A Multicentric Experience with Open Surgical Repair and Endovascular Exclusion of Popliteal Artery Aneurysms


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WHAT THIS PAPER ADDS
This study, collecting the largest number of endovascular procedures performed in popliteal artery aneurysms (PAAs), demonstrates that a careful analysis of the patient’s and lesion’s characteristics allows us to choose the right therapeutic approach providing excellent early and long-term results.

Introduction: The aim of this study was to analyse early and follow-up results of the treatment of popliteal artery aneurysms (PAAs) performed with open surgical repair or with endovascular exclusion with endografts in a multicentric retrospective registry involving seven Italian vascular centres.

Materials and methods: We retrospectively collected data concerning 178 open surgical interventions (OR group) and 134 endovascular exclusions (ER group) for PAAs performed between January 2000 and December 2011. Early and follow-up results were analysed in terms of mortality, graft patency, reintervention and limb preservation.

Results: OR patients were more frequently symptomatic (64%, 115 cases) than patients in the ER group (34%, 51 cases; \( p < 0.001 \)), had more frequently acute limb ischaemia (23% and 6.5%, respectively; \( p < 0.001 \)) and had more frequently a run-off score <2 (39% and 26%, respectively, \( p = 0.03 \)). In the OR group there were no perioperative deaths; six thromboses (3.3%) and one amputation occurred. In the ER group mortality was 1.5%; 13 thromboses (9.7%) and one amputation (0.5%) occurred. Mean duration of follow-up was 30.6 \( \pm \) 27.5 months. In the OR group primary and secondary patency, freedom from reintervention and limb preservation rates at 48 months were 63.5% (standard error (SE) 0.05), 76.5% (SE 0.05), 72.5% (SE 0.06) and 89.7% (SE 0.05), respectively. The corresponding figures in the ER group were 73.4% (SE 0.04), 85% (SE 0.04), 75% (SE 0.04) and 97% (SE 0.04), respectively.

Conclusions: In this large multicentric retrospective registry, open and endovascular treatment of PAAs are used in different patients with regard to clinical and anatomical characteristics. Both treatments are feasible and safe, providing satisfactory early and long-term results.

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The popliteal artery represents the second most frequent localisation of arterial aneurysms. Complicated popliteal artery aneurysm (PAA) can cause rupture, distal embolisation and thrombosis, leading to high risk of limb loss. For this reason, elective surgical management of asymptomatic aneurysms larger than 20 mm is currently recommended.

Open surgical repair provides very satisfactory results, particularly in the elective setting, and high rates of graft patency and freedom from amputation during follow-up have been reported. In recent years, PAA exclusion with stent graft has been emerging as a possible alternative to open surgery, particularly in high-surgical-risk patients.

There are however few reports in the literature comparing traditional open repair (OR) to the endovascular (ER) approach and single-centre experiences provide only small series of patients with limited statistical power. The aim of this study was to retrospectively review the
indications for treatment and the results of open and endovascular repair of PAAs in a large multicentric registry involving seven Italian vascular centres.

MATERIALS AND METHODS

From January 2000 to December 2011, 312 open and endovascular interventions for PAA were performed in seven Italian hospitals, in 178 cases with conventional OR and in 134 cases with an ER procedure. The results of one of the participating centres have been recently published.11

Data from all the interventions were retrospectively collected in a dedicated database, which included demographic data, preoperative risk factors, clinical and diagnostic assessment, intra-operative features and early and follow-up outcomes.

Risk factors and co-morbidities included arterial hypertension (defined as blood pressure >130/85 mmHg or the need for anti-hypertensive drugs), hyperlipaemia (defined as triglycerides and cholesterol values >200 mg dl⁻¹), coronary artery disease (history of myocardial infarction, angina and previous coronary revascularisation), diabetes mellitus (defined as the need for specific drugs to maintain metabolic control) and chronic obstructive pulmonary disease (COPD; defined as a forced expiratory volume in 1 s (FEV1) <70%).

All patients underwent Duplex examination and angiocomputed tomography (CT) scan or digital subtraction angiography (DSA) before surgery. The indication for treating asymptomatic aneurysms was a diameter >20 mm. In symptomatic patients indication for surgery was unrelated to aneurysms’ diameter.

While in the first years the indication for ER was the presence of a focal PAA with at least two patent tibial vessels, nowadays also longer lesions are evaluated for endovascular intervention, provided a proximal and distal landing zone of at least 2 cm length is present, with the patency of at least one tibial vessel. All ER procedures were carried out in the operating room.

