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Treatment of Popliteal Aneurysm by Open and Endovascular Surgery: A Contemporary Study of 592 Procedures in Sweden

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WHAT THIS STUDY ADDS

Previous comparisons between open and endovascular repair of popliteal aneurysms have focused on asymptomatic patients, and have short follow up. This study is strengthened by the fact that it is contemporary, population based, without any selection bias, reporting on all kinds of presentations, and has approximately 90% 1 year follow up data. It shows that endovascular repair has significantly inferior results compared with open repair, in particular in the group of patients who present with acute ischaemia. We believe these results will make many vascular surgeons think twice before they treat patients endovascularly in the future.

Background: Popliteal aneurysm (PA) is traditionally treated by open repair (OR). Endovascular repair (ER) has become more common. The aim was to describe time trends and compare results (OR/ER).

Methods: The Swedish vascular registry, Swedvasc, has a specific PA module. Data were collected (2008–2012) and supplemented with a specific protocol (response rate 99.1%). Data were compared with previously published data (1994–2002) from the same database.

Results: The number of operations for PA was 15.7/million person-years (8.3 during 1994–2001). Of 592 interventions for PA (499 patients), 174 (29.4%) were treated for acute ischaemia, 13 (2.2%) for rupture, 105 (17.7%) for other symptoms, and 300 (50.7%) were asymptomatic (31.5% were treated for acute ischaemia, 1994–2002, $p = .58$). There were no differences in background characteristics between OR and ER in the acute ischaemia group. The symptomatic and asymptomatic groups treated with ER were older ($p = .006$, $p < .001$). ER increased 3.6 fold (4.7% 1994–2002, 16.7% 2008–2012, $p = .0001$). Of those treated for acute ischaemia, a stent graft was used in 27 (16.4%). Secondary patency after ER was 70.4% at 30 days and 47.6% at 1 year, versus 93.1% and 86.8% after OR ($p = .001$, $<.001$). The amputation rate at 30 days was 14.8% after ER, 3.7% after OR ($p = .022$), and 17.4% and 6.8% at 1 year ($p = .098$). A stent graft was used in 18.3% for asymptomatic PA. Secondary patency after ER was 94.5% at 30 days and 83.7% at 1 year, compared with 98.8% and 93.5% after OR ($p = .043$ and 0.026). OR was performed with vein graft in 87.6% (395/451), with better primary and secondary patency at 1 year than prosthetic grafts ($p = .002$ and $<.001$), and with a posterior approach in 20.8% (121/581).

Conclusions: The number of operations for PA doubled while the indications remained similar. ER patency was inferior to OR, especially after treatment for acute ischaemia, and the amputation risk tended to be higher, despite similar pre-operative characteristics.

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INTRODUCTION

Popliteal artery aneurysm (PA) is a relatively uncommon disease that has been difficult to study.

Three previous studies of a large number of patients with PA have been published. Ravn et al.[1] reported 571 patients with 717 legs treated in Sweden in 1987–2002: pre-operative thrombolysis improved run-off and reduced the risk of amputation when the patient presented with acute ischaemia,[2] and open repair (OR) with a posterior approach

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(often using the inlay technique) had better long-term results because of the reduced risk of late expansion.[3] It was not meaningful to compare OR and endovascular repair (ER) during this time period. Johnson et al.[4] studied the outcome of open surgical treatment for popliteal aneurysm in 583 cases in 1994–2005. Low operative mortality and good limb salvage rates were reported.

In a retrospective study from seven Italian centres, Pulli et al.[5] described the outcome of 312 treated PAs, of which 134 had received ER. There were discrepancies between the two groups: more symptomatic patients (64% vs. 34%) and acute presentations (23% vs. 6.5%) in the OR group, and worse run-off score than patients treated with ER. Primary and secondary patency rates were similar for OR and ER, but the great differences in case mix were not addressed when the results were analysed. At 24 months the figures were similar, but in both groups more than half of the patients were lost to follow up, limiting the possibility to evaluate the midterm outcome.

In many centres, OR remains the gold standard for treatment of PA, even though there is diversity in the preferred technique: posterior or medial approach, vein or prosthetic graft. As endovascular treatment in general has become more common, it has emerged as an alternative treatment for PA. A minimally invasive procedure, performed under local anaesthetic, with a short hospital stay is an attractive option, but questions remain about its durability. A limited number of studies have been published, with small cohorts of mostly asymptomatic patients, and short follow up. In the Vascunet collaboration, PA repair could be identified in eight countries for comparison of contemporary treatment.[6] The operations per million person years varied from 3.4 in Hungary to 17.6 in Sweden. Overall, surgery was elective in 72% of cases, but in Hungary only 26%. The proportion of endovascular repair varied from 35% in Australia to zero in Switzerland, Finland, and Iceland.

