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## Long-term Patency Rates and In-Hospital Cost Analysis for Endovascular Repair of Popliteal Artery Aneurysms

Cote Elisabeth

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Département cœur-vasseaux

Service de chirurgie vasculaire

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Repair of Popliteal Artery Aneurysms**

THESE

préparée sous la direction du Docteur François Saucy

et présentée à la Faculté de biologie et de médecine de  
l'Université de Lausanne pour l'obtention du grade de

DOCTEUR EN MEDECINE

par

Elisabeth COTE

Médecin diplômée de la Confédération Suisse  
Originaire de Lausanne

Lausanne  
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*Ecole Doctorale  
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***Long-term Patency Rates and In-Hospital Cost Analysis  
for Endovascular Repair of Popliteal Artery Aneurysms***

*Lausanne, le 12 mai 2022*

*pour Le Doyen  
de la Faculté de Biologie et de Médecine*

  
**Monsieur le Professeur John Prior  
Vice-Directeur de l'Ecole doctorale**

L'anévrisme de l'artère poplitée est une maladie vasculaire relativement rare, découverte le plus souvent chez des patients asymptomatiques, mais responsable de complications potentiellement redoutables avec un taux d'amputation élevé. C'est pourquoi son traitement préventif est préconisé selon son diamètre et/ou en présence de thrombus mural.

Le traitement optimal de l'anévrisme de l'artère poplitée reste à ce jour controversé. La technique endovasculaire à l'aide de stents couverts connaît depuis plusieurs décennies une forte popularité en raison de son côté minimal invasif, avec des taux de perméabilité acceptables reportés dans la littérature. Néanmoins, l'option chirurgicale par pontage à l'aide de la grande veine saphène inversée semble demeurer le traitement de choix.

Du 1<sup>er</sup> octobre 2009 au 30 avril 2014, nous avons inclus tous les patients consécutifs à un traitement endovasculaire avec mise en place d'une endoprothèse Viabahn, au Centre Hospitalier Universitaire Vaudois, à Lausanne ; nous avons ainsi traité 38 anévrismes de l'artère poplitée chez 36 patients (dont 33 hommes, 91.7%). 27 (71.1%) patients étaient asymptomatiques. Les objectifs primaires étaient les taux de perméabilité primaire et secondaire, obtenus à l'aide de l'échodoppler lors d'un suivi en angiologie. Les taux de perméabilité primaire à 6, 12, 24 mois et 5 ans étaient de 78.9%, 76.3%, 73.7% et 68.4%, respectivement. Les taux de perméabilité secondaire à 6, 12, 24 mois et 5 ans étaient de 92.1%, 89.5%, 86.8% et 81.6%, respectivement. Les objectifs secondaires comprenaient les taux de sauvetage de membre (94.7%) et de survie (89%) au long cours ainsi que le taux de réintervention, qui était de 2.6% à 30 jours postopératoires et de 23.7% durant le suivi. De plus, nous avons analysé les coûts en intra-hospitalier, en comparant notre collectif de patients avec un groupe de patients traités par voie ouverte, avec un coût moyen par patient qui s'élevait à 13'585 ± 7690 francs suisses pour le groupe endovasculaire et à 19'138 ± 6225 pour le groupe chirurgical (P<0.027).

En conclusion, le traitement endovasculaire dans le cadre de l'exclusion d'un anévrisme de l'artère poplitée est réalisable et sûr. Les taux de perméabilité au long-terme sont acceptables, et les coûts intra-hospitaliers globaux en faveur de la technique endovasculaire. Néanmoins, le taux de réintervention étant plus important après mise en place de stent(s), une sélection prudente des patients qui bénéficieraient le plus de l'alternative endovasculaire est fortement recommandée.



Popliteal artery aneurysms are uncommon, mostly diagnosed in asymptomatic patients. However, they can be responsible for dreadful complications due to peripheral arterial embolization and thrombosis, with high rates of limb loss. Therefore, current recommendation for preventive repair include aneurysm size and presence of parietal thrombus.

Optimal treatment of popliteal artery aneurysm is controversial. In the last decades, endovascular treatment with covered stents has gained in popularity because of the decreased early morbidity. Literature shows acceptable patency rates. Nevertheless, reverse saphenous vein bypass surgery seems to remain the gold standard.

From 1<sup>st</sup> of October 2009 to 30<sup>th</sup> of April 2014, we included all consecutive patients with a popliteal artery aneurysm that underwent endovascular repair with a covered stent-graft (Viabahn), at Centre Hospitalier Universitaire Vaudois, in Lausanne. We treated 38 popliteal artery aneurysms in 36 patients (33 males, 91.7%). 27 (71.1%) patients were asymptomatic. The primary outcomes were primary and secondary patencies, assessed with duplex ultrasound. Primary patency rates at 6, 12, 24 months and 5 years were 78.9%, 76.3%, 73.7% and 68.4%, respectively. Secondary patency rates at 6, 12, 24 months and 5 years were 92.1%, 89.5%, 86.8% and 81.6%, respectively. Secondary outcomes were long-term limb salvage (94.7%) and survival (89%), as well as reintervention rates (2.6% within 30 days of surgery and 23.7% during follow-up).

Moreover, we estimated in-hospital costs comparing endovascular and open surgery repair in age- and sex-matched groups. The mean in-hospital cost per patient was 13'585 ± 7690 Swiss francs for the endovascular group and 19'138 ± 6225 for the open surgery group ( $P < 0.027$ ).

To conclude, endovascular repair of popliteal artery aneurysm is feasible and safe. Long-term patency rates were acceptable, and in-hospital costs were lower with the endovascular technique. Nevertheless, reintervention rate was high, suggesting a careful selection of patients who will most benefit from endovascular repair.





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## **List of abbreviations**

PAA	Popliteal artery aneurysm
AAA	Abdominal aortic aneurysm
ALI	Acute limb ischemia
ER	Endovascular repair
DUS	Duplex ultrasound scan
CTA	Computed tomography angiography
GSV	Great saphenous vein
SFA	Superficial femoral artery
PTFE	Polytetrafluoroethylene
COPD	Chronic obstructive pulmonary disease
PP	Primary patency
SP	Secondary patency
ISR	In-stent restenosis
BMI	Body mass index
ASA	American Society of Anesthesiologists
PTA	Percutaneous transluminal angioplasty
CHF	Swiss francs
EVAR	Endovascular aortic repair

## **Introduction**

Popliteal artery aneurysms (PAA) are the most common among peripheral aneurysms; they account for over 70%<sup>1-3</sup>. Half of PAAs are bilateral, and 40% are associated with abdominal aortic aneurysms (AAA)<sup>4,5</sup>. The diagnosis is typically performed in asymptomatic patients<sup>5,6</sup>. Natural history of PAA shows that patients will develop symptoms at a mean rate of 14% per year, increasing up to 70% at 5 years<sup>7-9</sup>. Clinical manifestations are mostly acute limb ischemia (ALI) (30%), but can also be chronic limb ischemia, venous or nerve compression or less frequently, rupture<sup>10,11</sup>. The main complication related to PAA is peripheral arterial embolization and thrombosis, with subsequent acute ischemia; in these cases, amputation rate can be as high as 30%<sup>12,13</sup>. Therefore, preventive therapy is currently accepted for treating large asymptomatic aneurysms (>2 cm) and/or asymptomatic aneurysms with parietal thrombus<sup>14-16</sup>. Symptomatic PAAs should be treated regardless of size<sup>17</sup>.

Nevertheless, PAA treatment remains debated. Recently, endovascular repair (ER) with covered stents have become popular. For specific indications, endovascular treatments have showed acceptable patency rates, as in a systematic review and meta-analysis from 2015, with a 12-month primary and secondary patency rates of 85.3% and 90.8%, respectively<sup>18</sup>. The main advantages of a minimally invasive technique are shorter operation time, reduced hospital stay, faster functional recovery and lower wound complication rate<sup>17,19-21</sup>. Still, the gold standard treatment remains surgery with a reverse saphenous vein bypass<sup>4,7,8,22</sup>. This approach shows excellent patency rates and long-term durability<sup>23,24</sup>. The drawback is a higher postoperative morbidity rate with surgery than with covered stents<sup>25</sup>.

Efforts to improve endovascular technology are both clinically and economically attractive. Despite the favorable early outcomes, durability of this promising technique is questioned, because of higher thrombosis and reintervention rates<sup>26,27</sup>. Moreover, cost-effectiveness analysis showed that the initial costs benefits seemed not to be sustained over time<sup>28</sup>.

## **General principles about Popliteal Artery Aneurysms (PAAs)**

### **A. Definition**

PAA is a focal dilatation of the popliteal artery of at least 1.5 times the diameter of the native adjacent vessel (normal diameter of the mid-popliteal artery ranges from 0.7-1.1cm)<sup>23,29</sup>.

### **B. Epidemiology**

PAA is a rare disease, with a low incidence (0.1-2.8%)<sup>21,30,31</sup>. It affects 1% of the 65-80 years old men, with a 20-to-1 male-to-female ratio<sup>23,30,32</sup>.

