Eur J Vasc Endovasc Surg (2019) 57, 393—398

Limb Salvage by Open Surgical Revascularisation in Acute Ischaemia due to Thrombosed Popliteal Artery Aneurysm

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WHAT THIS PAPER ADDS

This study reports a single centre series of open surgical management of acute presentation of thrombosed popliteal artery aneurysm. It stands out from other contemporary reports owing to the inclusion of patients with severe ischaemia and complete follow up (median 41 months, follow up index 0.99). Rapid open surgical revascularisation without pre-operative thrombolysis can lead to good rates of limb salvage and bypass patency despite poor runoff.

Objective: Acute ischaemia due to thrombosed popliteal artery aneurysm (PAA) is associated with a high risk of limb loss. The aim of this study was to analyse the outcome, in particular the limb salvage rate in patients undergoing urgent open surgery for acute ischaemia due to thrombosed PAA.

Methods: This was a retrospective analysis of consecutive patients undergoing urgent open surgery for acute limb ischaemia (Rutherford category $\geq$ II) due to thrombosed popliteal artery aneurysm between January 2007 and December 2016 at a tertiary referral centre.

Results: Fifty-one patients (92% male), median age 75 years (range 46—97 years), were identified. Twenty patients (39%) presented with category IIa acute limb ischaemia, 20 (39%) with category IIb, and 11 (22%) with category III. Four patients (8%) underwent primary major amputation. Forty-seven (92%) underwent bypass surgery, 43/47 (91%) using great saphenous vein. One vessel runoff was present in 27/47 patients (57%). Thirty day mortality was 4% ($n = 2$). Four patients needed major amputation within 30 days, resulting in an overall 30 day major amputation rate of 16% (8/51, 95% confidence interval 7.0—28.6). No further major amputations were necessary during a median follow up of 41 months (range 4—114 months) resulting in an estimated 4 year limb salvage of 84%. The one year primary assisted and secondary bypass patency rates were 90% and 95%, respectively. The estimated four year primary assisted and secondary patency rates were 82% and 87%, respectively.

Conclusion: Rapid open surgical revascularisation in patients with acute limb ischaemia due to a thrombosed popliteal artery aneurysm results in good long-term limb salvage rates, especially Rutherford category IIa and IIb acute ischaemia. Revascularisation may be attempted in clinically severe cases not fulfilling all criteria to be classified as category III. Such patients may, in fact, be borderline between IIb and III. Despite poor runoff, good bypass patency rates and low rates of claudication can be achieved.

Keywords: Acute limb ischaemia, Popliteal artery aneurysm, Popliteal artery aneurysm thrombosis, Revascularisation for acute limb ischaemia, Thrombolysis

Article history: Received 4 May 2018, Accepted 28 September 2018, Available online 2 November 2018

INTRODUCTION

Popliteal artery aneurysms (PAA) are relatively rare with a prevalence of approximately 1% in men aged 65—80 years,[1] accounting for > 80% of all peripheral aneurysms.[2] Acute limb ischaemia (ALI) due to aneurysm thrombosis or distal embolisation is the most severe complication of a PAA.[3] Revascularisation is challenging and usually performed by open surgery, although a complete endovascular approach has been reported.[4] As crural arteries are often occluded, options for complete revascularisation of the foot are limited, possibly resulting in major amputation. Amputation is associated with worse functional outcome, especially in elderly patients with cardiovascular comorbidities.[5,6] Furthermore, primary amputation offers no cost benefit over bypass surgery when considering the cost of the prosthesis and rehabilitation.[7] Thus, every effort should be taken to achieve limb salvage. The 2017 European Society of

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https://doi.org/10.1016/j.ejvs.2018.09.030

Cardiology guidelines on the management of peripheral artery disease cover ALI, but specific recommendations regarding PAA are lacking.[8] For patients with Rutherford category II, urgent revascularisation is indicated. For patients with acute Rutherford category III limb ischaemia, the current recommendation is amputation. There are contemporary series addressing outcome in ALI due to thrombosed PAA.[9,10] These registry papers may underestimate the amputation rate of thrombosed popliteal artery aneurysms because they either excluded primary amputations or lack adequate follow up.[9,10] In other articles reporting the open surgical management of PAA, follow up of patients presenting with acute ischaemia is also poor.[11] The use of pre-operative thrombolysis in ALI due PAA is controversial and a significant benefit has not been shown in a recent systematic review.[11] The aim was therefore to analyse peri-operative, as well as long-term outcomes of patients undergoing urgent open surgery for ALI due to thrombosed PAA, assessing limb salvage and mortality.

