



ORIGINAL ARTICLE / *Interventional imaging*

# Safety of elective percutaneous peripheral revascularization in outpatients: A 10-year single-center experience



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## KEYWORDS

Percutaneous angioplasty;  
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## Abstract

**Purpose:** To evaluate the safety and feasibility of peripheral percutaneous endovascular procedures in a large group of outpatients with peripheral arterial disease (PAD).

**Materials and methods:** We retrospectively evaluated all consecutive patients who underwent peripheral transluminal angioplasty (PTA) for PAD of the lower extremities as "Out-Patient Admission Protocol" (OPAP) from January 2005 until December 2015. A total of 498 consecutive patients (305 men and 193 women) with mean age of  $66 \pm 10$  (SD) years (range: 37–90 years) were evaluated. By protocol, patients were expected to be discharged 6 hours after the procedure. Clinical profile, procedure details and technical success were reviewed. Complications, conversion rate, readmission rate and long-term follow-up were evaluated.

**Results:** Ninety one percent of patients (454/498) suffered from claudication. Unilateral femoral access was performed in 75.4% (493/654) of procedures with a 6-French sheath in 80.7% (528/654) of procedures. Balloon PTA alone was performed in 17.3% (148/857) and stent placement in 82.7% (709/857) of treated segments. Technical success of lesion treatment was 98.2% (857/873). Closure devices were used in 55.4% (362/654) of procedures. Conversion and readmission rates were 1.8% (12/654) and 0.6% (4/654), respectively. Long-term follow-up was obtained in 386 target lesions, 5-year restenosis of lesion was 20.5% (79/386).

**Conclusion:** As designed, the OPAP was feasible, safe and effective with very low conversion and complications rates. These results strongly support a larger use of such approaches as routine practice.

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The aging population, along with increased cardiovascular risk factors has led to an increase in the incidence of peripheral vascular diseases and subsequently, an increased need for therapeutic procedures [1,2]. After excluding patients with cerebral and coronary disease, patients with peripheral arterial disease (PAD) constitute the majority of the referred population for treatment, with a worldwide estimation of PAD patients greater than 200 million people [3]. It is well known that most patients with PAD commonly present concomitant risk factors and comorbidities that are associated with an increased post-procedural risk of morbidity and mortality [2]. This justifies the current initiative to develop less invasive options in order to reduce patient discomfort and complications.

Several studies have attempted to demonstrate the feasibility and efficacy of peripheral transluminal angioplasty (PTA) in outpatient population without compromising clinical outcomes [4–7]. Despite promising results, most of these studies are limited by relatively small cohorts, the bias of highly selected patients with no predefined protocol for outpatients and a short follow-up period. Additionally, the absence of applying a unified classification for complications has led to dispersion in the definition of complications, especially in defining the major and minor complications in the published reports [5,8,9].

The goal of this study was to evaluate the safety and feasibility of PTA in a large group of outpatients with PAD.

## Material and methods

### Patient selection

Patients included in this study were extracted from an institutional registry of patients who have been treated in the Department of Radiology of our institution from January 2005 to December 2015. All patients with PAD of the lower limbs, aged from 30 to 90 years, admitted as an outpatient were included in this study. The institutional protocol for "Out-patient Admission" (OPAP) includes the following criteria:

- patient with preserved mental status;
- patient living no more than 30 minutes away from a hospital;
- patient being accompanied by a suitable adult after and during the first night post-procedure.

Patients with uncontrolled hypertension, poorly controlled insulin-dependent diabetes or heart failure, severe renal insufficiency (estimated glomerular filtration rate <30 mL/min) and known history of allergic reaction to contrast agent, patients with platelets count less than  $75 \times 10^9/L$ , and patients with international normalized ratio  $\geq 1.5$  were not included in the institutional protocol for OPAP. Patients with PAD of upper extremities, venous diseases, arteriovenous shunts, aneurysmal diseases and those with visceral arterial diseases were excluded from the present study. All patients gave informed consent for the procedure. The study protocol was approved by our institutional ethics committee.