Aside age and gender, the general risk factors for developing PAA are arterial hypertension, smoking, cerebrovascular and coronary heart diseases<sup>33,34</sup>, as well as the presence of other concomitant aneurysms<sup>4,35</sup>. 40% of PAAs have an associated AAA and 15% of patients with an AAA are at risk to develop a PAA<sup>35</sup>. For this reason, patients with PAA should be screened for AAA<sup>29,33</sup>.

### **C. Pathogenesis**

Aneurysm formation is mostly due to loss of the mechanical integrity of the vessel wall because of an altered balance between the production and degradation of vascular wall constituents.

Aside from trauma, PAAs are almost exclusively degenerative in origin; they are rarely inflammatory, mycotic or associated with connective tissue disorders<sup>23,36,37</sup>.

### **D. Natural history and clinical manifestations**

The natural history of PAAs is associated with a high incidence of thromboembolic events, both acute and chronic. Some authors observed a natural progression of PAAs with an average growth rate of 1.22mm/year<sup>34</sup>; some others reported a correlation between aneurysm size and clinical presentation<sup>7</sup>. The mean diameter during diagnosis was 16.9 mm and 57% presented with mural thrombus<sup>34</sup>. Symptoms tend to develop with a 15-25% complication rate at 1 year, which increases up to 60-70% at 5 years<sup>9,15,38</sup>. Lowell et al, in a retrospective study that evaluated the risk of nonoperative management of PAA, showed that aneurysm size of more than 20mm, thrombus or

poor runoff, predicted the development of symptoms<sup>15</sup>. Up to 30-50% of all symptomatic PAAs present with ALI<sup>27,30,40</sup>. ALI due to PAA is a difficult surgical problem with a 20-60% incidence of limb loss and up to 12% of mortality reported in the literature in the last decades<sup>35,39</sup>. As a fact, a conservative strategy is associated with a high risk of ischemic complications (30-40%): 57% of asymptomatic PAAs require at some point intervention, and 83% within 2 years<sup>5</sup>. It is nowadays difficult to justify a conservative management for this type of disease<sup>9,37</sup>.

Apart from the acute presentation, where patients will feel abrupt onset of foot or leg pain, foot coolness, or even sensory or motor deficits, some patients will present symptoms ranging from pain with walking (intermittent claudication) to symptoms of chronic limb ischemia in the context of repeated episodes of distal embolization which can progressively occlude the outflow vessels, slowing flow and leading to thrombosis of the aneurysm. Moreover, when the PAA is large, it can have a compressive effect on the adjacent structures, as nerves or veins, causing pain, leg swelling or even deep vein thrombosis<sup>10,35</sup>.

Unlike AAA, rupture is rare and occurs in 2-3% of cases<sup>6,40,41</sup>; patients can present a painful tumefaction, or sometimes hemorrhage, limited to the popliteal space<sup>23</sup>.

Data from the literature demonstrate that the results of surgical or endovascular treatment are strongly affected by the clinical presentation of PAA<sup>37</sup>.

## **Management of PAAs**

### **A. Diagnosis**

PAA should be suspected in any patient in whom a pulsatile mass of the popliteal fossa is palpated, or who is known for a contralateral PAA or associated AAA. The method of choice is the duplex ultrasound scan (DUS), confirming the diagnosis and giving information about the patient's anatomy, which is mandatory prior to repair. This imaging tool is noninvasive, available, without any radiation or contrast medium. It is helpful for a vein mapping, when a bypass is indicated, and can judge of the quality of the inflow and outflow vessels. Other imaging modalities, such as

computed tomography angiography (CTA) (or rarely magnetic resonance angiography) are interesting for the preoperative sizing, useful for determining extension of the aneurysm, and give accurate information about size (diameters) and length of the PAA which is necessary for selecting the right devices when ER is chosen (**Figure 1**).

## **B. Indications for repair**

Primary aim in the management of PAA is to prevent thromboembolic complications and subsequent high level of amputation.

Current indications for repair of asymptomatic PAA are based on a general consensus supported by literature, recommending the treatment of PAAs larger than 2.0 cm and/or with presence of mural thrombus<sup>14-16,37</sup>; some authors recommend as well PAA repair when there is altered runoff<sup>15</sup>. Symptomatic PAAs should be treated regardless of dimensions. These recommendations are based on the high incidence of thromboembolic complications as well as the the low morbidity and mortality associated with elective repair.

Risk factors for accelerated growth of PAAs are the size of the PAA, with a cut-off established at more than 20mm, the presence of mural thrombus and atrial fibrillation, as demonstrated by Cousins et al, who followed the natural progression of 87 PAAs during a mean time of 3.12 years<sup>34</sup>. Proper follow-up, surveillance and timing for intervention are therefore crucial in preventing complications. Intervening electively on aneurysms of more than 20mm or symptomatic ones has been proven to provide superior outcomes concerning limb salvage, morbidity and mortality, compared with those treated emergently<sup>10</sup>.

Indications for treatment in patients with chronically thrombosed popliteal aneurysm are the same as those used for patients with peripheral arterial occlusive disease.

Given the risk of negative outcomes associated with the condition of PAA, proactive treatment is of great importance.



## **C. Therapeutic options**

The goal of PAA repair is to eliminate the aneurysm from the circulation and maintain perfusion to the extremity. It can be accomplished by either open or endovascular techniques.

Despite the well-established conventional surgical treatment, the development of endovascular technique has become a new alternative for PAA treatment.

Technique of repair for PAA is a subject of debate, particularly with the increased utilization of endovascular techniques during the last decades and the paucity of evidence-based data evaluating these procedures<sup>27</sup>. There is limited data of quality comparing repair techniques, and major society guidelines provide no guidance in choosing between open surgical and endovascular repair. Surgical decision-making in a patient with a PAA is complex, and several factors have to be considered, including clinical presentation (elective or emergent), the degree of limb ischemia, the patient's medical comorbidities, their vascular anatomy (suitability for endograft insertion and status of the proximal/distal circulation), the presence of coexistent aneurysms, and availability of vein conduit. In fact, long-term patency rates are higher when autogenous vein rather than prosthetic graft is used for below-the-knee bypass, and thus the availability of vein may determine the approach to popliteal aneurysm repair<sup>7,16,39</sup>.

Each PAA repair should be selectively considered on a case by case basis<sup>18</sup>. See **Figure 2** for guidance in decision-making.

### **C1. Open surgical repair**

The most common operative technique is aneurysm ligation and bypass, using autologous vein, through a medial approach, as first described by Edwards in 1969<sup>42</sup>. The use of an interposition graft after resection of the aneurysm through a posterior approach has also been described, which may reduce the risk of aneurysm reperfusion<sup>42</sup>.

Since both approaches are effective, which one is employed for a given patient is dependent on the surgeon's experience, aneurysm size, proximal and distal extent of the aneurysm, as well as availability of great saphenous vein (GSV). Extension of the aneurysm into the superficial femoral artery (SFA) or infra-geniculate arterial tree precludes a posterior approach. In this anatomic situation, the proximal and/or distal anastomoses of the arterial reconstruction are best

approached medially. Acutely thrombosed PAA, or when there is evidence of embolization, are best treated by a medial approach, because of the necessary access to the distal arteries. One of the advantages of the medial approach is to be able to exclude the aneurysm from the circulation without the need to dissect it directly, thus reducing the risk of iatrogenic injury to the popliteal vein, common peroneal and tibial nerves as well as reducing the risk of distal embolization to the crural vessels<sup>36</sup>.

When PAAs are focal (limited to the popliteal space), or large enough to cause symptomatic compression of the surrounding structures, resection of the aneurysm with interposition grafting through a posterior approach is preferred<sup>37</sup>. The posterior approach has the benefit of complete aneurysm decompression, which does not always occur with medial ligation and bypass (up to one third has continued sac expansion after a medial approach)<sup>41</sup>.

There is no difference in terms of patency between the medial and posterior approaches.

Open surgery shows excellent long-term patency rates, with a well-known durability, and a limb salvage superior to 90% at 5 years for asymptomatic PAAs<sup>7</sup>. It's especially indicated in young and active patients.

Risk factors for bypass failure are mostly dependent of the type of conduit used (like prosthetic), the site of distal anastomosis and the initial clinical presentation, like acute limb ischemia or emergent intervention<sup>25,37</sup>. As well, poor runoff is a predictor of failure<sup>38,40</sup>.

Results of surgery are generally better with autogenous vein, when compared to Polytetrafluoroethylene (PTFE) grafts, with superior patency in the long-term<sup>15</sup> and better resistance to infection. The ideal vein is the GSV compared to arm veins. Below-the-knee prosthetic grafts have an increased risk of thrombosis and are avoided whenever possible<sup>40</sup>.

## **C2. Endovascular repair (ER)**

ER consists on the exclusion of the PAA by the implantation via the common femoral artery of a covered stent-graft (**Figure 3**). It was first described in 1994 by Marin and colleagues<sup>43</sup>. It was accomplished with a standard polytetrafluoroethylene (PTFE) graft that was introduced through the common femoral artery and fixed with stents at both ends. Since, this technique gained wider acceptance and use, especially after the development of expanded PTFE-lined nitinol stents, such as the Viabahn® stent (GORE, Flagstaff, AZ)<sup>14</sup>.