MATERIALS AND METHODS

This study was approved by the local ethics committee (ID 2017-01529). Consecutive patients with Rutherford category IIa, IIb, and III ALI due to thrombosed PAA undergoing urgent surgery between January 2007 and December 2016 were identified and reviewed retrospectively. Patients with category I ischaemia were excluded.

PAA was defined as a popliteal artery diameter of $\geq$ 13 mm and $\geq$ 1.5 times the diameter of the upstream and downstream segments measured on ultrasound or computed tomography (CT) images. The diagnostic algorithm for ALI and suspected PAA thrombosis included clinical examination and duplex ultrasound. Pre-operative CT angiography was performed at the discretion of the treating vascular surgeon to assess the extent of thrombosis and potential target vessels. The revised Rutherford category of acute ischaemia[12] was assessed pre-operatively by the treating vascular surgeon based on sensorimotor function and Doppler assessment. Of note, category III is described as “irreversible”, consisting of major tissue loss or permanent nerve damage (inevitable), profound sensory loss (anaesthetic), profound muscle weakness (paralysis, rigor), and inaudible arterial and venous Doppler signals. Patients with Rutherford category IIa, IIb, and III ALI were scheduled for urgent (IIa) or emergency (IIb and III) surgery.

Operative technique

Intra-operative angiography was performed to assess target vessels. For severe thrombosis without a suitable distal target vessel, all crural vessels were dissected and selective thrombectomy with or without intra-arterial thrombolysis was performed. Depending on the surgeon’s preference, between 100,000 and 500,000 IU Urokinase (Medac GmbH, Wedel, Germany) were delivered into the popliteal or crural arteries. If available, the ipsi- or contralateral great saphenous vein was used as a bypass graft. Arm veins were used as a second choice. If autologous vein material was unavailable, Omniflow® II (LeMaitre Vascular, Burlington, MA, USA) or expanded polytetrafluoroethylene (BARD Peripheral Vascular, Temple, AZ, USA) was used. The standard anticoagulant and antiplatelet regimen consisted of oral anticoagulation with coumadin and acetylsalicylic acid for at least three months and acetylsalicylic acid alone thereafter. In case of severely compromised (single vessel) runoff, lifelong oral anticoagulation was recommended.

Data collection

Pre-, intra-, and post-operative data were collected retrospectively from hospital records. Standard follow up after bypass surgery included outpatient duplex ultrasound performed at one and three months. After that, patients were followed every 6—12 months in the outpatient clinic with duplex ultrasound performed at the discretion of the treating physician, usually for claudication or drop in ankle brachial index (ABI). Follow up duplex ultrasound reports, ABI measurements, and information on re-interventions for patients who were followed elsewhere were requested from those institutions. Vital status or date of death was confirmed by contacting the patients’ primary care physician or extracted from communal databases. For all patients known to be alive, a standardised telephone interview was performed at the beginning of March 2017, assessing for claudication or re-interventions at other institutions. The study end date was 6 March 2017. Major amputation was defined as any amputation above the ankle. Patency was defined and assessed according to Rutherford.[12]

Statistical analysis

SPSS Statistics 25.0 (IBM, Armonk, NY, USA) was used for descriptive statistics and GraphPad Prism 7.00 (GraphPad Software, La Jolla, CA, USA) for Kaplan—Meier analysis and 95% confidence intervals (CIs) using the asymmetrical method. For univariable analysis, proportions were stated; for numerical data, mean $\pm$ SD or median (range). Patency rates and amputation free survival were estimated using the Kaplan—Meier method. For follow up patency rates, only patients with a graft (without in hospital amputation) were included. Patients known to have died during follow up were reported separately with the median time to death. For all other patients, follow up completeness was assessed using the Follow up Index (FUI).[13]

RESULTS

Patient characteristics and presentation

Fifty-one patients (92% male) with a median age of 75 years (range 46—97 years) were identified. Comorbidities are listed in Table 1. The median size of the PAA was 33 mm (range 13—80 mm). Six patients (12%) had already undergone open surgery for contralateral PAA and in an additional 25 patients (49%), contralateral PAA was detected at presentation or during follow up. Twenty patients (39%) presented with Rutherford category IIa ALI, 20

Table 1. Baseline characteristics of 51 patients presenting with acute limb ischemia due to thrombotic popliteal artery aneurysm occlusion

Parameter	Patients (total n = 51)
Median age (range), years	75 (46–97)
Male gender	47 (92)
Comorbidities	
Coronary artery disease	22 (43)
Previous vascular surgery	11 (22)
Hypertension	40 (78)
Diabetes	8 (16)
Dyslipidaemia	27 (53)
Smoking	31 (61)
Glomerular filtration rate ≤ 60 mL/min	5 (10)
Chronic obstructive pulmonary disease	3 (6)

Data are n (%) unless otherwise indicated.

patients (39%) with category IIb, and 11 patients (22%) with category III.