The Swedvasc Registry[7] introduced a specific registration for treatment of PA in 2008, offering a unique possibility to investigate these issues in a modern context. The overall aim was to study contemporary treatment of PA, and how the choice of technique affects 1 month and 1 year outcomes.

PATIENTS AND METHODS

The Swedish vascular registry, the Swedvasc, was created in January 1987, and since 1992 has registered more than 90% of open and endovascular vascular surgical procedures in the country.[7] In May 2008 the registry was thoroughly revised. Instead of one set of variables for all vascular surgical procedures, which had been used since the start, specific modules were created for different standard operations, based on the indication for surgery. One such set of modules was created for infra-inguinal arterial procedures, with PA as one specific indication.

All procedures for PA, open or endovascular, confined to the popliteal fossa or extending into the superficial femoral artery are registered in this specific module. Background characteristics and details of surgical technique are registered prospectively. At 30 days and 1 year, complications, patency, and amputation are recorded. Yet, there were some outstanding issues. Were all procedures on true PA, or were some performed on pseudoaneurysms? Were they all primary procedures, or were re-operations also registered? Were all the pre-operative thrombolysis procedures registered in the PA module as part of the reconstruction or as separate interventions for acute ischaemia? To validate the registry data, and to enable analysis of the details mentioned above, a questionnaire was created and sent to the 30 hospitals that had treated and registered the patients, and an additional case record analysis was performed.

Retrieval of operations

In the Swedvasc, 668 interventions for PA were registered between May 2008 and May 2012. Dual registrations such as pre-operative thrombolysis followed by aneurysm repair were identified in Swedvasc and merged. A protocol was sent out to the 30 institutions having registered the procedures to verify the remaining registrations (592). The principal investigator (A.C.) performed 165 of these protocols in site visits to four larger institutions. The remaining protocols were registered by co-authors of this paper or by the local Swedvasc representatives. The following 86 interventions were excluded or merged with other registrations: pre-operative thrombolysis and percutaneous transluminal angioplasty (29), reoperations (21), interventions on peripheral aneurysms other than PA (26), and other reasons (10). Ten non-registered interventions on PA during the designated period were identified and added (10/592, 1.7%), seven of which were performed on the contralateral leg.

When analysing time trends, data were compared with those during 1994–2002 from a previous publication from the same database,[1–3] except for the incidence of PA repair when 1994–2001 was used,[1] since data from the last 2 months of 2002 were suspected to be incomplete.

Statistics

The chi-square test was used for categorical variables. For continuous variables Levene's test was used to test normal distribution. If homogeneity was violated, it was adjusted for with the Brown–Forsythe test. The ANOVA test was used to compare differences between multiple subgroups, and the Tukey range test was used for inter-group comparisons. All tests were two-tailed. A p value $< .01$ was considered significant, adjusting for multiple comparisons. A p value $< .05$ was considered a statistical trend. Multivariate statistics were not considered feasible because of the small number of events (occlusion, amputation, death) in the different subgroups. All statistical analyses were performed using the software package SPSS version 20.0 (IBM SPSS, Inc.).

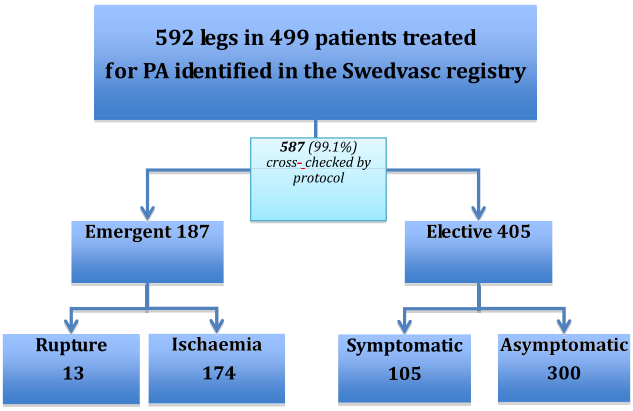

Figure 1. Study design.

RESULTS

Incidence of PA repair

There were 592 interventions for PA (in 499 patients) of which 587 (99.1%) were cross checked with supplementary protocols (Fig. 1). All 592 limbs were treated during 4 years (148/year). Sweden had a population of 9.4 million in 2010, resulting in an incidence of 15.7 operations/million person years.