Anatomical criteria are of great importance before choosing the endovascular approach: runoff status, proximal and distal landing zones, angulation and tortuosity. Relative contraindications to endovascular treatment include extension of aneurysmal disease to the SFA proximally or to the anterior tibial or tibioperoneal trunk arteries distally, as well as large aneurysms with compression symptoms. Moreover, patients with contraindications for dual antiplatelet therapy, or active patients with repetitive movements of flexion in the knee, should be treated by surgery.

ER is a very attractive option in elderly or frail patients, because of the faster recovery, and possibility to do the procedure under local anesthesia; in addition, it can be very interesting when no adequate vein is available<sup>16,18,44,45</sup>. Furthermore, ER seems to effectively exclude aneurysms with overall aneurysm sac volume shrinkage of 25.5ml at 7 years<sup>46</sup>.

Most studies show acceptable short and mid-term patency rates<sup>18,23</sup>. Nevertheless, reinterventions are high (20% at 2 years)<sup>26,27</sup>. Still, ER offers main advantages, as reduced in-hospital morbidity and mortality, because of the low invasiveness of this procedure<sup>1,13,17,23</sup>.

Predictors of graft occlusion are poor runoff and acute clinical presentation<sup>13,17,20,47</sup>, increased number of stents used<sup>44</sup>, as well as length of stent-graft used<sup>46</sup>. In addition, small stent-graft diameter and angulation of the PAA are risk factors for failure<sup>48</sup>.

#### **D. Preoperative assessment**

Prior to open surgical or ER of the popliteal artery, the patient's condition, medical comorbidities and vascular anatomy, including the presence of other large vessel aneurysms, are evaluated. These factors influence the timing of repair and the choice between repair techniques. Generally, for asymptomatic repair, aneurysms proximal to the popliteal aneurysm should be managed first, as these have a potential to embolize distally and may occlude the popliteal bypass or stent.

Asymptomatic patients and those with viable limbs that are not threatened, can undergo outpatient preoperative evaluation and repair. For those who present acutely with a threatened extremity, urgent inpatient evaluation and repair are undertaken. In patients with acute thrombosis, an intravenous heparin infusion should be initiated to limit the extension of thrombus.

When patients develop acute thromboembolic complications, the degree of arterial occlusion is often so great that no outflow vessel is visualized by the different imaging modalities. Many of these patients also have thrombosis of the microcirculation. In such patients, bypass is often not possible or subject to failure due to poor runoff. In this situation, the use of pre-repair intra-arterial thrombolytic therapy can be useful to reestablish runoff and improve microcirculation, thereby allowing success of bypass or stenting. Following acute thrombosis of a PAA, patency and limb salvage rates after initial successful thrombolysis, have been reported to be superior to early operative intervention alone, without compromising results of surgery if unsuccessful<sup>37</sup>. Catheter-directed thrombolysis is indicated when there is mild to moderate ischemia at presentation; it's less appropriate for immediately-threatened extremities because duration of time needed to dissolve the clot is usually prolonged (12-24hours)<sup>40</sup>. For severe presentation, thrombectomy followed by bypass is effective<sup>40</sup>.

In case of unsuccessful thrombolysis, aggressive attempt at surgical revascularization should be immediately initiated, with thrombectomy of the crural arteries, which could be associated to peri-operative lysis if needed, followed by bypass if runoff patency is restored<sup>49</sup>.

Ruptured popliteal artery aneurysm is uncommon, and may be best managed using an hybrid approach, with endovascular technique for initial control of hemorrhage, and open technique to manage hematoma compression, if needed. However, ruptured PAA may be associated with infection which necessitates complete excision of the PAA and ideally autogenous reconstruction.

We should offer aggressive cardiovascular risk reduction strategies, such as tight glycemic and blood control, dietary and smoking cessation advice, and antiplatelet pharmacotherapy. This should be similar to what is offered to patients with peripheral artery disease to reduce incidence of future myocardial and cerebrovascular events<sup>42</sup>.

### **E. Perioperative management**

Following elective ER, the patient is admitted for observation and maintained at bedrest for a minimum of 6 hours, to ensure adequate closure of the groin puncture site. Dual antiplatelet therapy is recommended for at least 4 weeks. It is associated with a lower incidence of early stent-graft thrombosis<sup>19,25</sup>.

Following open surgical repair, the patient is transferred to a monitored care setting. The integrity of the repair is monitored with frequent pulse checks. The patient is placed ad bedrest overnight and is generally allowed to ambulate the next day.

Patients with acute limb-threatening ischemia who have not already undergone aponeurotomy are monitored for compartment syndrome.

The main complications after open surgery concern wounds (hematoma, seroma, infection) and reperfusion oedema<sup>4,24</sup>. Because of a more invasive procedure, and because open surgery is more frequently performed in emergent or acute situations, cardiorespiratory complications and blood transfusions are responsible for higher rates of short-term morbidity and mortality. As well, aneurysm sac expansion tends to happen more often in open surgery (medial approach) than in ER (30 versus 8%), due to persistent backflow from one or more of the geniculate vessels<sup>4,18</sup>. The risk of a continued sac expansion is secondary rupture. Moreover, complications that are unique to lower extremity venous bypass are the development of vein graft aneurysms.

Most common complications after endovascular technique are related to the percutaneous access site, with hematomas or pseudo-aneurysms. The most feared complication is stent-graft thrombosis (early or late), and device-related complications such as stent migration, kinking or fracture. Endoleaks are described as well (10-20%, mostly type 1 and 3), often due to migration and/or fracture<sup>46,50</sup>.

# **Long-term Patency Rates and In-Hospital Cost Analysis for Endovascular Repair of Popliteal Artery Aneurysm: A retrospective Study**

## **Objective**

Our study aimed to assess long-term patency rates of covered stents in patients with PAA, evaluate potential adverse events, and analyze the costs of this technique, comparing in-hospital costs of patients treated with the endovascular approach to a matched-group of patients treated with open surgery.

## **Materials and Methods**

### **A. Study design and population**

This retrospective observational study included all consecutive patients with PAA that underwent an endovascular procedure with a Viabahn® stent-graft (Gore®, Flagstaff, USA) at the Centre Hospitalier Universitaire Vaudois (Lausanne, Switzerland), between the 1<sup>st</sup> of October 2009 and the 30<sup>th</sup> of April 2014. Data were retrieved from a prospective vascular database (Secutrial, Interactive Systems, Germany). Ethical approval was obtained (Commission Cantonale Vaudoise d'éthique de la recherche sur l'être humain).

ER was the first option for patients at high surgical risk and with favorable anatomy. High surgical risk was defined as previous cardio-respiratory illnesses, coronaropathy, chronic obstructive pulmonary disease (COPD), transitory ischemic attack, age of more than 70 years or renal insufficiency. Favorable anatomy was defined as the presence of > 2cm proximal and distal landing zones. We did never land further than the departure of the tibial anterior artery. All our patients had an available GSV. Technical success was defined as the exclusion of an aneurysm after the intervention and stent-graft patency.

We had no financial support.

## **B. Endovascular technique**

All endovascular procedures were performed by vascular surgeons in operating rooms using a C-arm fluoroscopy. We used systematically a Viabahn® (Gore, Flagstaff, USA) stent-graft for ER. We performed open and percutaneous vascular accesses, under general or local/locoregional anesthesia, depending on the size of the introducer sheath diameter we used (an open access was performed for introducer sheaths of 9F or more). After inserting the sheath, an intravenous bolus (50 UI/kg) of heparin was injected. Stent-graft diameters and lengths were selected, based on a preoperative CTA, and compatibility was confirmed with an intraoperative angiogram. All graft diameters were oversized by 10-15%. Stent-grafts were deployed to cover the aneurysm, with 2cm landing zones, defined as sites of healthy popliteal artery where the stent-graft ends proximally and distally to the PAA. Multiple stent-grafts were used for extensive PAAs or when the diameters of the proximal and distal landing zones were significantly different (>3mm). When we used more than one stent-graft, the overlap zone, defined as the zone where one endograft was inserted into the other, was of minimum 2cm. The landing zones were postdilated with a standard balloon of the same diameter as the stent's size, to ensure full expansion of the stent-graft. A final angiogram was performed to assess stent-graft position, endoleak exclusion, and distal flow preservation. A lateral view of the stent-graft was systematically performed with the knee flexed at 90°. At the end of a percutaneous approach, haemostasis was achieved using dedicated devices like Angio-seal (St. Jude Medical, St. Paul, USA) or by manual compression, depending on the diameter of the introducer sheath.

## **C. Outcomes**

The primary outcome comprised the primary patency (PP) rate (defined as an uninterrupted patency without procedures performed on or at the margin of the treated segment), and the secondary patency (SP) rate (defined as a restored patency through the original treated segment), at 6, 12, 24 months, and 5 years. Patients systematically underwent DUS, assessing presence of an occlusion or an intra-stent restenosis (ISR), analyzing quality of flow and measuring the Ankle Brachial Index. ISR was defined as a peak systolic velocity >2.5 m/s. Secondary outcomes were 30-day and long-term postoperative complications, including major amputations (defined by a level of

amputation above the ankle), as well as mortality and reintervention rates at 30-day and during follow-up.