Treatment/surgical procedures

Four patients (8%) underwent primary major amputation due to lack of patent outflow vessels on intra-operative angiography images and severe ischaemia (Rutherford category IIb in one and category III in three patients). In the remaining 47 patients, revascularisation surgery was performed with 44 bypass and three interposition grafts. Great saphenous vein (GSV) was used in 43/47 patients (91%). Other grafts used are listed in Table 2. The distal target vessel was the below knee popliteal artery in 26 patients (55%) and the crural arteries in the remaining patients (Table 2). The surgical approach was medial in 44/47 (94%) and posterior in 3/47 (6%). All bypasses were routed orthotopically. Intra-operative intra-arterial thrombolysis was used as an adjunct in 17 patients (36%) with more severe limb ischaemia (three with category IIa, seven with category IIb, and seven with category III; no intra-operative thrombolysis in 17 patients with category IIa, 13 with category IIb, and four with category III [$p = .007$]). Fasciotomy for compartment syndrome was performed in 15/51 patients (29%). Two patients underwent pre-operative local thrombolysis, which is not consistent with the standard approach. In these two patients, the diagnosis of PAA had not been established on admission. The mean length of hospital stay was 14 ± 11 days.

After revascularisation, 12 patients (26%) had three vessel runoff, five patients (11%) two vessel runoff, and 27 patients (57%) one vessel runoff, as assessed by intra-operative angiography. Three patients (6%) had no patent runoff vessel with bypass outflow to the foot through collaterals only, representing an unsuccessful revascularisation (Fig. 1). In these three patients, the bypass target was the below knee popliteal artery in one and the peroneal artery in two patients.

Thirty day outcomes

Limb salvage. Four patients needed secondary major amputation within 30 days, resulting in an overall 30 day major amputation rate of 16% ($n = 8/51$; 95% CI 7.0–28.6). Excluding the primary amputations, the 30 day major amputation rate was 9% ($n = 4/47$). Two of those undergoing secondary major amputation were patients with collateral perfusion only and progressive tissue loss despite a patent bypass. The remaining two patients had single vessel runoff after initial revascularisation; in one the bypass failed after one day and in the other amputation became necessary due to progressive necrosis of the foot despite a patent bypass.

In the third patient with collateral only flow to the foot, the bypass remained patent, but amputation was recommended owing to progression of necrosis. However, the

Table 2. Clinical presentation and surgical data of 51 patients with popliteal artery aneurysm (PAA)

Parameter	Patients (total n=51)	%
Rutherford class at presentation[a]		
IIa	20/51	39
IIb	20/51	39
III	11/51	22
Contralateral PAA	31/51	61
Previous surgery on contralateral side	6/31	19
Intra-arterial thrombolysis		
Pre-operative	2/51	4
Intra-operative	17/51	33
Type of surgery		
Primary amputation	4/51	8
Bypass/interposition graft	47/51	92
Great saphenous vein (GSV)	43/47	91
Omniflow ®	2/47	4
Omniflow ® with cephalic vein	1/47	2
Polytetrafluroethylene with GSV	1/47	2
Approach		
Medial	44/47	94
Dorsal	3/47	6
Target vessel		
Below knee popliteal artery	26/47	55
Anterior tibial artery	2/47	4
Tibioperoneal trunk	5/47	11
Posterior tibial artery	4/47	9
Peroneal artery	6/47	13
Combined	4/47	9

[a] = Rutherford classification of acute ischemia.