Validity of registry based data

To validate the registrations in Swedvasc they were compared with the Inpatient Registry and it was found that interventions for PA that were listed in either of the registries and 91.4% (583/638) were registered in Swedvasc. Smoking status had missing values in 25%; other pre-operative risk factors were missing in approximately 7%. In three of the 484 cases (0.6%) who had undergone open repair, the exact surgical technique (medial or posterior) was unknown.

Patient characteristics

Of the 592 PAs, 187 (31.6%) were treated emergently and 405 (68.4%) electively. The following four subgroups were created based on the indication for treatment: rupture 13 (2.2%), acute ischaemia 174 (29.4%), elective symptomatic 105 (17.7%), and asymptomatic 300 (50.7%). In the previous database,[1–3] 31.5% were treated for acute ischaemia (1994–2002, $p = .58$).

The baseline characteristics of the four groups are described in Table 1. The p values in Table 1 refer to comparing all four groups with ANOVA. When comparing two groups, the group with ruptured PA differs from the acute ischaemia group in age ($p = .006$) and frequency of heart disease ($p = .022$, trend), from the elective symptomatic in age ($p = .023$, trend) and from the asymptomatic in age ($p = .013$, trend) and frequency of heart disease ($p = .006$). The groups acute ischaemia, elective symptomatic and asymptomatic, did not differ significantly from each other in this analysis, nor with an ANOVA test including these three groups only.

Surgical technique

The proportions of surgical techniques used in the four groups are presented in Fig. 2. There were no differences in background factors such as heart disease, diabetes, smoking, cerebrovascular disease, hypertension, or age in the acute ischaemic group when comparing those treated with ER or OR. In both the elective symptomatic and the asymptomatic groups, however, those treated with ER were older than those treated with OR: 78 versus 68 years ($p = .006$) and 74 versus 68 years ($p < .001$) (Table 2). The proportion of ER increased from 4.7% 1994–2002 (26/558) to 16.7% 2008–2012 (97/581) ($p = .0001$) a 3.6 fold increase.

Incompletely treated patients

Eleven patients (1.9%) were treated incompletely: nine with acute ischaemia (all Rutherford 2b, with neurological impairment) and two with other symptoms. One underwent successful thrombolysis but committed suicide before definitive treatment. The remaining eight patients with acute ischaemia had no benefit to the run-off from thrombolysis, were all amputated within a week, and two died within 30 days.

Two elective patients underwent incomplete treatment: one was a 91 year old man with rest pain who underwent thrombolysis without effect, the other had a distal bypass, which occluded during the operation; none was amputated. These 11 patients are not included in Fig. 2, nor in the description of the medium-term outcome, since different definitive treatments are compared.

The emergent group

Among the 187 legs that were treated emergently, 13 had a ruptured aneurysm. This small and special group is not elaborated on further. The remaining 174 had acute ischaemia, and they were classified according to Rutherford[8]: 23 (13.2%) had Grade 1, 85 (48.9%) Grade 2a, and 63 (36.2%) Grade 2b.

The acute ischaemia group

The treatments given to the 174 with acute ischaemia are summarized in Fig. 3: 118 (67.8%) received pre-operative thrombolytic treatment, and 92 of those (78.0%) improved their outflow. The duration of thrombolysis was a maximum of 4 days. Most limbs (87.6%) were treated during 1 or 2 days. In 28 (24%) cases the thrombolysis had to be terminated. The reasons were severe intra cerebral haemorrhage (1), other bleeding (6), compartment syndrome (6), massive embolization (1), no effect of thrombolysis (5), and unknown (9). The time between thrombolysis and operation was within a week in 79.8% (75/94), median 3 days. Including the incompletely treated group, the total number of amputations was 17/170 (10%) at 30 days and 20/159 (13%) at 1 year. Excluding the limbs that were not completely treated the cumulative amputation rates were 5.6% (9/161) and 8.6% (112/140) at 30 days and 1 year.

Table 1. Background characteristics.