Another outcome of interest was the global in-hospital cost of this technique, including costs for the hospital stay, the intervention materials, and surgeon/anesthetist charges. We estimated in-hospital costs based on the Swiss DRG medical reimbursement system. The calculations were based on the codification system of the hospital, made by an economist of our institution.

We compared treatment costs between endovascular and open surgery (bypass) approaches by selecting 15 patients with PAA that underwent ER and 11 sex and age-matched patients with PAA that underwent open surgery, treated in the same hospital, by the same surgeons, during the same period.

#### **D. Statistics**

Continuous variables are reported as the mean  $\pm$  standard deviation or as the median and range, when data were not normally distributed. Descriptive variables are expressed as percentages or numbers. The cumulative stent patency rate was assessed with the Kaplan-Meier analysis. The Student-t test and the Wilcoxon signed rank test were used to compare costs between endovascular and open PAA repairs. P-values  $<0.05$  (2-sided) were considered statistically significant. All analysis were performed with SPSS v.12 (SPSS Institute, Chicago) or with Stata.

### **Results**

#### **A. Patient demographics and aneurysm characteristics**

38 PAAs were treated in 36 patients (2 patients with bilateral PAAs were treated during the same hospital stay). Most patients were men (91.7%). The mean age was 74 years (range: 50-93). The majority of patients had dyslipidemia (60.5%), cardiac diseases (57.9%) including coronaropathy, valvulopathy, and heart failure, as well as arterial hypertension (55.3%), and were active smokers (57.9%). The mean body mass index (BMI) was 26 kg/m<sup>2</sup>, which is considered overweight. Most patients had ASA (American Society of Anesthesiologists) scores of 2 (44.7%) and 3 (50%).



Comorbidities are reported in **Table 1**. Of the 38 PAAs, 27 (71.1%) were asymptomatic and 11 (28.9%) symptomatic. Two patients were admitted with ALI Rutherford I and loss of runoff flow. These patients required pre-operative thrombolysis; thus, their PAA treatments were delayed by 24 to 48hours. All other symptomatic patients were planned for elective PAA treatment. Three patients had multiple distal emboli (27.3%), and six (54.5%) had intermittent claudication. Aneurysms had a mean diameter of 2.3cm (range: 1.0-5.3) and a mean length of 4.4cm (range: 2.5-10.0). They often contained mural thrombus (92.1%). In our study, at presentation, most patients had 3 patent crural vessels (60.5%), 13 patients had 2 patent vessels (34.2%), and one patient had only 1 patent vessel (5.3%). Clinical details are shown in **Table 2**. Details about the surgical group are summarized in **Table 1-3**.

### **B. Operative findings**

PAAs were mostly excluded with 1 (47.4%) or 2 (50%) stents, only 2.6% required 3 stents. Most interventions required an incision (68.4%) and general anesthesia (63.2%). These rates could be explained by the use of large introducers ( $\geq 9\text{Fr}$ ), or when open access or a combined open procedure was indicated. Hybrid procedures were performed in 3 cases (7.9%). One required an open surgical revascularization of the common femoral artery; the second required a femoro-femoral prosthetic bypass (because of an ipsilateral iliac occlusion). The third was treated simultaneously with a contralateral femoro-popliteal bypass for a bilateral PAA.

Technical success was achieved in all subjects [**Table 3**]. We observed two intraoperative type I endoleaks, which were immediately treated with an additional stent-graft. One distal intra-operative embolization was treated with thromboaspiration of the emboli.

### **C. Postoperative results**

The median hospital stay was 6 days (range: 2-95). The longest stay was due to acute ischemia in the contralateral limb. That patient required a bypass and aponeurotomy. Three patients stayed 30 days, due to poor general condition and a long waiting list for rehabilitation.

Thirty-three patients (86.8%) received postoperative dual antiplatelet therapy (acetylsalicylic acid and clopidogrel) for at least 3 months. Patients already treated with an anticoagulant, for other indications (mostly vitamin K antagonist), received single antiplatelet therapy like acetylsalicylic acid (13.2%). All patients were on statin.

The mean follow-up was 33 months (range: 0.32-90.4). Twelve events occurred during follow-up, and 83% occurred within 12 months. Of these, 9 were occlusions and one was a significant symptomatic intra-stent restenosis. All events required revisions during follow-up, except one occlusion in a patient that was asymptomatic.

#### **D. Primary outcomes**

PP rates at 6, 12, and 24 months were 78.9%, 76.3%, and 73.7%, respectively. SP rates at 6, 12, and 24 months were 92.1%, 89.5%, and 86.8%, respectively. At 5 years, primary and secondary patencies were 68.4% and 81.6%, respectively (**Figures 4 and 5**). It should be mentioned that we had a high rate of patients lost during follow-up due to non-compliance.

#### **E. Secondary outcomes**

Freedom from postoperative complications was 84.2% at 30 days and 81.6% during follow-up. Complications included 1 ALI, 1 heart failure with pneumonia, 2 acute renal failures and 1 bleeding at the puncture site. During follow-up, amputation-free survival was 94.7%, with one major amputation at 10 days postsurgery with a patent stent-graft but an uncontrolled infection, and a second major amputation at 62 months because of the occlusion the stent-graft. No death occurred within the first 30 days after procedure. Mortality was 11% during follow-up, and 75% of all deaths were related to cancer. The postoperative reintervention rate was 2.6% within 30 days and 23.7% during follow-up. The majority of reinterventions were percutaneous transluminal angioplasty (PTA) and thrombolysis, and most occurred within 12 months.

#### **F. Costs analysis**

Costs were estimated based on the Swiss DRG reimbursement system. We compared treatment costs between endovascular and open surgery (bypass) approaches by selecting 15 patients with PAA that underwent ER without significant postoperative complications (which would prolong the hospital stay) and 11 sex and age-matched patients with PAA that underwent open surgical revascularization, treated in the same hospital, by the same surgeons, during the same period. Most costs included the materials, the time in the operating room, and in-hospital care. Our cost analysis showed mean costs of 13'585 ± 7690 Swiss francs (CHF) versus 19'138 ± 6225 CHF (P<0.027) for the endovascular and open treatment groups, respectively. In the endovascular

group, most costs were due to materials (5857 CHF). The open group had higher In-hospital care costs than the endovascular group (5698 versus 2590 CHF); this difference could be explained by the longer hospital stay after open surgery, and the need for wounds care. Furthermore, anesthesia and operating room costs were higher in the open group (1811 and 2790 CHF) than in the endovascular group (849 and 1292), probably because of the longer operating times in the bypass group. Details for in-hospital costs are reported [Table 4].

## Discussion and review of literature

Our study showed that ER was feasible, with acceptable primary (76.3%) and secondary (89.5%) patency rates at 12 months, compared to those reported in the literature<sup>1,19,40,51</sup>. At 5 years, PP was 68.4.1% and SP was 81.6%. We didn't assess the primary assisted patency in this study because only 1 event was due to a stenosis, all the others were occlusions, which would not be meaningful. The mean follow-up was 33 months, with a maximum of 90.4 months (7.5 years). DUS was performed systematically at 1, 3, 6, and 12 months, then once a year. Most postoperative events (83%) occurred within 12 months; all events during follow-up required revision, except one asymptomatic patient, who was treated conservatively. In our experience, but also demonstrated in literature, close surveillance is required, particularly during the first postoperative year because of most events occurring in the early follow-up<sup>46,48,52</sup>.

Many studies that compared endovascular with open surgery for PAA repair showed that endovascular technique was a potential alternative treatment, with satisfactory patencies and successful aneurysm exclusion; nevertheless, reintervention rates were higher compared to surgery<sup>2,53</sup>. Galinanes et al demonstrated a four-time risk increase of reintervention at 30 days postprocedure and a three-time risk increase at 90 days, mostly caused by short-term graft complications<sup>27</sup>. Our reintervention rate was 2.6% within 30 days after ER and 23.7% during follow-up, and most reinterventions were PTA and thrombolysis, thus minor procedures. Despite a higher reintervention rate than in open procedures, in selected patients, endovascular treatment seems justified due to minimal invasive reinterventions, as compared with higher morbidity rates reported with open surgery<sup>10</sup>.

Freedom from postoperative complications was 84.2% after 30 days. One patient presented ALI at 10 days postprocedure, which required a venous bypass. Amputation-free survival was 94.7% during follow-up. Two major amputations were required; one at 10 days postoperative due to an infection related to a patent stent-graft; and the second at 62 months, despite a lysis that was performed at 12 months, because of the reocclusion of the stent-graft. Most studies show no difference in terms of limb salvage between the endovascular and open techniques<sup>26,27,54</sup>, except Wrede et al, who showed a higher rate of limb loss at 1 year which was similar later during follow-up<sup>29</sup>.

Mortality was 11% during follow-up, assessed by the in-hospital mortality registry. Three deaths were related to cancer (esophagus, stomach and pancreas), and one to sepsis due to pneumonia. Patient's survival rates were significantly worse in patients with a previous myocardial infarction or history of cerebrovascular disease, as well as for patients with renal failure<sup>42,49</sup>.