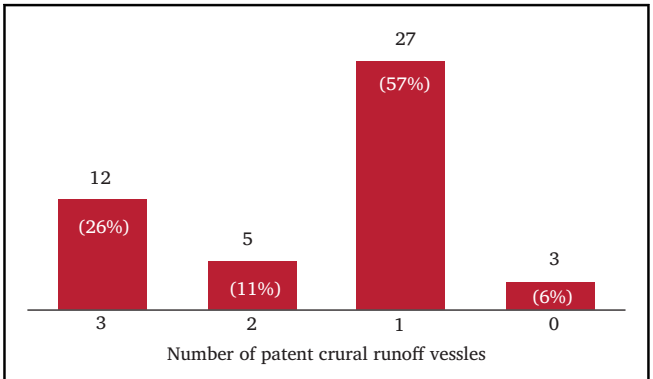

Figure 1. Distribution of patent crural vessel after revascularisation (n=47).

patient refused amputation and died three months later as a result of septic complications.

Category IIb and III limb ischaemia at presentation was significantly associated with 30 day major amputation (8/31 with category $\geq$ IIb vs. 0/20 with category IIa; $p = .02$). Overall, of 11 patients presenting with category III ischaemia, six patients (55%) underwent primary or secondary amputation and one refused the recommended amputation (mentioned above). In the remaining four patients (36%) with category III ischaemia and in 18/20 (90%) with category IIb ischaemia limb salvage was successful.

Mortality and morbidity. Two patients died within 30 days of surgery, resulting in a 30 day mortality of 4%. One patient died from congestive heart failure due to severe aortic stenosis after successful limb revascularisation, and one patient died owing to multi-organ failure after refusing surgery for complicated diverticulitis after primary amputation. Non-fatal in hospital complications included surgical site haematomas ($n = 5$), delirium ($n = 3$) and surgical site bleeding needing re-intervention ($n = 1$), false aneurysm ($n = 1$), muscle necrosis of the anterior tibial muscle ($n = 1$), wound infection ($n = 1$), and pneumonia ($n = 1$), respectively. No patient experienced acute renal failure requiring haemodialysis.

Follow up

Seventeen patients died during follow up after a median of 14 months (range 0—93 months; interquartile range 42 months). Thirty-two patients were alive at the study end date (6 March 2017) with a median follow up of 41 months (range 4—114 months) and a FUI of 0.99.

During follow up, no further major amputations were necessary, resulting in an estimated four year limb salvage of 84%. Excluding primary amputations, the estimated four year limb salvage was 91%. Of 32 patients alive at the end of follow up, 28 were free of major amputation and the estimated four year amputation free survival was 52% (Fig. 2). Two minor amputations were performed 2 and 4 years after initial revascularisation, respectively.

Of 28 amputation free survivors, one patient reported claudication after 500 m (Fontaine classification IIa) at the end of follow up, while all other patients were claudication free. The four patients with limb salvage in category III ischaemia were ambulating without complains after revascularisation, but three died during follow up after a median of 1.9 years (median age at presentation 89 years); one was alive and free of claudication at the study end date (3.5 years after revascularisation).

Graft patency. Estimated one year primary assisted and secondary patency rates were 90% and 95%, respectively. Estimated four year primary assisted and secondary patency rates were 82% and 87%, respectively (Fig. 3).

Re-interventions. Three re-interventions were performed for primary assisted patency: an anastomotic stenosis was treated by stenting in two patients and by open patch plasty

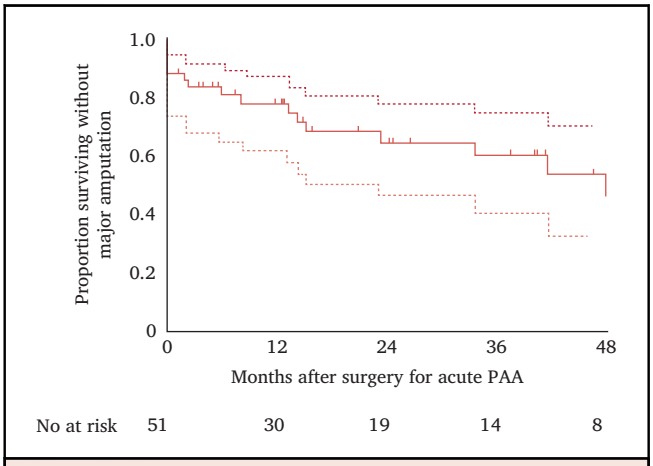

Figure 2. Kaplan—Meier estimate of amputation free survival including 95% confidence intervals (dotted lines) in 51 patients presenting with acutely thrombosed popliteal artery aneurysm (PAA), including 4 primary amputations at presentation.

in one. Seven patients had bypass occlusion after a median of 36 months (range 0—97) after initial revascularisation. In four patients, a bypass thrombectomy was performed. In three of these patients, a focal stenosis was identified as the cause of bypass occlusion and was treated by patch plasty. Three patients underwent a redo bypass procedure after failed bypass salvage; of these, two underwent a second redo bypass procedure and additional endovascular interventions owing to repeated bypass failure.