	Rupture	Acute ischaemia	Elective symptomatic	Elective asymptomatic	ANOVA *p*	All patients
Number	13	174	105	300		499
Median age (range)	79 (63–93)	69 (42–102)	69 (46–93)	69 (50–90)	.013	70 (42–102)
Male gender (%)	100	93	95	97	.138	95
Diabetes (%)	0	11	14	16	.288	13
Heart disease (%)	62	26	30	21	.005	27
Respiratory disease (%)	27	11	12	11	.437	12
Hypertension (%)	67	65	62	70	.453	68
RRT (%)	0	0	0	1		1
CVD (%)	25	14	9.3	10	.227	11
Smoker (%)						
Never	28	22	26	17	.270	21
Former	43	43	52	57		52
Active	29	35	22	26		27

Note. The clinical subgroups refer to legs, all patients refer to patients, some of them operated on bilaterally, thus sometimes belonging to two groups. RRT = renal replacement therapy; CVD = cerebrovascular disease; ANOVA = analysis of variance.

Of the ER, 21/27(78%) had pre-operative thrombolysis while in the OR group the proportion was 81/137 (60.1%, $p = .083$). Outflow was improved after thrombolysis in 19/21 (91%) ER and in 72/84 (86%, $p = .566$) OR. Another five (3.6%) in the OR group had intra-operative thrombolysis.

Primary and secondary patency, amputation, death, and amputation free survival at 30 days and 1 year among those operated on with OR and ER are given in Table 3.

In 116 of the bypasses a vein graft was used (89.9%), in 13 a synthetic graft (10.1%), and in nine patients this information is missing. There was no difference in patency depending on graft material used ($p = .488$).

Within 1 year, five of the patients originally treated with ER were converted to OR. Three of these were patent 1 year after re-operation, one was patent after 8 months, and the information is missing in one.

At 1 year, OR secondary patency with vein grafts was 91% (87/96) compared with 56% (5/9) among those who had a synthetic graft ($p = .002$).

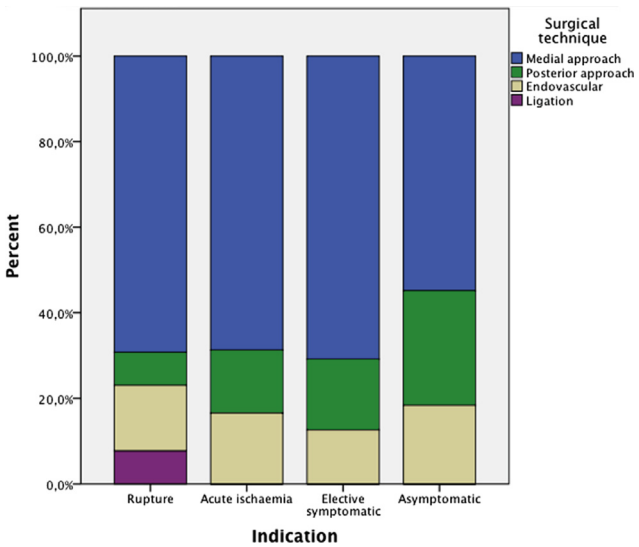

Figure 2. Surgical technique.

The elective symptomatic group

Of 405 elective operations, 105 were symptomatic, and 103 of those underwent complete treatment of the PA. The main symptoms were claudication (40/103, 38.8%), rest pain (29, 28.2%), ischaemic ulcer (22, 21.4%), venous compression or thrombosis (5, 4.9%), and microembolism (2, 1.9%). Five cases (4.9%) were considered symptomatic, but for unknown reasons. Primary and secondary patency, amputation, death, and amputation free survival at 30 days and 1 year among the 103 limbs operated on with OR and ER are given in Table 4.

One aneurysm in the ER group was converted to an open bypass and remained patent. Two of the stents were multilayer stents; one occluded after 4 months, was reopened by thrombolysis, and relined with a covered stent graft. The other remained patent at 1 year.

The asymptomatic group

Of the 300 legs with asymptomatic PA, 55 (18.3%) were treated by ER and 245 (81.7%) by OR. Outcomes among those operated on by OR and ER are given in Table 5.

In the ER group, one was converted to a bypass within a month and another two within a year. Two of these were examined and found to be patent after 1 year. Two legs were treated with multilayer stents, neither of which was patent at late follow up.

Of the OR 83.5% (197/236) were reconstructed with vein bypass, 37 (15.7%) with prosthetic, and two with composite graft. Vein grafts had a patency of 99.4% at 30 days compared with 94.7% for prosthetic grafts ($p = .017$). The corresponding patency rates at one year were 95.9% versus 80.0% ($p = .001$).

Open repair

Outcomes after OR by graft type are shown in Table 6, and by surgical approach in Table 7. Vein grafts were used in 87.6% (395/451), and had significantly better results both overall and in the subgroups. A posterior surgical approach was used in 20.8% (121/581), had better patency at 30 days

Table 2. Background characteristics in context of treatment modality.

