stent introduction to avoid the possibility of a type II endoleak (Fig 1). If multiple stent grafts were required to seal the PAA, the endografts were overlapped by at least 1 cm.¹⁹

The ET is considered successful when the PAA is completely excluded with no signs of endoleaks at the

intraoperative DSA. To verify the flexibility of the endograft during the knee joint movement, an intraoperative control DSA in lateral projection with a knee flexion $>120^\circ$ was performed (Fig 2). During this examination, a plain radiograph was obtained to detect any deformity of the structure of the endograft skeleton. The presence of an endograft kinking resulting in a stenosis $>50\%$ was considered positive and a criterion for surgical conversion.

Immediately after the procedure, antiplatelet therapy was started with a single intravenous dose of 125 mg of acetylsalicylic acid (ASA). Double antiplatelet therapy of ASA (100 mg daily) plus ticlopidine (250 mg twice a day) was started from the first postoperative day and continued for 1 month; thereafter, the antiplatelet therapy was continued indefinitely with ASA (100 mg daily).

Open surgical technique. Direct endoaneurysmorrhaphy and bypass through a medial approach was the preferred method of repair. Aneurysm excision as an alternative method was used in presence of small PAAs.

The bypass was performed with an end-to-side anastomosis, preferably from the above-knee to the below-knee popliteal artery. When the surgeon intraoperatively judged that these arteries were not suitable to receive a vascular anastomosis for the reason that their macroscopic aspect was suspicious of a dysplastic degeneration and therefore at risk of developing an anastomotic pseudoaneurysm, the superficial first or, thereafter, the common femoral artery were chosen as the inflow artery and the tibioperoneal trunk as outflow artery.

Reversed great saphenous vein was the conduit of choice. When the great saphenous vein was not available or suitable for a bypass, preference was given to a 7-mm PTFE graft. The bypass pathway was always anatomic. At discharge, antiplatelet therapy was started with ASA (100 mg daily) indefinitely.

Postoperative assessment and clinical data follow-up examination. The follow-up protocol consisted of a duplex ultrasound scan the day before discharge to evaluate the graft patency, PAA exclusion, and the ankle-brachial index (ABI), including during forced leg flexion for group B patients. A reduction of ABI of $\geq 20\%$ from rest to leg flexion was considered a sign of endograft kinking and an ET failure. The long-term follow-up was based on clinical evaluation at 1 and 3 months, and every 6 months thereafter, with duplex ultrasound scan and ABI measurements as previously described. In case of a sign of $>50\%$ restenosis at the duplex ultrasound scan, a DSA was always performed. A restenosis of $>50\%$ was considered a failure of the procedure.

To evaluate the patency and the stent skeleton integrity and flexibility, the group B patients underwent an angio-CT scan and plain radiograph of the knee joint with forced leg flexion ($>120^\circ$) at 6 and 12 months and then yearly.

Statistical analysis. Data were analyzed by using the χ^2 and the Fisher's exact test for noncontinuous variables, the Student's *t* test for continuous variables, and the log-rank test for Kaplan-Meier analysis.