In our cohort, the majority of PAAs (71.1%) were asymptomatic. Most of the patients were treated electively (94.7%). Elective treatment has been correlated with a better prognosis than emergency repair<sup>10,18,37,40</sup>. In fact, some authors showed that after endovascular emergency repairs, there were more major adverse events<sup>12</sup>, and that elective repair seemed to improve patency and limb salvage rate<sup>10,35</sup>. Limb salvage is worse for symptomatic PAAs (70-80%) compared to asymptomatic (> 90-95 %) at 5 years<sup>7</sup>. Aulivola et al reported that even if outcomes were not significantly different between emergent and elective repairs, ALI was associated with poor prognosis<sup>39</sup>. As a result, some authors do not recommend ER for PAAs with ALI, due to a 12% associated mortality<sup>35</sup>. In fact, acute presentation of PAA carries cardiac morbidity and consequently higher mortality; as a fact, they have prolonged intensive care unit and hospital stay<sup>7</sup>. Early elective repair is recommended because these patients had no surgical mortality (<1%), a low rate of complications and asymptomatic patients had a higher limb salvage rate<sup>7</sup>. In comparison, emergent repair has a mortality rate which ranges from 3-5%<sup>12</sup>.

Therefore, there is a general consensus that aggressive repair should be performed to prevent advanced presentations<sup>55</sup>.

The two ALI (Rutherford I) we observed at admission benefitted from preoperative thrombolysis, and repair procedures were delayed by 24-48 hours. Preoperative thrombolysis can improve runoff status by restoring it partially or completely, and reduce subsequent limb loss in cases of

ALI<sup>22</sup>. Nevertheless, even if it appears to improve results, the 8% early and 15% late amputation rates after ALI remain ominous<sup>7</sup>.

Moreover, open surgery should be preferred when runoff is altered, often related to acute thrombosis, which is associated with worse outcomes<sup>2,10,40</sup>. Similarly, ER should be weighted in critical limb ischemia; this can be explained by distal embolization which is common in critical limb ischemia and which will slowly occlude the distal arteries, affecting runoff and outcomes<sup>56</sup>. Garg et al observed that poor runoff was a predictor of graft occlusion when treated either with stenting or open repair<sup>20</sup>. Moreover, poor runoff is an independent factor for worse primary patency<sup>16,57</sup>. Diabetic patients are also known to have worse results and this is related to poor tibial vessel condition<sup>47</sup>.

In our study, at presentation, most patients had 3 patent crural vessels (60.5%). Only one patient had 1 patent vessel (5.3%), and he did not present with acute ischemia.

A Cochrane review by Joshi et al, up-dated in 2019, was unable to identify new studies helping in the decision-making of which treatment between endovascular and open surgery would be the best, as far as asymptomatic PAAs are concerned<sup>55,58</sup>. The conclusion remains the same since 2014, with a limited evidence in determining effectiveness of one or the other technique, suggesting that PP is better at 1 year in the open group, but becomes similar at 4 years, with a limb salvage rate of 100% in both groups.

The only randomized controlled study comparing endovascular and open surgery repair techniques for PAA, published in 2005, concluded that there was no significant difference between both treatments, but included only asymptomatic patients<sup>19</sup>.

According to some authors, emergency procedures should always favour open surgery<sup>38</sup>.

Most of our patients were older than 60 years. Currently, patients with high surgical risk, including patients that are older, obese, and/or have poor cardiorespiratory fitness, can be selected for ER, when the PAA anatomy is suitable<sup>18,19,30,44</sup>. Most patients had ASA scores of 2 (44.7%) and 3 (50.0%), which are correlated with moderate to high surgical risk<sup>12</sup>. Among electively repaired PAAs, the endovascular group population was older<sup>29</sup>. As a result, more COPD and congestive heart failure were observed in the endovascular group<sup>24</sup>.

Many studies showed more early complications with the open technique<sup>51</sup>. In fact, traditional cardiovascular risk factors such as smoking and ischemic heart disease are the most important

predictors of early graft failure and patient's death after open surgery<sup>42</sup>. Preoperative functional status and perioperative blood transfusions are predictive indicators of negative outcomes in the surgical management of PAAs<sup>8</sup>.

ER offers several advantages, because of its low invasiveness, with shorter intervention, hospitalization and recovery times<sup>19,26,29,59,60</sup>. In addition, fewer wound complications and minor blood loss have been reported with ER<sup>24</sup>. Nevertheless, reintervention and thrombosis rates at 30days are higher after ER, often without any consequence on mortality and limb loss<sup>26,27</sup>.

In our analysis, the mean operative time was 48 min, ranging from 19 to 190 min; this longer operative time could be explained by the fact that a contralateral PAA was treated with a bypass during the same operation. The mean hospitalization time was 6 days, ranging from 2 to 95 days. Three patients had long hospitalizations, due to medical complications and poor general condition, with a long waiting list for rehabilitation. Moreover, one patient developed ALI for a PAA in the contralateral leg, extending his hospital stay.

Smialkowski et al showed that all endovascular PAA repairs could be performed percutaneously with ultrasound<sup>59</sup>. This approach resulted in less blood loss, a lower infection risk, and faster recovery, compared to open surgery. In addition, with a percutaneous approach, we can perform our ER under local anesthesia, reducing risks related to general anesthesia<sup>61</sup>. In our study, one bleeding occurred at the puncture site, but was resolved with manual compression. According to some authors, ER would be the best choice for high surgical risk patients because of lower rate of peri and postprocedural complications<sup>61</sup>.

A 33-year experience with surgical management of PAA demonstrated excellent durability of open surgery in the long-term, with low rates of long-term complication. They conclude that the well-known shift toward endovascular treatment seems not to be justified<sup>62</sup>. The same conclusion was made for Wagenhauser et al; in their opinion, open surgery is still the gold-standard repair for PAA, with a limb salvage rate of 86.7% for symptomatic and 100% for asymptomatic PAAs. PP was 92.5% for asymptomatic and symptomatic patients<sup>63</sup>. As a result, endovascular approach should be strictly reserved for multimorbid patients.

Recent studies showed independent risk factors for bypass or stent-graft occlusions: in the open surgery group, occlusions were associated with prosthetic conduits and emergency procedures<sup>8,41</sup>;

in the endovascular group, it was associated with ALL, small size stent-graft (diameter) and/or arterial elongation<sup>48</sup>.

More authors confirmed these results, with factors known to influence patency rates after a bypass, like quality of outflow arteries, acute presentation, and type of material<sup>17,51</sup>. Poor runoff and acute presentation are also predictors of occlusion after endovascular repair<sup>17</sup>. In a retrospective study, the length of bypass was a risk factor for failure as well, especially when distal anastomosis is localized on the crural arteries<sup>45</sup>. It is a well-accepted fact that patency rates are lower with prosthetic grafts (29-74% at 5years), compared to saphenous vein grafts (77-100% at 5 years)<sup>7,22,30,39</sup>. Limb-loss seems also to be affected by prosthetic bypass, compared to venous<sup>41</sup>. As a fact, availability of GSV should always favour venous bypass over prosthetic. Venous autologous conduit offers long-term advantages and should be considered the first choice<sup>7,41</sup>.

Furthermore, a PTFE bypass showed worse outcomes than those achieved with stenting in some studies<sup>23,45</sup>. Endovascular treatment could be a better option than prosthetic bypass, in patients without any adequate vein, because of a much simpler procedure<sup>16</sup>. In fact, ER could be a good alternative, when no vein is available<sup>18,45</sup>.

According to Tielliu et al, in a prospective study from 2005, clopidogrel is the only significant predictor for success after endovascular treatment<sup>25</sup>. Many authors confirm the benefice of dual antiplatelet therapy after stenting, there is unfortunately no clear recommendation about how long it should be given. Most studies suggest a minimum of 4 weeks<sup>19,30</sup>; some other a maximum of 2 months, especially in elderly patients because of the risk of bleeding<sup>21</sup>. In our analysis, all patients had dual antiplatelet therapy after stenting for at least 3 months, or simple antiaggregation associated with previously prescribed anticoagulant.

Technical improvements in the design and constitution of endoprostheses have led to the development of flexible self-expanding covered stents like the Hemobahn or Viabahn, the last one being nowadays the favorite device for endovascular PAA repair<sup>64</sup>.

Some complications were related to flexion of the stentgraft in the knee joint. In fact, the mean weakness of PAA stent placement is that the constant flexion of the knee joint demands unique resistance and flexibility, in order to reduce the risk of stent fracture, migration or occlusion<sup>64</sup>. However, stent flexibility has improved with the development of new materials<sup>20,22,38,52</sup>. The Viabahn stent-graft evolved from the Hemobahn with a contoured instead of a straight proximal

edge, to prevent infolding in case of oversizing<sup>51</sup>. Moreover, the heparin-bonded surface appears to be less thrombogenic.

Some authors focused on morphological changes during flexion in patients undergoing PAA repair with Viabahn stent-grafts<sup>66</sup>. Repetitive flexion of the knee articulation induces vessel foreshortening and increases mean curvature and tortuosity of the femoropopliteal segment, both within and without the area of the stent-graft. These deformations can lead to kinking and compression of the endovascular device, contributing to thrombosis and fracture with consequent failure of endovascular treatment<sup>66</sup>.