	Acute ischaemia		*p*	Elective symptomatic		*p*	Elective asymptomatic		*p*
Surgical technique (*n*)	ER (27)	OR (138)		ER (13)	OR (90)		ER (55)	OR (245)	
Median age, years (range)	70 (46–88)	69 (42–102)	.627	78 (63–88)	68 (46–93)	.006	74 (53–89)	68 (50–90)	<.001
Male gender (%)	85	94	.099	85	97	.059	100	97	.174
Diabetes (%)	20	9.4	.122	8	15	.499	15	16	.884
Heart disease (%)	30	26	.657	46	27	.216	34	18	.012
Respiratory disease (%)	17	10	.303	33	9.4	.018	9.8	11	.742
Hypertension (%)	58	65	.510	64	61	.862	68	70	.725
Cerebral insult (%)	8.3	14	.471	0	9.0	.231	12	10	.621
Smoker (ever) (%)	81	79	.812	63	76	.417	80	84	.525

($p = .007$), and a trend towards lower amputation risk at 1 year ($p = .012$). A prosthetic graft was used in 12.0% (36/337) of medial approach cases and in 18.0% (20/111) ($p = .043$) of posterior cases. When a distal bypass was performed, two of 45 (4.4%) were with a prosthetic graft.

DISCUSSION

This observational study was based on prospective reporting to the Swedvasc Registry. It gives an opportunity to study the treatment of this rather rare disease with a population based design in a contemporary context, and where time trends can be analysed. One year complete follow up data were available for 87%, 84%, and 90% among the survivors in the acute ischaemia, symptomatic, and asymptomatic groups, respectively, comparing favourably with previous reports. The main results were an increased overall surgical activity, a shift towards ER, as well as towards the posterior approach when OR was chosen. Furthermore, inferior results after ER compared with OR were found, in particular when the leg was operated on for acute ischaemia.

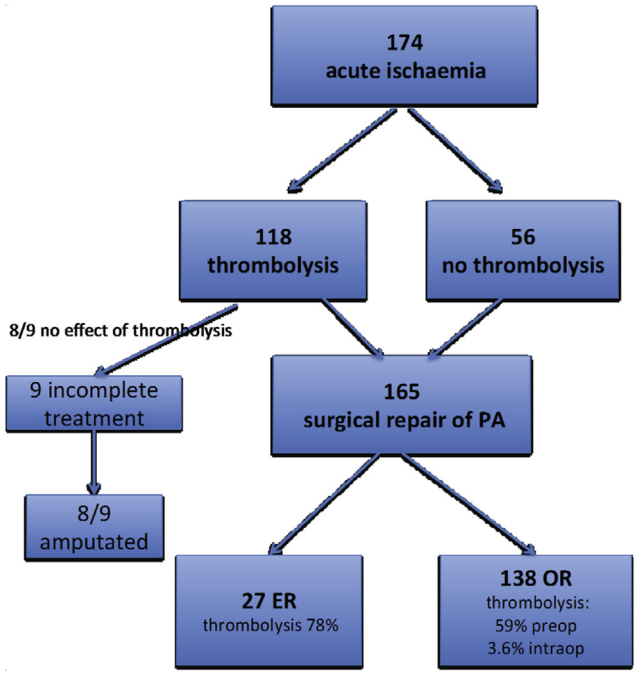

Figure 3. Flow chart of treatment given in the subgroup treated for acute ischaemia.

In a previous analysis Ravn et al.[1] reported an incidence of PA repair of 8.3 per million person years in 1994–2001 in Sweden, compared with 15.7 per million person years during 2008–2012, a doubling of the total surgical activity. There are great international differences in surgical activity for PA, and in the recent Vascunet report Sweden had the highest activity of the eight countries studied.[6]