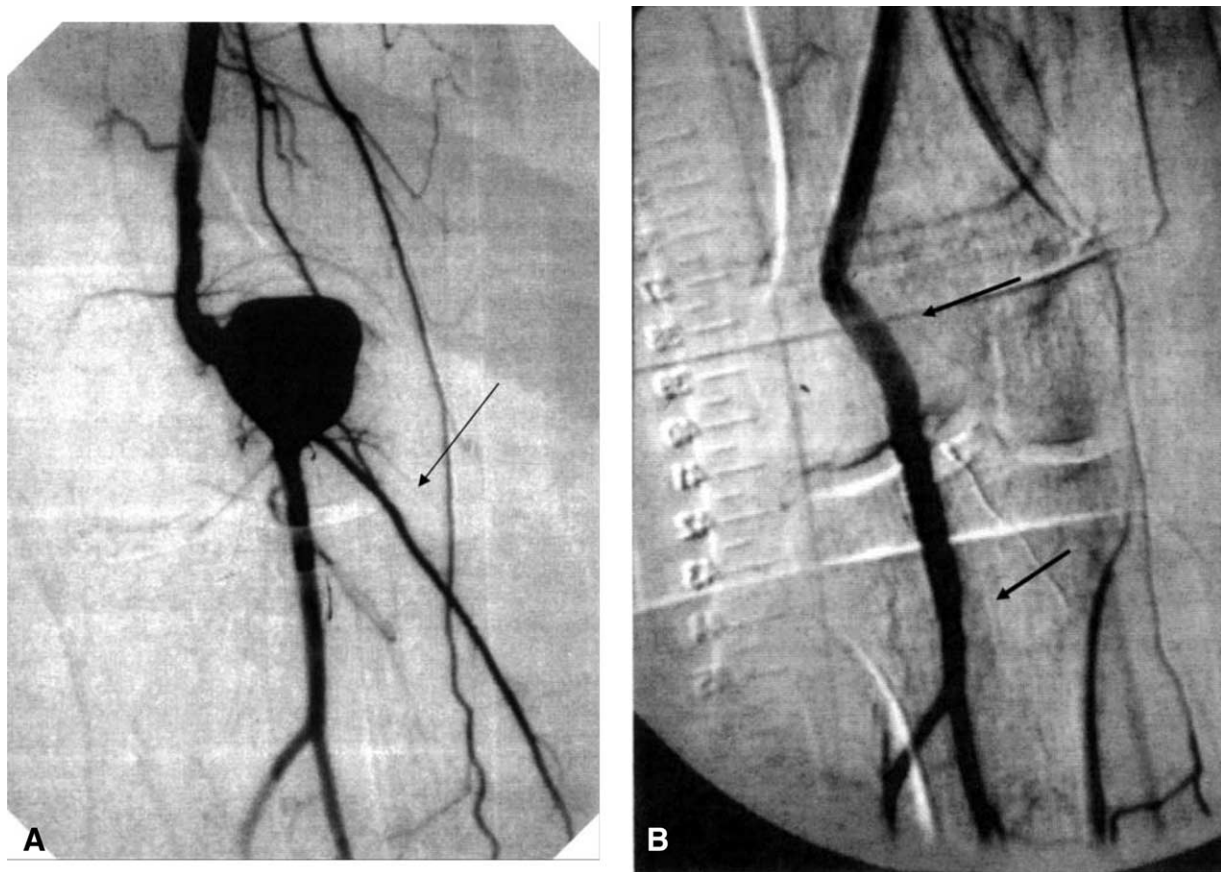


Fig 1. **A.** Preoperative digital subtraction angiography demonstrates a collateral artery (*arrow*) originating from the aneurysmal sack of the popliteal aortic aneurysm. **B.** Digital subtraction angiography after coil-embolization of the collateral vessel and endograft deployment (*arrows* point to endograft location).

RESULTS

Between January 1999 and December 2003, 30 PAAs (15 group A [OR] and 15 group B [ET]) were performed in the cohort of 26 randomized patients (4 with bilateral PAAs). Of the four patients with bilateral PAAs, two were randomized twice into group B, and the others were assigned to both treatments. In the same period, another 16 patients underwent 18 PAA corrections with OR outside of the study. Seven of these patients were symptomatic: six had acute ischemia, with an associated thrombosed PAA, and one patient had critical leg ischemia with a patent fusiform PAA. Seven were asymptomatic, presenting with a poor distal runoff in four and a distal neck length of <1 cm in three. Two patients were excluded because they were <50 years old. The mean PAA diameter of these patients was 3.4 ± 0.4 cm.

The randomized patients represented the 65.2% of the whole population that underwent PAA surgery at the Department of Vascular Surgery, University of Padua.

There were no statistical differences between the demographic and clinical data of the two groups (Table I).

Open repair. Bypass and exclusion of the PAA with direct endoaneurysmorrhaphy was the preferred method of

repair; two (13.3%) had aneurysm excision. All patients had their aneurysms repaired through a medial approach. OR was performed under locoregional anesthesia in nine patients (60%) and general anesthesia in six (40%).

Reversed greater saphenous vein was the conduit of choice. In four patients (26.7%), a prosthetic bypass using ePTFE was performed for an unsuitable saphenous vein. Inflow arteries varied among the study patients: the common femoral artery was used in two (13.3%), the superficial femoral artery in seven (46.7%), and the above-knee PA provided inflow in six patients (40%). The infrageniculate PA served as the outflow artery in most cases. Four bypasses (26.7%) required a distal anastomosis on the tibioperoneal trunk. No perioperative graft failure was observed.

Endovascular treatment. ET of PAAs was performed under locoregional anaesthesia in all cases. Twenty stent grafts were placed in 15 PAAs: single devices were used in 10 aneurysms (66.7%), four (26.7%) required two stent grafts, and one (6.7%) needed three. The mean diameter and length of the implanted endografts were 7.9 ± 1.1 mm and 11.4 ± 3.2 cm.