Because of considerable rate of graft thrombosis with the Viabahn stent, as high as 7-20% in some reports, with conversion to surgery in up to 14% of cases, some authors highlighted the possibility to use different kind of stent-grafts, for example the Supera Stent® (Abbott Vascular, Illinois, USA), a wire-interwoven nitinol stent, which is designed for superior radial strength, flexibility and fracture resistance. They reported encouraging mid-term results, with no stent fracture or thrombosis, and freedom from sac enlargement of 100%, during a follow-up of 24 months<sup>64</sup>. The advantages of this device for PAA repair are collateral vessel patency and a 100% percutaneous access feasibility, due to reduced introducer sheath profiles, permitting local anesthesia.

Another study evaluated the Multilayer Flow Modulator® stent-graft (Cardiatis, Isnes, Belgium), in 25 PAAs, showing that it's a safe and feasible option in selected patients, with freedom of sac enlargement of 100%, of which 68% had aneurysmal sac shrinkage<sup>65</sup>. Limb salvage rate was 91% at 24 months<sup>65</sup>.

As already mentioned, deployment of a stent-graft across a joint undergoing constant flexion increases the risk for graft migration, occlusion or fracture<sup>11</sup>. As a result, anatomic suitability should be mandatory before endovascular approach: presence of adequate proximal and distal landing zones of more than 1.5-2cm, without excessive mismatch in diameter (less < 3mm)<sup>51</sup>, as commented by Golchehr et al, and presence of at least 2 patent runoff vessels<sup>17</sup>. Angulation inferior to 60 degrees and supra-popliteal localization of the aneurysm, are also predictors of technical success<sup>48</sup>. Moreover, ER in presence of calcifications or large introducer sheaths (with no possibility of using percutaneous closure systems for example) should in some situations be reconsidered<sup>59</sup>. According to many studies on PAA repair, anatomical considerations are very important when opting for the ER<sup>6,21</sup>. That's why feasibility of the endovascular approach should



be reserved for selected patients<sup>1,56</sup>. To conclude, anatomy should represent one of the mandatory decision-making points when choosing between endovascular and open treatment.

Hellwig et al evaluated the eligibility of ER for PAA according to the GORE instructions for use<sup>67</sup>; the anatomical criteria are at least one run-off patent vessel, landing zones proximally and distally of more than 2 cm, minimal mismatch in diameter between proximal and distal vessel segments, no overstenting of collateral vessels if not necessary and the absence of tortuosity leading to kinking. They conclude that more than one third of repairs were not eligible, which confirm that ER should remain a treatment option in selected patients only, based mostly on anatomical aspects.

Some studies showed that stent thrombosis was as high as 20% at 2 years<sup>20,49</sup>; other device-related complications included migration, kinking, endoleaks, and fracture. In the present study, two type I endoleaks were observed peri-operatively, and they were immediately treated by placing an additional stent-graft. According to literature, endoleaks seem to occur in about 0-20% after stenting<sup>30,46</sup>; types 1 and 3 need reintervention for relining with additional endografts<sup>18,38</sup>. Types 2 are mostly managed conservatively<sup>18</sup>. We did not report any stent fracture among our patients. Multiple stents were used in 44.7 %. According to the literature, the number of stents required varies between 1.6 and 2.1<sup>18</sup>. The higher the number of stent-grafts used, the more the risk for loss of patency<sup>13,50</sup>. Moreover, patients requiring long segment coverage (>20cm) may be at increased risk for failure<sup>46</sup>. Stent fracture seems to occur in about one third of PAAs treated by the endovascular approach as described by the team of Golcwehr et al, with a subsequent risk of thrombosis of 30%<sup>51</sup>. They had no reperfusion on limb loss. They mainly occurred at the overlap zones and were often associated with the young age of the patient (more active). We should avoid placing the end of an overlap zone in the bending zone of the knee (upper margin of the patella), because this can lead to stent fracture and eventually to occlusion of the stent-graft<sup>25</sup>. Landing zones should always be at least 2 cm<sup>11,20</sup>; some authors even recommended 3cm, as well for overlap zones, to overcome complications of migration<sup>50</sup>.

Aggressive graft oversizing (>3mm) can also cause thrombosis due to incomplete graft unfolding. It is recommended to oversize 10-15%, but not more<sup>6</sup>.

A lateral view of the stent should systematically be performed with the knee flexed at 90°, to confirm the correct graft position and the absence of kinking.

We compared the in-hospital costs between 11 and 15 age- and sex-matched patients treated with open and endovascular approaches, respectively, in our institution. The open revascularization group had less comorbidities than the endovascular group, and a majority was symptomatic at diagnosis (64%). We reported a mean total costs of 13'585 CHF for the endovascular group and 19'139 CHF for the open group ( $P < 0.027$ ). For the endovascular group, the major cost was related to the device (5857 CHF)<sup>23,27</sup>. This might be explained by the use of 2, and sometimes 3 stents for complete PAA exclusion. In comparison, in the open group, the major costs were related to in-hospital care (5698 CHF), presumably due to the prolonged hospital stay, the need for wound care, and the management of complications. In addition, costs related to anesthesia, operative room, intensive care and emergency units were higher in the open group, because of longer operating times, more invasive technique and peri-operative morbidity, as well as more symptomatic patients at admission.

In 2015, a retrospective study showed that ER was not cost-effective compared to open surgery; they concluded that only patients with high operative risk should receive endovascular treatment<sup>26</sup>. Similarly, some studies demonstrated an increase of endovascular procedures compared to open ones<sup>58</sup>, without any benefit in terms of mortality or costs, especially because of the greater reintervention rate after endovascular treatment<sup>12,27</sup>. Fanari et al compared endovascular and surgical revascularization of patients with peripheral occlusive arterial disease<sup>68</sup>. The cost of endovascular interventions was influenced by age, the presence of ischemic cardiopathy, female gender, and the presence of complications. Amputation was shown to be twice as expensive as limb salvage.

In fact, studies showed that PAA repair with endovascular treatment required shorter operation and hospital stay durations than with open revascularizations<sup>12,26</sup>, but the stent group had a higher reintervention rate<sup>27,28</sup>. As a fact, the initial cost savings of endovascular therapies (12'389 US dollars for the open surgery group versus 6739 for the endovascular group) were not sustained over time<sup>28</sup>.

Interestingly, a study analyzed the cost-effectiveness of elective endovascular AAA repair compared to open surgical<sup>69</sup>. They showed that endovascular aortic repair (EVAR) was less expensive than open surgery, with a reduced 30day mortality risk and a reduced length of hospital stay. The economic gain was lost at 2 years because of the higher reintervention rate in the endovascular group. Moreover, the costs of EVAR were highly dependent on the device used<sup>69</sup>.

In our study, ER was less expensive than open treatment in the peri-operative period. However, previous long-term cost analyses showed that, when the follow-up and reinterventions were included, stenting became less economically attractive<sup>23</sup>.

A large number of studies have evaluated the safety and feasibility of the endovascular procedure. Nevertheless, we lack evidence-based recommendations. Antonello et al published the first and only contemporary prospective randomized study, in 2005<sup>19</sup>. They concluded that PAAs could be safely treated with an endovascular approach in asymptomatic PAAs. No statistical difference was observed between open and endovascular asymptomatic repairs; PP rates at 12 months were 100% and 86%, respectively. The advantages of the endovascular approach were quicker recovery and less morbidity.

The first meta-analysis by Lovegrove et al in 2008, concluded that ER offers similar medium-term benefits as open repair, however short-term graft thrombosis and reintervention rates were significantly higher after endovascular treatment; it was difficult for the authors to justify ER<sup>53</sup>.

Patel et al performed a systematic review and meta-analysis in 2015<sup>18</sup>. They showed a 12-month primary and secondary patency rates of 85.3% and 90.8%, respectively, but they couldn't establish specific criteria for identifying patients that might benefit most from open or ER. Anatomic considerations should be respected in order to proceed with ER. Interestingly, they reported a continued sac expansion after surgery as high as 30%.

The actual major meta-analysis, including 4880 PAAs, reported that endovascular technique for selected patients with favorable anatomy had better outcomes<sup>17</sup>. They showed in their algorithm (**Figure 2**) that endovascular approach should be restricted to asymptomatic patients, with strict anatomical criteria, and high surgical risk, or when no vein is available<sup>17</sup>. Endovascular treatment seems to be safe, because most studies didn't show any difference in mortality and limb loss during follow-up<sup>17</sup>. Even so, open surgery seems to remain the gold standard, with excellent durability over time (76% at 5 years), and lower reintervention rates.

A retrospective study showed patency rates at 10 years (longest follow-up) with acceptable results for the endovascular technique<sup>51</sup>. There were less complications at 30 days postprocedure compared to the surgical approach. The reintervention rate was nevertheless higher (16% at more than 1 year), but mainly composed of thrombolysis or minor reinterventions<sup>51</sup>.

Currently, patients should be selected for endovascular treatment, on a case by case basis, favouring suitable anatomy and/or high surgical risk<sup>13,14,45,57</sup>. When no vein is available for bypass, endovascular treatment should be considered<sup>23</sup>.