The proportion of patients operated on for acute ischaemia has not changed over time (29.4 vs. 31.5%, $p = .58$). Thus, a change in the indications for surgery does not seem to have taken place. A more reasonable explanation for the increase in surgical activity is either a true increase in the prevalence of PA or an increased detection rate. The Swedish abdominal aortic aneurysm (AAA) screening programme started in Uppsala in 2006, and reached a more than 99% population coverage in 2014.[9,10] Many vascular centres perform a routine ultrasound examination of the popliteal arteries on patients with newly detected AAA, but that cannot explain the increase in operations for symptomatic PA. The improved imaging routines, including duplex ultrasound, computed tomography angiography and magnetic resonance angiography may result in a thrombosed PA being detected more frequently in a patient with acute ischaemia. Finally, there may be issues concerning the structure of the Swedvasc, which was changed in 2008[7] permitting a more precise registration of patients treated for PA. Even before 2008, however, there was a specific procedure code for PA repair in the Inpatient Registry. A previous focused validation of registration of PA repair in Swedvasc, scrutinizing the case records of patients with this specific procedure code showed that in 141 of 146 bilaterally operated patients, 97% had the contralateral operation registered in Swedvasc, thus showing an excellent external validity.[3]

The proportion of ER increased from 4.7%[1] to 16.7% in the present report, a 3.6 fold increase. This seems to be a global trend, in the previously mentioned Vascunet report the overall proportion of ER was 22.2%.[6] The Vascular Quality Initiative, a registry including 290 centres in the USA and Canada, reported an increase of ER from 34.8% in 2010 to 47.6% in 2013.[11]

This trend could be questioned on the basis the results of this study.[11,12] For the first time it has been possible to

Table 3. Outcome after treatment of popliteal aneurysm with acute ischaemia depending on treatment modality.

Total no. 165	Open repair (138)		Stent graft (27)		*p*
	N/Total[a]	%	*N*/Total[a]	%	
Primary patency, 30 days	113/128	88.3	17/27	63.0	0.001
Secondary patency, 30 days	122/131	93.1	19/27	70.4	0.001
Amputation within 30 days	5/134	3.7	4/27	14.8	0.022
Death within 30 days	2/138	1.4	1/27	3.7	0.423
Amputation free survival, 30 days	128/135	94.8	23/27	85.1	0.069
Primary patency, 1 year	89/113	78.8	9/21	42.9	0.001
Secondary patency, 1 year	99/114	86.8	10/21	47.6	<0.001
Amputation within 1 year	8/117	6.8	4/23	17.4[b]	0.098
Death within 1 year	6/138	4.5	4/27	14.8	0.037
Amputation free survival, 1 year	109/122	89.3	19/25	76.0	0.070

[a] The total number varies because of some missing data.
[b] The total number of amputations did not increase between 30 days and 1 year, but two patients died, and two were lost to follow up.

Table 4. Outcome after treatment of symptomatic popliteal aneurysm depending on treatment modality.

Total no. 103	Open repair (90)		Stent graft (13)		*p*
	N/Total[a]	%	*N*/Total[a]	%	
Primary patency, 30 days	83/89	93.2	10/13	77.0	.052
Secondary patency, 30 days	84/89	94.4	12/13	92.3	.767
Amputation within 30 days	3/90	3.3	0/13	0	.504
Death within 30 days	0/90	0	0/13	0	—
Amputation free survival, 30 days	87/90	96.7	13/13	100	.504
Primary patency, 1 year	60/74	81.1	4/7	57.1	.137
Secondary patency, 1 year	64/74	86.5	6/7	85.7	.955
Amputation within 1 year	7/81	8.6	0/9	0	.358
Death within 1 year	5/90	5.6	1/13	7.8	.758
Amputation free survival, 1 year	73/83	88.0	9/9	100	.270

[a] The total number varies because of some missing data.

analyse a large cohort of patients treated with both ER and OR for acute ischaemia, as well as for symptomatic and asymptomatic chronic disease. As can be seen in Table 3, patency rates at both 30 days and 1 year for those treated for acute ischaemia are significantly worse after ER, and there is even a trend towards a higher amputation risk. The secondary patency of ER is almost half that after OR (48% vs. 87%). Results would have been even worse for ER had not five patients been converted to OR between 30 days and 1 year, since these patients went on to do well without re-occlusion or amputation. The difference in outcome does not seem to be explained by case selection; as can be seen in Table 2 there are no differences in the background characteristics between those operated on with OR or ER in the acute ischaemia group. In the symptomatic and asymptomatic groups those treated with ER were older, but there are no significant differences in the frequency of co-morbidities.

All the numerical trends disfavour ER including those presented in Tables 4 and 5 comparing results for patients treated for symptomatic and asymptomatic disease. The fact that many of these comparisons do not show significant

Table 5. Outcome after treatment of asymptomatic popliteal aneurysm depending on treatment modality.