Fig 2. Intraoperative digital subtraction angiography shows the absence of endograft kinking during leg flexion (arrows point to endograft location).

Two patients required the embolization of a collateral artery originating from the aneurysmal sac before the endograft was placed to prevent a type II endoleak (Fig 1).

Aneurysmal exclusion was successful in all patients; none required conversion to open surgery, no signs of endoleak, and no endograft kinking during leg flexion were observed at the intraoperative DSA (Fig 2).

Endograft thrombosis occurred in one patient (6.7%) the day after the procedure, and it was related to an intraoperative difficulty during the release of the distal part of the endograft. The patient underwent successful intra-arterial thrombolytic therapy, and thereafter, in an additional endovascular procedure, dilatation of the distal part of the endograft re-established the patency of the stent-graft.

The mean operation time (155.3 minutes for OR and 75.4 minutes for ET) and hospital stay (7.7 days for OR and 4.3 days for ET) were statistically longer for group A compared with group B ($P < .01$) (Table II).

Follow-up. The mean follow-up period was 46.1 months (range, 12 to 72 months) for group A and 45.9 months (range, 12 to 65 months) for group B.

Table II. Procedural early results

	Group A (OR)	Group B (ET)	P
Graft/endograft occlusion	0	1 (6.7%)	NS
Primary patency rate	100%	93.3%	NS
Assisted patency rate	—	100%	NS
Limb salvage rate	100%	100%	NS
Endoleaks	—	0	NS
Mean operative time (min)	75.4 (50-90)*	195.3 (120-255)*	<.01
Mean hospital stay (days)	7.7 (7-11)*	4.3 (2-9)*	<.01

OR, Open repair; ET, endovascular treatment; NS, not significant.

*Range.

Two group A patients had a thrombosis of a ePTFE femoropopliteal above-knee bypass and of a greater saphenous vein femorotibioperoneal trunk bypass after 28 and 41 months. These patients were not considered for redo surgery, because after the acute event, they presented with lower limb claudication >500 m at the treadmill test.

The Kaplan-Meier analysis showed a primary patency rate of 100% at 12 months, 90.9% at 36 months, and 81.8% at 48 months (Fig 3). The clinical examination and the duplex ultrasound scan performed during the follow-up period showed the patency of the remaining bypasses.

The duplex ultrasound scan performed during the follow-up period at 6 and 24 months revealed an asymptomatic restenosis of >60% in the distal part of the endograft in two group B patients, which DSA confirmed. These patients underwent an adjunctive endovascular procedure of dilatation and deployment of a covered stent.

No signs of any type of endoleak, of aneurysmal sac increasing (36.9 ± 14.6 cm of diameter at the preoperative angio-CT; 36.7 ± 14.3 cm at angio-CT performed 12 months after the procedure), or of endograft kinking during leg flexion were observed at the angio-CT or at the plain radiograph performed during the follow-up period (Fig 4). No significant variation of the ABI was observed during the follow-up period between the rest position and during forced leg flexion.

The primary patency rate was 86.7% at 12 months and 80% at 48 months, with a secondary patency rate of 100% in the same period (Figs 3 and 5). No statistical differences were observed at the log-rank test for the primary patency rate at 12 months and for the secondary patency between the two groups at 36 months.

During the follow-up period, no deaths occurred in any study patients.

DISCUSSION

Surgical treatment is indicated for all symptomatic or complicated PAAs; controversy still exists over the optimal management of asymptomatic PAAs. The recommendation for the ideal treatment of these patients should be based on the PAA's natural history, but few data are available. Indications for surgical intervention for asymptomatic PAAs

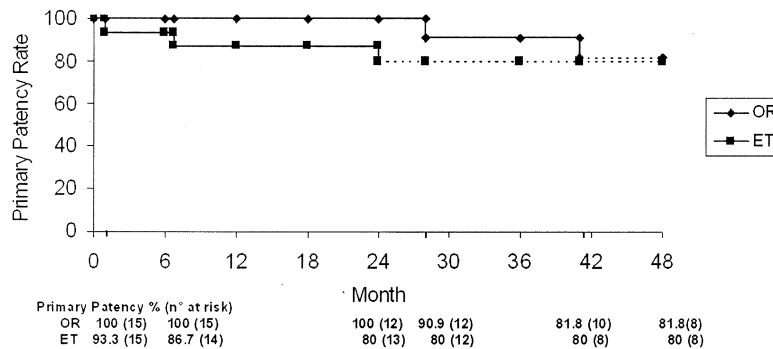


Fig 3. Kaplan-Meier analysis shows the primary patency rate for open repair (OR) (group A) and endovascular treatment (ET) (group B) at 6-month intervals. Standard error is >10% after 42 months for OR and after 24 months for ET (dashed line).

have varied. Lowel et al¹⁰ reported aneurysm diameter of 2 cm, presence of thrombus, and poor runoff as risk factors for complications in a group of 67 aneurysms treated conservatively. Inahara and Toledo²⁰ found no significant correlation between aneurysmal sac diameter and the risk for complication.