In selected patients with mild-to-moderate ischaemia (grade I or IIa according to Rutherford’s classification of acute ischaemia) due to acute aneurysms’ thrombosis, preoperative catheter-directed thrombolysis with urokinase was performed.

Thrombolytic treatment was administered in a bolus of 100,000 I.U., followed by continuous infusion with a delivery rate of 70,000–100,000 I.U. h⁻¹ on the basis of the patient’s characteristics and surgeon’s habits. Thrombolysis was defined successful in the presence of restored patency of the popliteal artery and at least one tibial vessel. Surgical intervention was performed within a few days from the cessation of administration of thrombolytic treatment. In the case of unsuccessful thrombolysis a prompt surgical attempt was performed. All the patients underwent systemic heparinisation during thrombolysis; the route of administration and the dose of heparin were at surgeon’s discretion on the basis of institutional habits. Patients presenting with grade IIb or worse ischaemia underwent prompt open surgical repair.

Demographic, clinical and anatomical characteristics of the two treatment groups were compared with the chi-squared test.

The surveillance programme consisted of clinical and ultrasonographic examinations at 1, 6 and 12 months and yearly thereafter. Patency of the graft and status of anastomoses, of inflow and outflow vessels and of the contralateral femoro-popliteal axis were assessed. In patients who had undergone ER treatment, also the exclusion of the aneurysmal sac from the blood flow was examined.

Due to the significant clinical and anatomical differences between patients treated with open and endovascular repair, which made a direct comparison not reliable, we reported the early and late outcomes of the two treatment strategies without comparing them.

Early (<30 days) results were analysed in terms of mortality, graft thrombosis and amputation rates. Incomplete data concerning hospital length of stay were recorded and the mean values for the collected data were analysed.

Follow-up results (survival, primary and secondary patency, freedom from amputation and freedom from reintervention) were analysed by Kaplan–Meier curves. Data were reported at the maximum time frame with a standard error (SE) <0.10.

Primary patency was defined as uninterrupted patency without procedures performed on or at the margin of the treated segment, whereas secondary patency was defined as restored patency through the original treated segment. Freedom from amputation was defined as the avoidance of above- or below-knee amputation, while freedom from reinterventions was defined as the avoidance of any open or endovascular new procedure on the treated artery.

Univariate analysis for primary patency during follow-up in the whole study group was performed; multivariate analysis (Cox regression) for factors that resulted significant at univariate analysis was performed, as well. Statistical significance was defined as a p value <0.05.

Statistical analysis was performed with a dedicated software for Windows (Statistical Package for Social Sciences, SPSS Inc., Chicago, IL, USA).

RESULTS

Demographic data, clinical and anatomical status

Main demographic, clinical and anatomical characteristics in the two groups of patients are listed in Table 1. There were no differences between the two groups in terms of gender, risk factors for atherosclerosis and co-morbidities; there was a trend towards older age at the time of intervention in the ER group than in the OR group. There were significant differences between the two groups in terms of clinical presentation; also, the status of run-off was different between the two groups. Mean diameter of the treated lesion was 33.5 mm in OR patients and 34.7 mm in ER patients (p = 0.2).
In 126 cases contralateral PAA was present (68 in OR patients and 58 in ER patients). Other aneurysms were present in 58 cases (18.5%), 42 in the OR group (23.5%) and 16 in the ER group (13.5%, p < 0.001), whose locations are detailed in Table 1. Twenty-two patients (7 in the OR group and 15 in the ER group) had been previously operated on for abdominal aortic aneurysm.

### Acute ischaemia and rupture

Forty patients with mild-to-moderate acute ischaemia due to PAA thrombosis underwent preoperative intra-arterial thrombolysis, 30 among the OR patients (17%) and 10 ER patients (7.5%; p = 0.07, odds ratio (OR) 0.2, 95% confidence interval (CI) 0.04–1.1). Eleven patients with grade IIb ischaemia underwent prompt OR. The mean duration of thrombolytic treatment was 64.5 ± 46.5 h in OR patients and 48.6 ± 34.4 h in ER patients. Thrombolysis was successful in 18 out of the 30 patients in the OR group and in 9 patients of the ER group. The remaining patient of the ER group had complete recanalisation of PAA but only partial recanalisation of tibial vessels.

Five major complications (11.5%) occurred during thrombolysis. Among the OR patients, one developed a severe (>50,000) thrombocytopaenia, requiring the cessation of thrombolytic drug and of heparin, while another patient suffered from a contralateral femoral pseudo-aneurysm, requiring surgical repair during the same intervention for the treatment of the PAA. One further patient had a sudden increase of the aneurysm’s diameter during thrombolysis, with compartment syndrome, requiring immediate surgical intervention. In the ER group, two contralateral femoral pseudo-aneurysms requiring surgical repair occurred.