Total no. 300	Open repair (245)		Stent graft (55)		*p*
	N/Total[a]	%	*N*/Total[a]	%	
Primary patency, 30 days	232/244	95.1	50/53	94.3	.823
Secondary patency, 30 days	242/245	98.8	52/55	94.5	.043
Amputation within 30 days	0/245	0	1/55	1.8	.035
Death within 30 days	0/245	0	0/55	0	—
Amputation free survival, 30 days	245/245	100	54/55	98.1	.035
Primary patency, 1 year	186/209	89.0	31/46	67.4	<.001
Secondary patency, 1 year	200/214	93.5	41/49	83.7	.026
Amputation within 1 year	2/220	0.9	1/50[b]	2.0	.507
Death within 1 year	3/242	1.2	3/55	5.4	.045
Amputation free survival, 1 year	216/221	97.8	48/52	92.3	.048

[a] The total number varies because of some missing data.
[b] The total number of amputations did not increase between 30 days and 1 year, but three patients died, and two were lost to follow up.

Table 6. Outcome after open repair depending on graft material.

Indication	All procedures		p	Acute ischaemia		p	Elective symptomatic		p	Elective asymptomatic		p
Graft material (*N*)	Vein 395	Pros. 56		Vein 116	Pros. 13		Vein 82	Pros. 5		Vein 197	Pros. 38	
Prim. patency (*N*)	363/386	45/53	.015	96/108	9/11	.488	77/81	3/5	.003	190/197	33/37	.056
30 days (%)	94.0	84.9		88.9	81.8		95.1	60.0		96.4	89.2	
Sec. patency (*N*)	378/389	49/54	.018	104/111	10/11	.722	78/81	3/5	.001	196/197	36/38	.017
30 days (%)	97.2	90.7		93.7	90.9		96.2	60.0		99.4	94.7	
Amputations (*N*)	6/391	2/56	.282	4/112	1/13	.473	2/82	1/5	.037	0/197	0/38	—
30 days (%)	1.5	3.6		3.6	7.6		2.4	20.0				
Prim. patency (*N*)	288/331	32/46	.002	79/95	3/9	<.001	55/67	2/4	.117	153/168	27/33	.112
1 year (%)	87.0	69.6		83.2	30.0		82.1	50.0		91.1	81.8	
Sec. patency (*N*)	310/334	35/48	<.001	87/96	5/9	.002	59/67	2/4	.034	164/171	28/35	.001
1 year (%)	92.8	72.9		90.6	55.5		88.1	50.0		95.9	80.0	
Amputations (*N*)	12/347	5/51	.036	6/98	2/10	.110	6/73	1/5	.373	0/176	2/36	.002
1 year (%)	3.5	9.8		6.1	20		8.2	20.0			5.6	

Pros. = prosthetic graft.

differences ($p < .01$) is likely to be a result of type II statistical error.

Is it possible that these results after ER, representing everyday vascular surgery with a mix of academic and county hospitals, are significantly worse than those reported from highly specialized endovascularly oriented centres? Rather the opposite: these results are similar to those previously published.[5,13–15] Those investigators have reported high occlusion rates after operation for asymptomatic PA, but better secondary patency, and low amputation rates. Thus the results are similar to those in Table 5, which is the relevant comparison, given the fact that asymptomatic patients dominate in those published series. Yet, these patients are subjected to the risks associated with re-interventions,[16] verified in a recent large registry based survey of the US Medicare population.[17] Furthermore, thrombolysis was shown to be at particularly high risk of complications when performed after a thrombosed PA,[18] and the patients will also suffer ischaemic symptoms that are the result of a thrombosed reconstruction.

Why have these bad results after ER of PA treated for acute ischaemia not been reported previously? There are several studies[13–15,19,20] looking at stent graft treatment for PA with short-term results similar to open repair. The numbers of treated legs are quite small however, and most of the patients are asymptomatic. Furthermore, long-term results are seldom reported. An exception is a single centre study from Padova, Italy, on 46 ER (93% elective), reporting 5 year follow up in 59%.[21] Pulli et al.[5] reported the largest experience of ER to date, but of those 134 treated legs only 10 were treated for acute ischaemia, and the results of those operations were not presented separately. Based on the results of this investigation one can question whether it is ethically acceptable to perform ER of PA outside trials.

The results of OR are generally speaking excellent. This is partly a result of the frequent use of vein grafts, the importance of which has been demonstrated previously.[1,22–24] As can be observed in Table 6, the use of vein was associated with better patency in all sub-groups, but again the patients with acute ischaemia benefited most from this technique. Primary patency in this group was 83% at 1 year compared with only 30% in those who had a prosthetic graft, and the secondary patency rates were also quite different, 91% versus 55%, confirming the great advantage of vein grafts. A possible explanation for this clinically important observation is that patients who suffer acute ischaemia from a PA often have severely

Table 7. Outcome after open repair depending on surgical approach.