Many authors support surgical management as the treatment of choice for asymptomatic PAAs for preventing the ischemic complications from aneurysm embolism or thrombosis and have achieved good surgical results in terms of graft patency and limb salvage rate.¹¹⁻¹⁴ The goals of surgical treatment of PAAs are isolation of the aneurysm, preventing distal embolization, and effective revascularization. Five-year patency rates after surgical repair are >90% for asymptomatic aneurysms and >75% in patients with symptoms.¹¹⁻¹⁴

Surgical mortality is low, ranging from 0% to 1% in asymptomatic patients and 2.1% in acute patients.²¹ However, morbidity rates as high as 30% to 40% have been reported, usually associated with wound complications.²²⁻²³

During recent years, endovascular surgery has become a valid alternative to open repair. Particularly significant progress has been observed in the endovascular treatment of arterial aneurysms, especially of the abdominal aorta. Potentially, PAAs are also treatable by an endovascular approach. Moreover, compared with conventional surgical treatment, the percutaneous endoluminal exclusion of lower-extremity aneurysms as a minimally invasive procedure offers some advantages, including lower blood loss, quicker recovery, and shorter hospital stay.²⁴⁻²⁶

However, given the currently available stent-graft designs, a percentage of aneurysms are not amenable to percutaneous exclusion because of their position at the hip or knee joint or at the branching of major vessels. Owing to these limitations and the low incidence of femoropopliteal aneurysms, the experience with endoluminal grafting for aneurysm disease in this vessel segment has been limited and largely anecdotal.¹⁹⁻²⁸ Endovascular repair of a popliteal aneurysm was first described in 1994 by Marin et al,²⁷ who used a homemade stent graft consisting of a PTFE

graft and 2 Palmaz stents to seal the ends of the graft to the vessel wall. In others reports, a variety of stents (Palmaz, Cragg, Wallstent, or Gianturco) covered with PTFE, polyester, polyurethane, or autologous vein were used.²⁸⁻³⁵

The early models—polyester and PTFE grafts supported by stents—were only marginally successful; but more recently, encouraging preliminary results were achieved with Wallstent-PTFE (Boston Scientific, Natick, Mass) and the Wallgraft (Wallstent covered by a polyester graft) for endoluminal treatment of popliteal aneurysms with a secondary patency rate of 92% as described by Howell et al¹⁷ in a series of 13 PAAs in which a secondary patency rate of 92% was achieved.³³⁻³⁵ Tiellu et al¹⁵ have also observed good early outcomes with the Hemobahn stent-graft in 21 patients (23 procedures), with a cumulative primary patency rate at 15 months of 75%. Gerasimidis et al¹⁶ reported a series of 11 patients with 12 PAAs who underwent ET using Hemobahn with a secondary patency rate of 75% at 12 months.

All these studies, with the only exception being the one of Tiellu et al,¹⁵ are retrospective, and especially, none compare the results of ET with OR. To our knowledge, our study, which used a Hemobahn endograft for asymptomatic PAAs in a cohort of 26 patients, is the first prospective randomized trial that compares OR versus ET. We chose this device because of its technical characteristics: it is a self-expanding nitinol stent, internally covered by an ultra-thin PTFE graft with the special nitinol stent design that reduces the number of net junctions, thus allowing the combination of flexibility and radial stiffness and therefore minimizing the risk of kinking during the knee joint flexion.