In one case of a patient with known PAA presenting with severe pain of the affected leg, a contained rupture of a large (5 × 6 cm) PAA was present at preoperative CT scan, and this case was treated with an urgent ER procedure.12

### Operative details

In the OR group, 13 cases were treated with aneurysmectomy and graft interposition (in 11 cases with prosthethic graft and in 2 cases with an autologous saphenous vein), while in 73 cases the aneurysm was opened and a graft (an autologous saphenous vein in 48 cases and a prosthetic graft in 25 cases) was placed inside the aneurysm in a fashion similar to that used to repair aortic aneurysms. In 92 cases, proximal and distal ligation of the aneurysm with bypass grafting (76 with a prosthetic graft and 16 with an autologous vein) was carried out. A medial approach was used in 139 cases (78%) and a posterior approach was used in 39 cases. In 111 interventions, the inflow vessels were the common or the superficial femoral artery and in the remaining 67 it was the above-knee popliteal artery. The outflow vessel was in most cases the below-knee popliteal artery (152 cases, 85%), while in 26 cases it was the tibioperoneal trunk or a tibial vessel. Associated interventions at the distal anastomotic site were performed in 13 cases (vein cuff in four cases, patching in four cases, arterio-venous fistula in three patients and tibial angioplasty in the remaining two). Two adjunctive patients had common-to-deep femoral artery short bypass for concomitant involvement of common or deep femoral arteries, while another patient had ipsilateral iliac angioplasty for improving the inflow.

In this group, all the patients had intra-operative administration of 30–50 I.U. kg⁻¹ of intravenous heparin at arterial clamping.

Postoperative and long-term medical treatment consisted of single anti-platelet therapy in 78 cases, of double anti-platelet therapy in 64 cases and of oral anticoagulants in 36 patients, the regimen for anticoagulation or anti-platelet being determined just on the basis of the surgeon’s preferences and habits.

In the ER group, all the patients had endoprosthesis placement (Hemobahn or Viabahn®, W.L. Gore & Associates Inc, Flagstaff, AZ, USA).

In 92 cases an ipsilateral surgical femoral approach was used, while 39 patients had ipsilateral percutaneous access; in three cases contralateral femoral access was used. Inflow vessels were the superficial femoral artery in 119 cases and the proximal popliteal artery in 15 cases; the outflow vessel was in all but two cases the proximal and the middle popliteal artery (P1 in 78 cases and P2 in 54 cases), while in the remaining patients it was the distal popliteal/tibioperoneal trunk.

The mean number of placed stents was 2 (range 1–7), with a mean length of 200 mm (range 100–350). Adjunctive
distal angioplasty of tibial vessels was performed in 13 cases.

All these patients had intravenous administration of 5000 I.U. of sodium heparin at the beginning of the procedure. Postoperative and long-term medical treatment consisted of double anti-platelet therapy in all the cases.

**Perioperative (<30 days) results in OR patients**

No perioperative deaths occurred. There were six thromboses (3.3%), four of them occurring in patients with acute limb ischaemia ($p < 0.001$ in comparison with patients without acute presentation); these patients were successfully treated in three cases (with thrombolysis and stenting of distal anastomosis in two cases and with surgical thrombectomy in one), while in the other three cases (all acute ischaemia) major amputation was unavoidable despite a new surgical attempt (cumulative amputation rate 1.6%; amputation rate in acute patients 7.5%). Three adjunctive early reinterventions were required due to significant bleeding at anastomotic sites (reintervention rate 5%). Mean length of stay in 115 out of 178 patients was 10.4 days (range 4–45).

**Perioperative (<30 days) results in ER patients**

Technical success occurred in all the cases. There were two perioperative deaths (mortality rate 1.5%); one patient who had undergone concomitant endovascular aneurysm repair (EVAR) and PAA endografting developed in the first postoperative day an acute thrombosis of popliteal endografting, which required conversion to below-knee femoro-popliteal bypass, followed by major amputation due to graft occlusion. During the postoperative course in the intensive care unit (ICU), the patient suffered from a fatal, acute myocardial infarction. Another patient suffered from fatal cerebral haemorrhage in the fourth postoperative day, although he had not undergone thrombolytic treatment.

Thirteen 30-day thromboses occurred (9.7%), in one case in a patient with acute presentation; in all the cases reintervention was performed, in one patient leading to major amputation (cumulative amputation rate 0.5%; no amputation in acute patients). The rate of early reinterventions was 9.7%. Mean length of stay in 64 out of 134 patients was 6.4 days (range 2–17).