DISCUSSION

In this single centre retrospective series, the outcome of 51 patients with ALI due to a thrombosed popliteal aneurysm

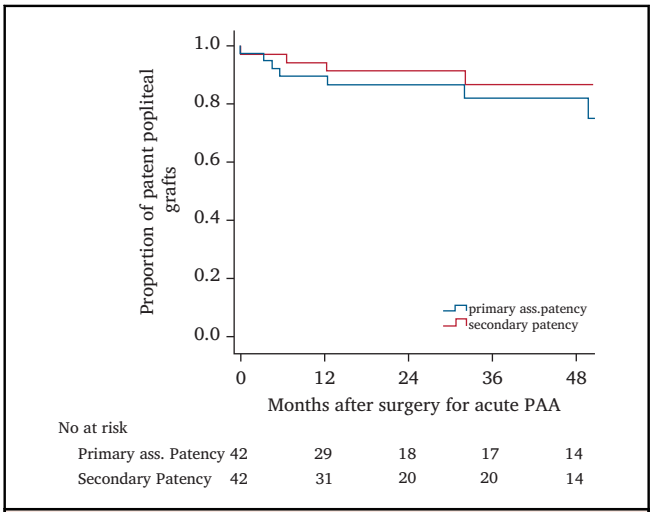

Figure 3. Kaplan—Meier estimates of primary assisted and secondary patency rates after surgical revascularisation of acutely occluded popliteal artery aneurysm (PAA, n = 47). From 51 patients, 4 were primarily amputated and 4 received a bypass graft but were amputated after some days. Figure 3 looks at the long-term patency of the bypass grafts and includes all patients without major amputation or death during initial hospitalisation (n = 42).

is reported. Revascularisation in this setting remains a surgical challenge since runoff is usually poor and patients may be admitted following a considerable time delay. Patients with PAAs may have had multiple silent thromboembolic events before presenting with acute ischaemia due to complete aneurysm thrombosis.[14,15] This results in very poor outflow complicating revascularisation. In the present series, 57% of patients had single vessel runoff and 6% had no patent vessel in the lower leg. Similarly, decades ago Lilly et al. described the arterial anatomy below popliteal aneurysms to be distinctly abnormal in 90% of cases, with 86% of patients with severe ischaemia having only single vessel runoff.[15]

The thirty day major amputation rate in the present series was 16% (95% CI 7.0—28.6) with four patients undergoing primary amputation and four patients undergoing secondary amputation after attempted revascularisation. As no further major amputations were necessary during follow up, the four year estimated limb salvage rate was 84%. A multicentre Italian study from 2013 reported a two year limb salvage rate for ALI due to PAA treated surgically of 81.5% (41 patients).[16] Similarly, a systematic review by Kropman et al. reported a five year limb salvage rate of 74%.[17] A Swedvasc report showed a similar one year amputation rate of 13.4% (including primary amputation), but the follow up at one year was only 87% and the patient cohort was markedly different (13.2% category I patients).

A Vascunet report with data from eight countries, excluding primary amputations, showed a discharge/30 day amputation rate of 6.5%.[10] However, the category of ischaemia was not reported. Excluding primary amputations in the present series, the one year amputation rate was 9%.

Estimated four year primary assisted and secondary patency rates in the present series were 82% and 87%, respectively. This is in line with the findings of Kropman et al. of a five year secondary patency of 80%.[17] In the current series, 96% of patients without major amputation denied any claudication symptoms at follow up, which is also satisfactory, considering the high prevalence of outflow vessel obstruction in these patients.

Clinical assessment and categorisation according to Rutherford et al. is crucial when reporting ALI. Eleven patients were classified pre-operatively as category III. This would actually define their ischaemia as irreversible, leading to amputation.[8,12] As four patients were salvageable, it must be assumed retrospectively that these cases were initially misclassified and did not show all the characteristics described by Rutherford et al. and therefore were severe category IIb patients. Only the post-operative course may have definitely showed that these cases were only mimicking category III, and were therefore salvageable. However, if no runoff can be achieved intra-operatively by means of thrombectomy and thrombolysis, placement of a bypass does not seem advisable.