This comparative trial was performed with the assumption of a theoretic advantage in using the ET, but results showed no statistical difference in primary and secondary patency rates at 12 months between the two treatments. The primary patency rate estimated with the Kaplan-Meier analysis at 12 months was 100% for OR and 86.7% for ET, the secondary patency rate at 36 months was 90.9% for OR and 100% for ET. The primary patency rate for OR is comparable to those reported by other previous studies,



Fig 4. A. Angio-computed tomography scan and (B, C) plain radiographs of the knee 24 months after the procedure show the flexibility and the integrity of the Hemobahn stent graft during rest position and forced knee flexion ($>120^\circ$).

and the results on primary and secondary patency rate for ET are slightly better rather than those from other studies that reported a primary patency rate at 1 year ranging from 47% to 75%.¹⁵⁻¹⁶

This may be the result of patient selection and of the postoperative therapy. In fact for this trial, only patients with optimal anatomic characteristics for ET and especially with a runoff score of <8 according to the system recom-

mended by the Joint Council of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery were enrolled. Postoperative therapy based on a single 125-mg intravenous dose of ASA immediately after the surgical procedure, followed by double antiplatelet therapy with ASA (100 mg daily) plus ticlopidine (250 mg twice a day) continued for 1 month, differs from the other reports in which a single oral dose of ASA (100 mg daily) or

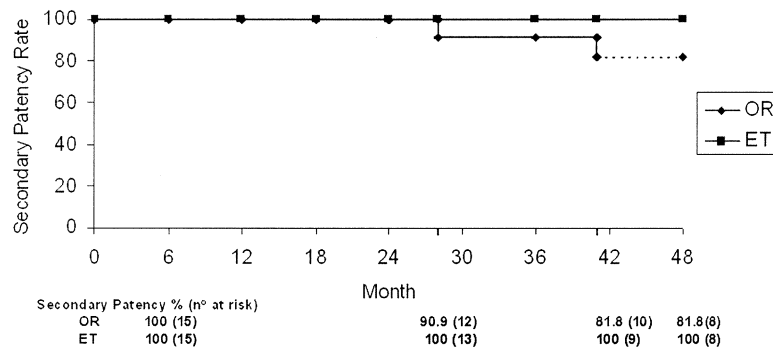


Fig 5. Kaplan-Meier analysis of the secondary patency rate for open repair (OR) (group A) and endovascular treatment (ET) (group B) at 6 months intervals. Standard error is $>10\%$ after 42 months for OR (dashed line).

an anticoagulant therapy with low-molecular-weight heparin were used.

As expected, statistical differences emerged for the mean operation time (155.3 minutes for OR, 75.4 minutes for ET) and, particularly, for the mean hospital stay (4.3 days for OR, 7.7 days ET) ($P < .01$). The ET permits a quicker recovery and appears to have a great potential advantage, not only for young patients that needed to re-establish their normal activity quickly but also for older patients in which a prolonged hospital stay is harmful.

No signs of endoleak were observed during the follow-up period. This may be the result of our approach, which included the embolization of any significant collateral vessels originating from the aneurysmal sac and evaluated at the preoperative DSA. No significant variation of ABI was observed during the follow-up period between the rest position and during forced leg flexion ($>120^\circ$). This is an important goal; in fact, one of the most problematic points of ET for PAAs is the great mobility of this anatomic region and the possibility of kinking of the device.

Previous anatomic radiologic studies have found that the distal part of the popliteal artery is relatively fixed at the origin of the anterior tibial artery and at a more proximal point that corresponds to the origin of the descending genicular artery.³⁶⁻³⁸ Posterior movement of the popliteal artery between these two fixed points does occur during flexion, with the creation of flexures behind the posterior articular structures of the knee.^{37,38} Moreover, it was shown that knee flexion increases tortuosity of the supra-articular popliteal artery, while the middle and the lower part of the popliteal artery kept an even curve retracted from the posterior surface of the joint. The tortuosity of the popliteal artery is more pronounced in elderly patients and did not disappear during knee extension.³⁸ These findings are similar to those observed in our study of the intraoperative DSA and plain radiograph of the knee with forced leg flexion, in which the tortuosity of the endograft was more marked in the supra-genicular segment of the artery.

The Hemobahn endograft seems to be suitable for this procedure, thanks to its particular structure that minimizes the risk of kinking during knee joint movement; in fact in our experience, no signs of any deformity of the structural

skeleton of the endograft was seen at the plain radiograph of the knee during forced leg flexion ($>120^\circ$). Especially in the supragenicular region of the popliteal artery, the most critical region for tortuosity during knee flexion, the endograft showed a good compliance. A longer follow-up is required to analyze the risk of fracture and fabric disruption of the stent graft that was designed to treat occlusions rather than aneurysmal disease.

We can conclude, with the power limitation of the study and waiting for a prospective randomized trial with a larger number of patients and longer follow-up, that PAA treatment can be safely performed using either OR or ET. The choice of the ET has several advantages, such as quicker recovery and shorter hospital stay, and should be preferentially used in patients with a high surgical risk.

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