**Follow-up results in OR group**

Follow-up was available in 168 interventions (94.5%) with a mean follow-up time of 27 months (range 1–156). In this period there were five new deaths; the cause of death was cardiac in three patients, while one patient died from cancer. In one case the cause of death was unknown. Estimated survival rates at 12, 24 and 48 months were 99.2% (SE 0.008), 97.2% (SE 0.016) and 95.7% (SE 0.05), respectively. Thirty-six new thromboses occurred; estimated primary patency rates at 12, 24 and 48 months were 78.8% (SE 0.03), 77.1% (0.03) and 63.4% (SE 0.05), respectively (Fig. 1).

Primary patency rates at 4 years were significantly better in patients operated on with an autologous vein (86.3%, SE 0.05) than in patients who had a prosthetic graft (56.3%, SE 0.06; $p = 0.01$); there was a trend towards better primary patency rates in patients with the posterior approach than in patients with the medial approach ($p = 0.07$, log rank 3.2).

In patients with thrombosis, a reintervention was performed in 23 cases; nine of the 13 remaining patients had graft thrombosis without critical ischaemia and were medically managed, while in the other four cases major amputation was unavoidable.

Recurrence thrombosis despite reintervention occurred in 12 patients, leading to five major amputations.

Rates of limb salvage at 12, 24 and 48 months were 94.3% (SE 0.02), 92.6% (0.022) and 89.7% (SE 0.05), respectively.

The rate of limb salvage at 48 months in patients with acute ischaemia was 81.5% (SE 0.07).

**Follow-up results in ER group**

Follow-up was available in 128 interventions (95.5%), with a mean follow-up time of 35 months (range 1–124). Twenty-one deaths occurred: the cause of death was cancer in two patients, while another patient died from cardiac
In two cases rupture of thoracic aortic aneurysm occurred, while two patients had a fatal stroke and one patient died from pulmonary embolism. The cause of death was unknown in 12 cases.

Estimated survival rates at 12, 24 and 48 months were 91.1% (SE 0.027), 87.3% (SE 0.034) and 83.9% (SE 0.04), respectively. There were 14 new thromboses; estimated primary patency rates at 12, 24 and 48 months were 79.1% (0.037), 76.9% (SE 0.04) and 73.4% (SE 0.05) (Fig. 1).

In patients with thrombosis, reintervention was performed in 12 cases; the two remaining patients developed mild claudication and they were medically managed. Freedom from reintervention rates at 12, 24 and 48 months were 90.8% (SE 0.027), 85.5% (SE 0.035) and 85% (SE 0.04), respectively (Fig. 2). Recurrent thrombosis despite reintervention occurred in seven patients leading to three major amputations.

The rates of limb salvage at 12, 24 and 48 months were 98.1% (SE 0.013), 96.9% (0.04) and 96.9% (SE 0.04), respectively. The four-year limb salvage rate in patients with acute ischaemia was 87.5% (SE 0.09).

In one patient a type II endoleak from a large genicular artery was noted at 12 months, with a slight increase (<5 mm) in sac diameter with respect to preoperative value; a conservative approach was decided in this case, which is still under surveillance.

Univariate analysis in the whole group of 312 interventions showed that aneurysmal preoperative symptoms, limb-threatening ischaemia a poor run-off status and the need for adjunctive distal procedures significantly affected primary patency during follow-up; at multivariate analysis preoperative symptoms, poor run-off status and the use of distal procedures maintained their significance (Table 2).

DISCUSSION

Although traditional surgical repair is still considered the gold standard in the treatment of PAA, the ER approach has been gaining popularity and interest, due to the easy deployment of stent grafts and to the low invasiveness of the procedure. As a consequence, a great deal of papers on this issue have been published in recent years.4–11 However, at the moment, only a shorter length of hospitalisation in endovascularly managed patients has been reported in the few papers comparing the two treatments.7–11 Furthermore, the very limited number of patients collected in these single-centre comparisons did not allow the authors to draw any consistent conclusions.

Antonello and colleagues7 compared in a randomised study the results of 15 ORs with those of 15 ER procedures performed in asymptomatic PAAs with good run-off status and found no significant differences between the two options at 12-month follow-up, with some advantages for ER in terms of operative time and hospital stay. The same authors updated their study9 and they did not still find any differences in terms of primary and secondary patency at 72 months, with a 14% rate of late conversion to open surgery.