The current surgical approach for PAAs remains the reverse saphenous vein bypass; it shows excellent patency rates<sup>24</sup> and a high limb salvage rate<sup>8</sup>. Cervin et al, one of the most recent and largest study, concluded that patency was better after open surgery, and that endovascular technique had more complications, with a 2.7-fold time more risk of any occlusion and 2.4-fold time more risk of a permanent occlusion, as well as more reinterventions, compared to open repair<sup>48</sup>. Moreover, operative mortality was low even in high risk patients. Thus, the potential benefit of a minimally invasive treatment for elderly or frail patients should be weighed against the increased risk of complication and reintervention in the endovascular group.

The same conclusions were made in a very recent meta-analysis<sup>54</sup> in 2020 showing that short-term thrombosis and reintervention rates are higher in the endovascular group; even so, ER is safe, with no repercussion in terms of survival or limb salvage. At 3 years the results are comparable as far as patency is concerned.

International collaboration of vascular registries, initially between 8 countries published in 2014<sup>33</sup>, more recently between 14 countries<sup>70</sup>, including data of 10764 PAA repairs, showed great variability in incidence, indications and choice of treatment regarding open or endovascular techniques, which emphasizes the lack of consent recommendations for treatment among different countries, regions or centers<sup>70</sup>. In many Institutions, open surgery remains the gold standard. Nevertheless, the endovascular approach, with its minimally invasive benefits, is attractive, even if its durability is still hardly questioned. The authors of this VASCUNET collaboration reported better patency in the open surgery group, regardless of the acute or emergent presentation, with similar amputation rate at 1 year, and advise to reconsider the use of the endovascular technique, as well as the use of prosthetic conduit in the open treatment, based on these results. However, endovascular approach in selected cases seemed to be associated with a lower frequency of wound complications, acute coronary events and renal failure at short term<sup>70</sup>.

It seems not possible to determine the best treatment for PAA repair because of the absence of evidence-based studies<sup>26</sup>. The low incidence of PAA treatment makes it hard to study, with difficulties in recruiting enough patients<sup>58</sup>; management remains controversial and differs between institutions and countries<sup>41,70</sup>. Even with some large and recent meta-analysis for PAA repair, the quality of studies is mostly low; there is lack of sufficient data, as well as limited statistical power, to draw reliable conclusions<sup>54,56</sup>. To date no study has been able to show any major difference between the 2 modalities. The overall literature is lacking in quality, and the need for well-controlled studies is critically important<sup>17</sup>.

With appropriate use, and in selected patients, endovascular treatment can challenge open repair, with comparable results, especially in terms of limb salvage and prevention of aneurysm growth in a less invasive approach. Nevertheless, there are several concerns about durability of this technique. Currently open surgery with GSV bypass will remain the gold standard for PAA repair<sup>45,48,70</sup>.

The present study has some limitations, including the retrospective design, the small sample size, and the absence of inclusion and exclusion criteria. Lost of follow-up and patient's non-compliance were also important limitation factors. The choice of endovascular treatment was made for patients with favorable anatomy and high medical history or comorbidities, without any strict criteria for open or endovascular therapy, with potential confounders between the 2 treatments.

## **Conclusion**

This study showed that endovascular repair of PAAs was a feasible option with acceptable short and long-term patency rates. The stent-graft provided successful aneurysm exclusion and offers several advantages because of its lower invasiveness. However, despite the low mortality and morbidity, stent-graft occlusion and reinterventions occurred frequently. Moreover, our cost analysis showed lower costs in the endovascular group compared to open surgery, during hospital stay; we didn't analyse the costs during follow-up, which would probably be increased because of the higher reintervention rate, as described in the different cost-analysis studies from the literature.

In our opinion, endovascular PAA treatment should be considered only in selected cases. It offers an adequate alternative, when no vein is available, when anatomy is favorable (landing zones proximally and distally of more than 1.5 cm and no excessive tortuosity), when runoff is sufficient (more than 2 patent distal vessels) and in elective conditions or in asymptomatic patients. It should be discussed for high surgical risk patients. Reinterventions are more frequent, but mostly less invasive than bypass and without significant consequences on limb loss or mortality. Advances in technology and careful patient selection will maybe improve results over time. Appropriate pre-operative stent sizing is necessary. Dual antiplatelet therapy should be given postprocedure for at least 1 month. Close surveillance, mainly during the first postoperative year, is mandatory, due to the high risk of occlusion during this period. More studies of quality are needed for identification of criteria for selecting patients who would be the best candidates for ER.

**Table 1. Demographic characteristics**

Variables	Endo N=38		Open N=11	
	N, Mean	(%), [Range]	N, Mean	(%), [Range]
Age (years)	74	[50-93]	74	[65-87]
Gender (male)	33	(91.7)	11	(100)
Hyperlipidemia	23	(60.5)	4	(36.4)
Hypertension	21	(55.3)	4	(36.4)
Smoking (current)	22	(57.9)	9	(81.8)
Cardiac diseases	22	(57.9)	5	(45.5)
Diabetes mellitus	10	(26.3)	1	(9.1)
COPD	9	(23.7)	4	(36.4)
Chronic kidney disease (GFR<60ml/min)	6	(15.8)	0	(0)
BMI (kg/m <sup>2</sup> )	26	[19-36]	23.5	[18.5-27.8]
ASA				
2	17	(44.7)	5	(45.5)
3	19	(50.0)	6	(54.5)
4	1	(2.6)	0	(0)
5	1	(2.6)	0	(0)
Aspirin	5	(13.2)	10	(90.9)
Aspirin and clopidogrel	33	(86.8)	0	(0)
Anticoagulation	5	(13.2)	5	(45.5)
Statin	27	(71.1)	9	(81.8)

*Cardiac diseases, coronaropathy, valvulopathy and heart failure; COPD, Chronic obstructive pulmonary disease; GFR, glomerular filtration rate; BMI, body mass index; ASA, American Society of Anesthesiologists*

**Table 2. Clinical data**

Variables	Endo N=38		Open N=11	
	N, Mean	(%), [Range]	N, Mean	(%), [Range]
Asymptomatic	27	(71.1)	4	(36.4)
Symptomatic	11	(28.9)	7	(63.6)
Intermittent claudication (IIb)	6	(54.5)	0	(0)
Chronical rest pain (III)	0	(0)	1	(9.1)
Osteomyelitis (IV)	0	(0)	1	(9.1)
Acute lower limb ischemia	2	(18.2)	3	(27.3)
Rutherford I	2	(18.2)	2	(18.2)
Rutherford IIa	0	(0)	1	(9.1)
Distal emboli	3	(27.3)	2	(18.2)
Parietal thrombus of PAA	35	(92.1)	11	(100)
Length of stay (days)	6	[2-95]	12	[7-20]
Runoff vessels				
I	2	(5.3)	4	(36.4)
II	13	(34.2)	2	(18.2)
III	23	(60.5)	5	(45.5)



**Table 3. Intraoperative data**

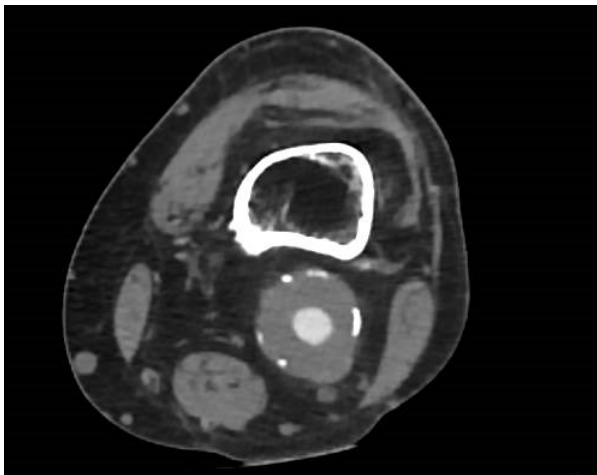
Variables	Endo N=38		Open N=11	
	N, Mean	(%), [Range]	N, Mean	(%), [Range]
Vascular access				
Open surgery	26	(68.4)	11	(100)
Percutaneous	12	(31.6)	NA	
Operating time (min)	48	[19-190]	138	[80-252]
Technical success	38	(100)	11	(100)
Number of stent-grafts				
1	21	(55.3)	NA	
2	16	(42.1)	NA	
3	1	(2.6)	NA	
Anesthesia				
General	24	(63.2)	9	(81.8)
Local/regional	14	(36.8)	2	(18.2)