Indication	All procedures		p	Acute ischaemia		p	Elective symptomatic		p	Elective asymptomatic		p
Surgical approach (*N*)	Medial 349	Post. 121		Medial 112	Post. 24		Medial 73	Post. 17		Medial 164	Post. 80	
Prim. patency (*N*)	309/340	118/120	.007	91/105	22/23	.225	66/72	17/17	.218	152/163	79/80	.063
30 days (%)	90.9	98.3		86.7	95.7		91.7	100		93.3	98.8	
Sec. patency (*N*)	325/341	120/121	.052	97/105	23/24	0.549	67/72	17/17	.263	161/164	80/80	.224
30 days (%)	95.3	99.2		92.4	95.8		93.1	100		98.2	100	
Amputations (*N*)	8/345	0/121	.091	5/108	0/24	0.283	3/73	0/17	.395	0	0	—
30 days (%)	2.3	0		4.6	0		4.1					
Prim. patency (*N*)	247/296	89/101	.261	71/91	18/22	0.696	48/60	12/14	.623	127/144	59/65	.582
1 year (%)	83.4	88.1		78.0	81.8		80.0	85.7		88.2	90.8	
Sec. patency (*N*)	267/297	95/104	.668	79/91	19/22	0.956	51/60	13/14	.439	137/146	63/68	.743
1 year (%)	89.9	91.3		86.8	86.4		85.0	92.9		93.8	92.6	
Amputations (*N*)	17/308	0/109	.012	8/94	0/22	0.156	7/65	0/16	.170	2/149	0/71	.327
1 year (%)	5.5	0		8.5	0		10.8	0		1.3	0	

Post. = posterior approach.

compromised run-off, which may explain why both prosthetic grafts and endografts perform badly in this low flow environment.

No difference was shown in patency between OR with the medial or posterior approach in any of the subgroups (Table 7) but adding the groups together there was an advantage with the posterior approach. The main advantage of the posterior approach is the decreased risk of late expansion due to a phenomenon similar to Type II endoleak after EVAR for AAA.[25] This is often a late complication that develops many years after the primary operation,[26] and could not be expected to affect results within 1 year, which was the follow up period in this investigation. This point favouring the posterior approach has been taken up by many Swedish vascular surgeons, because the use of the posterior technique increased from 8.6% (60/717) between 1987–2002[3] to 21.0% (122/581) between 2008 and 2012, and is used even more often in the elective situation, 26.7% (80/300). If late expansion after ER happens, it remains an unresolved problem, but in a recent investigation on 46 ER with a median follow up of 56 months, no cases of sac expansion were reported.[21]

Performing research based on registry data has its limitations; both external and internal validity can be questioned. Fortunately, all previous validations of the Swedvasc Registry have shown excellent general validity,[27] as well as specifically for registration of PA repair.[3,28] We were also able to supplement registry data with a specific protocol, which achieved a high response rate (99.1%), illustrating the dedication of the local Swedvasc representatives and the collaborative atmosphere. Some important data, such as the size and thrombus of the PA, the anatomy of the run-off vessels, and post-operative medication are still lacking. The advantage is the large number of treated limbs, which has made it possible for the first time to perform sub-group analyses when comparing ER and OR. A follow up study, a case control study nested in this cohort, is underway in order to address these outstanding issues. Such a nested case control study addresses the major weakness of a case control study, the selection of controls, and is therefore considered robust by epidemiologists.

This investigation confirms the fact that rupture is an uncommon event among patients with PA, and the fact that only 13 patients were treated for rupture makes it difficult to perform any meaningful analysis. It is obvious from Table 1, however, that these patients are older than the other groups, and more than half of them have heart disease.

In conclusion, this contemporary study shows a clinically important difference in outcome between OR and ER treatment of PA, favouring OR. Although this finding may have been expected, the magnitude of difference in outcome, in particular among those treated for acute ischaemia, was unexpected and puts in question the use of ER for PA outside trials. The use of ER has increased almost fourfold compared with 1994–2001, illustrating the importance of this finding. The advantage of using a vein graft was confirmed, but since a vein was used in 87.6%, and some patients may not have a suitable vein graft, there is not much room for improvement in this respect.

CONFLICT OF INTEREST

None.

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