Curi and colleagues10 retrospectively reviewed their results in 15 endovascular PAA repairs compared with 41

<table>
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<th>Female gender</th>
<th>Diabetes</th>
<th>Symptomatic PAA</th>
<th>Limb-threatening ischaemia</th>
<th>Run-off score 0–1</th>
<th>Preoperative thrombolysis</th>
<th>Endovascular intervention</th>
<th>Adjunctive distal procedure</th>
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Table 2. Univariate and multivariate (for significant factors at univariate) analysis for primary patency during follow-up in the whole study group.
open interventions; similarly to the previously cited studies, ER treatment was performed mainly in asymptomatic patients (13 cases, 87%) and all acute PAA thromboses were treated with open intervention. Estimated 24-month curves were similar between the two techniques, with 83% and 100% of primary and secondary patency for ER treatment.

Stone and colleagues reported seven cases of ER treatment, performed in all but one case in asymptomatic patients, and 48 open interventions; even if the study was not mainly designed to compare the outcomes of the two procedures, two out of the seven endografts thrombosed during follow-up, while graft thrombosis occurred only in two patients who had undergone OR. However, the need for secondary procedures to maintain the patency of the graft was significantly higher in the open surgery group.

In spite of these encouraging outcomes, Lovegrove et al. in their meta-analysis did not justify a shift towards an ER treatment and in a more recent paper Cina concludes that a randomised controlled trial (RCT) is necessary to define the true role of this new modality of treatment for PAs. However, in the scientific community it is well known how difficult is the planning of a RCT and often the registries better reflect the so-called daily practice.

In this paper we collected data from seven Italian hospitals in the attempt to accomplish a large data set for analysing early and intermediate results of ER treatment of PAs and we reported the results obtained with OR in the same period of time.

In our experience, the indications to open and endovascular treatment were significantly different: open surgery was preferred in symptomatic aneurysms, with complex anatomical features and often in the presence of acute of limb-threatening ischaemia. However, it must be underlined that in the present study we collected a percentage of symptomatic PAs endovascularly treated that is largely higher (29%) than in previous papers; in addition, about one-quarter of the patients of the ER group had only one patent distal vessel.

As the two groups were not homogeneous under a clinical and anatomical point of view, we preferred anyway not to perform a direct comparison between the two treatment strategies.

The outcome of OR remains good in both symptomatic and asymptomatic patients, confirming the results of previous studies, even in the presence of a higher percentage of interventions performed with a prosthetic graft rather than with an autologous vein. It has been clearly demonstrated that the vein graft offers an advantage in terms of early and late results in patients with PAA and this was also in our experience, suggesting that an autologous vein can be considered the material of choice in OR patients. The relevant percentage of expanded polytetrafluoroethylene (ePTFE) bypasses in the present series is probably due to the good performance of this kind of graft in patients with obstructive femoro-popliteal disease in the experience of the participating centres. Moreover, about 60% of our patients had more than one patent tibial vessel, and this fact could have contributed to the choice of preserving the autologous vein for further revascularisations. We found a trend towards better results in OR patients who had a posterior approach, and this result had been already underlined in the series of one of the participating centres.

Only clinical and anatomical complexities of the lesions seem to significantly affect late failure in our experience. We found a higher percentage of early reinterventions in the ER group and a higher limb salvage rates during follow-up, again in the ER group. These results seem in contrast, but the possible explanation is that early reinterventions often consisted of a new endovascular adjustment and they did not influence the long-term outcomes. In addition, at uni- and multi-variate analyses the ER approach did not represent an adjunctive risk factor. The risk of developing an endoleak is low in our experience and probably it does not represent the main complication of ER of PAs.

In our endovascular series there were about 10% of patients with acutely thrombosed PAs that represented in previous reports an exclusion criterion for endografting. The use of intra-arterial thrombolysis in selected patients with moderate ischaemia allowed us to achieve satisfactory results; once the patency of the popliteal artery and tibial vessels is restored, a choice between open and ER on the basis of clinical and anatomical consideration is requested.

This study has several limitations: it is a retrospective non-randomised study, with several discrepancies between open and endovascular groups in terms of clinical presentation and of run-off status, a relatively short period of follow-up and a low number of events. Moreover, due to its retrospective nature, some data are missing or not complete. On the other hand, in our opinion its strength lies in the significant number of collected endovascular interventions, which makes it the largest report on this topic at the moment, and in the representation of the current attitude towards this disease in the daily practice.

CONCLUSIONS
In this large multicentric retrospective registry, open and endovascular treatment of PAs was used in different patients with regard to clinical and anatomical characteristics. If a careful analysis of the patient’s and lesion’s characteristics is performed in choosing the right therapeutic approach, early and long term results are satisfactory. An RCT comparing the two treatment options is warranted.

CONFLICT OF INTEREST/FUNDING
None.

REFERENCES