Pre-operative thrombolysis has been extensively discussed for ALI due to thrombosed PAA.[18] A recent systematic review could not show significant reduction in amputations after pre-operative thrombolysis. Five year primary patency rates, secondary patency, and limb salvage rates were not different after thrombolysis when compared with patients who did not undergo thrombolysis.[17] Many open surgical series included in this review had low patient numbers and acute ischaemia was classified only in 122/895 patients.[17] In other series investigating this issue, data on the severity of ischaemia are lacking.[3] Neurological deficits (Rutherford category IIb and III) are well known indications for emergency revascularisation.[12] Pre-operative thrombolysis may only lead to a better outcome in patients with less severe ischaemia who per se have better outcomes regarding limb salvage. Only patients with limb threatening ischaemia (Rutherford category $\geq$ II) were included in the present series. These patients should be treated immediately because of the considerable threat of permanent neuromuscular and tissue damage.[8] Pre-operative thrombolysis may lead to a delay in open surgical revascularisation.[12] The data do not add knowledge to the topic of pre-operative thrombolyis, as it was only performed in two cases.

Open bypass surgery is the standard treatment for ALI due to thrombosed PAA at the authors' institution. A complete endovascular approach has been reported in the literature. The largest series, by Fargion et al.,[4] included six patients. One patient died shortly after early stent thrombosis and major amputation. The remaining five patients had a primary patency rate of 60% and a secondary patency rate of 80% after a mean follow up of 28.6 months. The authors stated that this approach is an alternative in selected high risk patients with specific anatomical requirements but should not replace GSV bypass as the gold standard.[4]

Another important issue is the association of PAA with other aneurysms, especially contralateral PAA or AAA.[11] Sixty-one percent of patients in the present series had contralateral PAA. Six patients had already undergone open surgery for contralateral PAA when presenting with ALI due to PAA thrombosis on the other side. The median interval from previous PAA surgery to contralateral PAA thrombosis was nine years. This emphasises the importance of lifelong follow up in these patients, not only to assess bypass patency after PAA repair, but also for surveillance of aneurysmal disease of the contralateral leg and elsewhere. In an elective setting, PAA can be treated with low morbidity and mortality and excellent long-term outcomes that are far superior to the results in acute ischaemia.[11,19] Therefore, the aim is to search for PAA in patients with known aneurysms at other sites and operate on them electively at a diameter of 20 mm.

Limitations

As this was a retrospective single centre study, certain factors may limit the generalisability of the study results. The limited number of patients is reflected by the broad 95% CI found. A future large multicentre collaboration could allow for analyses of subgroups to provide more insight concerning the best treatment option for each patient. The category of acute ischaemia was documented by the treating vascular surgeon. It is assumed that there was

misclassification for some category III patients, as they were not all treated by amputation. Because this was a retrospective analysis, a detailed clinical reassessment of these cases could not be performed, and the clinician's evaluation provided back then had to be relied upon. However, publications in this field suffer also from this particular bias, for example some do not report the category of ischaemia of the patients included.

There was no comparator group, as all patients were treated by open surgery. The selection of graft material, surgical technique, the use of thrombolysis, and the anticoagulation and antiplatelet regimen were at the discretion of the vascular surgeon who operated and were therefore not standardised. Although regular follow up visits at the outpatient clinic were documented in most patients, some were followed at other institutions and therefore clinical and ultrasound follow up was not standardised. Thus, asymptomatic bypass occlusion might not have been detected in some patients. Causes of death are not known in most of the patients. Furthermore, over the span of 10 years substantial improvements in interdisciplinary treatment have been achieved. This might have led to less time to intervention and hence higher limb salvage rates. Owing to the small study population, trends were not analysed over time. The time from symptom onset to revascularisation is an important issue in ALI. Most of the patients had gradually worsening symptoms and were not able to report a precise time of symptom onset. A strength of the present study is the defined study end date with almost complete follow up (FUI 0.99) and standardised telephone interviews with all surviving patients at the end of follow up.

CONCLUSION

Rapid open surgical revascularisation in patients with ALI due to thrombosed PAA results in good long-term limb salvage rates in the present series, especially in Rutherford category IIa and IIb ALI. Revascularisation may be attempted in clinically severe cases not fulfilling all criteria to be classified as category III. Such patients may, in fact, be borderline between IIb and III. Despite poor runoff, good bypass patency rates and low rates of claudication can be achieved.

CONFLICTS OF INTEREST

None.

FUNDING

None.

ACKNOWLEDGMENT

The authors acknowledge the contribution of Dimitri Aristotle Raptis, MD, MSc, PhD, for support in analysis of data.

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