*NA, not applicable*

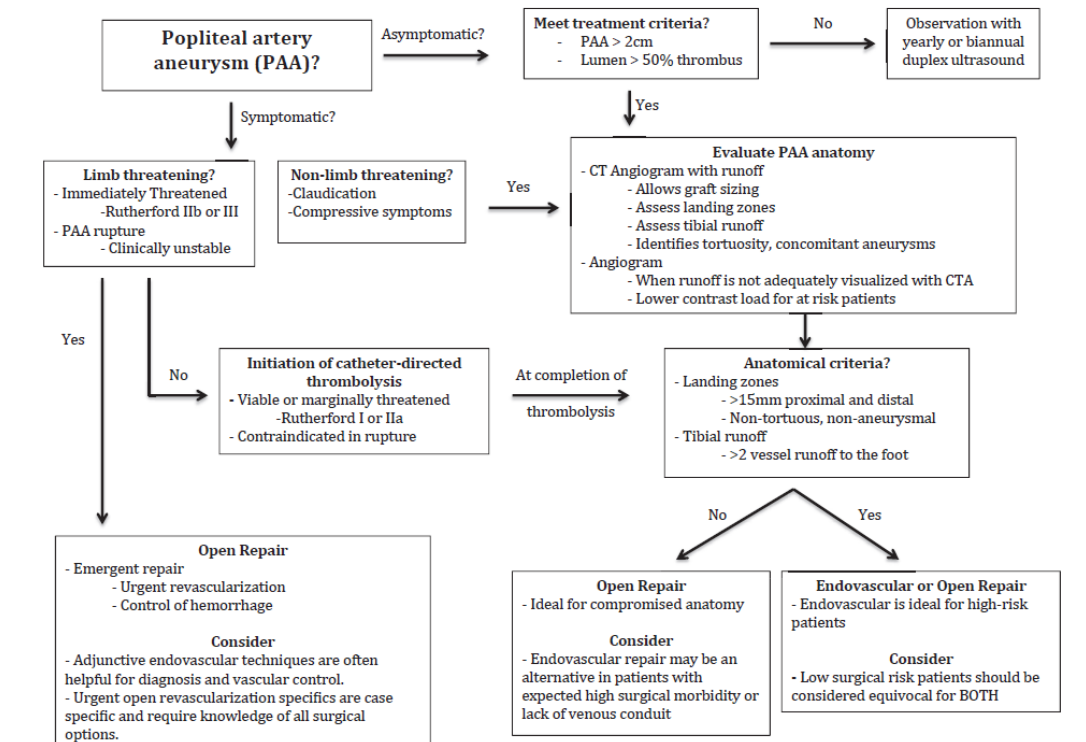
**Table 4. Costs**

<b>Variables</b>	<b>Endo N=15</b>	<b>Open N=11</b>
	<b>Mean (CHF)</b>	<b>Mean (CHF)</b>
In-hospital care (nurse staff)	2590	5698
Medical services (physician's clinical activity)	623	1784
Intensive care unit (staff)	120	1395
Emergency unit (staff)	-	109
Materials (devices)	5857	-
Medical materials (instruments, etc.)	529	633
Anesthesia (medical and nurse staff, medication)	849	1811
Operating room (operative nurse staff, all material used)	1292	2790
Accommodation (facilities, room and cleaning)	128	587
Catering	231	809
Administrative management (Admission, coding, invoicing, archiving)	329	383
Medication	213	729
Imaging (medical staff)	128	444
Laboratory	140	389
Physiotherapy	38	219

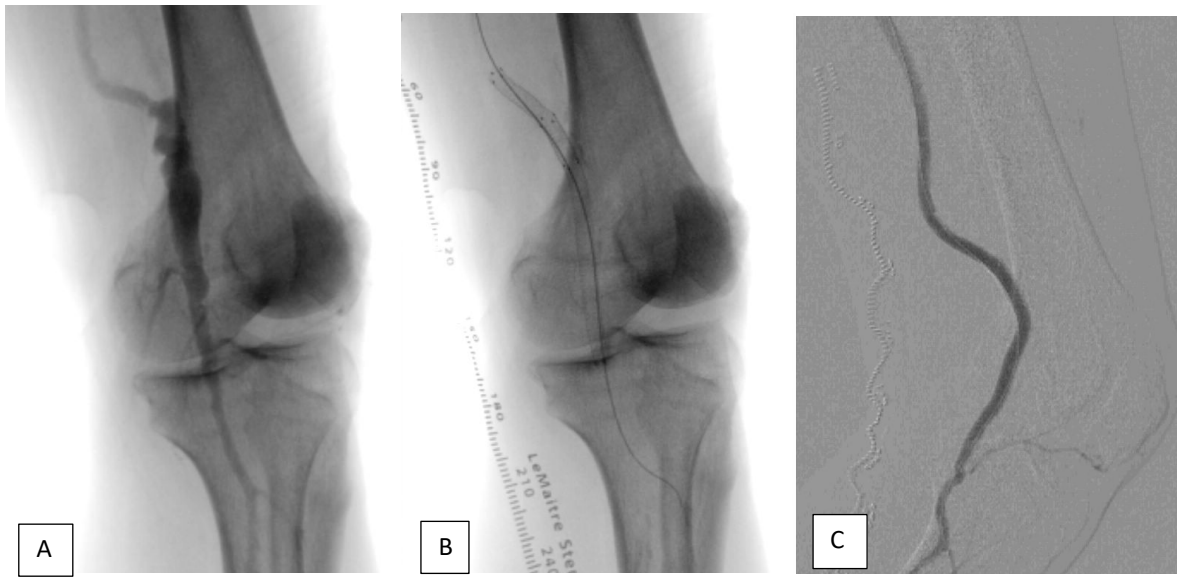
*CHF, Swiss francs*



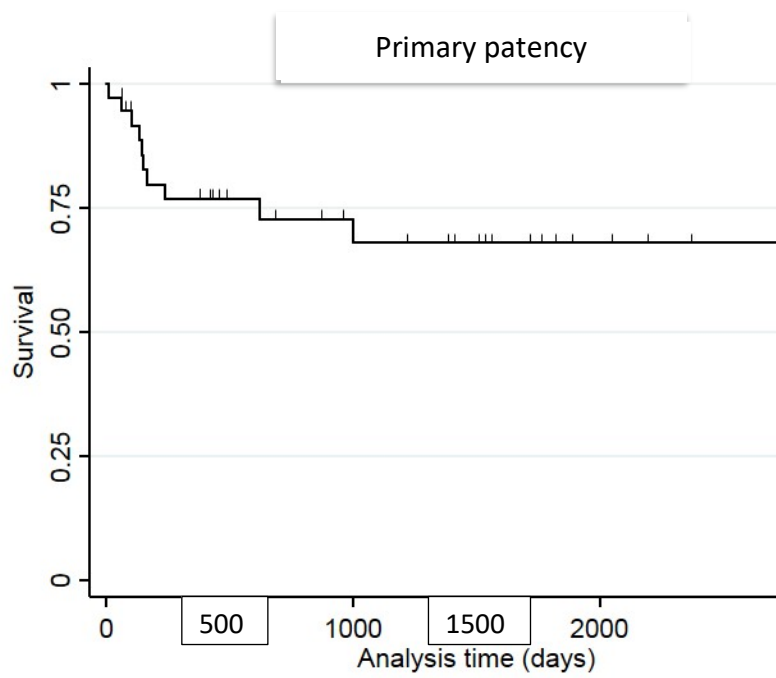
**Figure 1. Preoperative computed tomography scan : a popliteal artery aneurysm of 3.5cm of diameter with mural thrombus (Centre Hospitalier Universitaire Vaudois).**



**Figure 2. Popliteal artery aneurysm treatment algorithm by Leake et al, J Vasc Surg, 2017.**

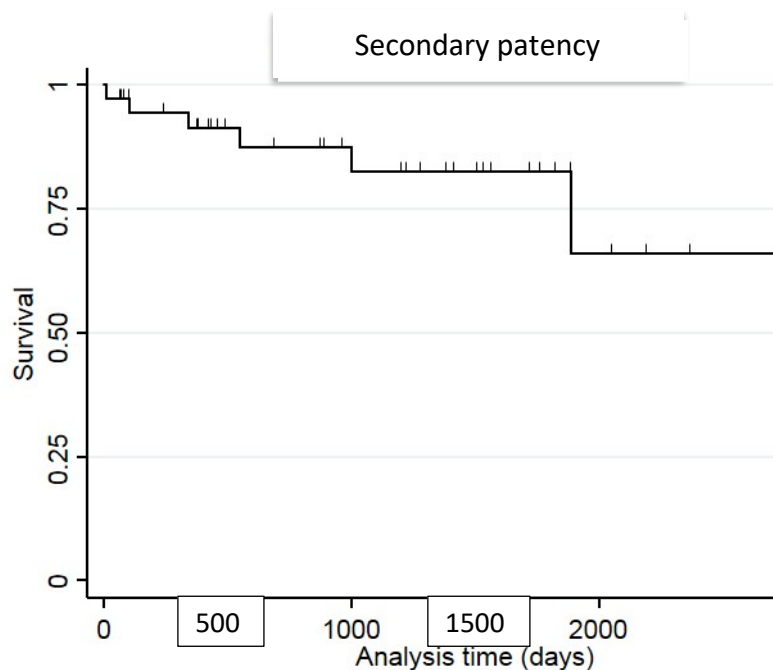


**Figure 3. Endovascular repair:** intraoperative angiogram showing the popliteal artery aneurysm (A), followed by insertion of a 6mm and 7mm Viabahn stents in the distal and proximal aspects of the aneurysm, respectively (B). Control angiography after stent placement in flexion of the knee joint (C) (Centre Hospitalier Universitaire Vaudois).



Number at risk	38	21	14	12	7
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**Figure 4. Primary patency.** Kaplan-Meier analysis shows the cumulative primary patency rate after endovascular popliteal aneurysm repair.



Number at risk	38	25	16	14	8
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**Figure 5. Secondary patency.** Kaplan-Meier analysis shows the cumulative secondary patency rate after endovascular popliteal aneurysm repair.

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