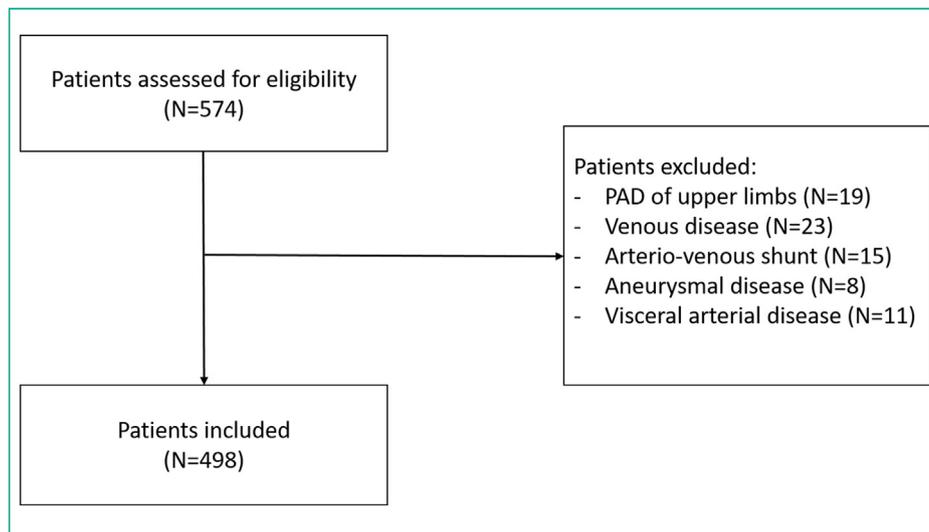
### Procedure description

The typical workup flow consisted on a clinical visit with an interventional radiologist at least 1 week before the procedure. Pre-therapy imaging assessment was reviewed and the patient was informed about the procedure details and inclusion in the OPAP. Patient was admitted at least one hour before the procedure in the Short Stay Unit (SSU) that is part of the Department of Radiology, equipped with trained registered nurses covering 7 AM to 8 PM period.

All procedures were performed by interventional radiologists or by fellows under close supervision. A percutaneous vascular access was done under local anesthesia. Selection of vascular introducers was usually driven by materials intended to be used. Balloon angioplasty characteristics and stents selection depended on the target lesions and were at the discretion of the operator. By protocol, anticoagulant therapies were interrupted before the initiation of all procedures and all patients were under antiplatelet therapy at the time of the procedure. During each procedure an initial injection of 2500 IU heparin with an additional dose of 1000 IU per hour was given. After the procedure, the hemostasis was achieved by manual compression (at least 10 minutes) of the puncture site or with a closure device, as the discretion of the operator. Different types of closure device were used including Exoseal<sup>®</sup> (Cordis Corporation), Celt ACD<sup>®</sup> (Vasorum), Starclose<sup>®</sup> (Abbott Vascular) and Angioseal<sup>®</sup> (St. Jude Medical). No mechanical compressions other than manual were used. Following the procedure, patient was closely observed (in a supine position) for a minimum of 4 hours in the SSU, where vital signs and puncture site were regularly checked. Before mobilization and discharge, patient underwent duplex ultrasound examination to evaluate the effects of revascularization and search for potential puncture site complication. Patient was discharged when he had no complaints. The typical treatment at discharge combined aspirin and clopidogrel for 3 months. Patient was informed to stay at home with a responsible person for the first night, limiting physical activities for the first 24 hours and minimizing physical activities for the following 48 hours. At discharge patient was provided a contact number of an on-call interventional radiologist and was instructed to immediately manage puncture site bleeding by manual compression.

### Data analysis

Medical files were reviewed for patient's demographics and cardiovascular risk factors. Previous history of cerebrovascular events, coronary events and renal insufficiency were considered. Indications of treatment for PAD were classified using the Fontaine classification. The target lesion anatomic level (aorto-iliac, femoropopliteal and infrapopliteal) and the type of the lesion (stenosis or occlusion), site of puncture, size of vascular introducers and the type of treatment (PTA and/or stent) were documented. Complications detected during the procedure and puncture site or systemic complications detected during the 6 hours observation period at the SSU were noted and further classified on major and minor, based on the CIRSE classification of complications from 1 to 6 according to CIRSE classification.



**Figure 1.** Flow diagram shows patient selection and exclusion criteria. PAD: peripheral arterial disease.

Minor complications include grade 1 and 2, which correspond to complications that could be resolved without further treatment/observation or with prolonged observation but no additional therapy, respectively. Major complications comprise grades 3, 4, 5 and 6, ranging from additional post-procedure therapy to death [10]. The puncture site complications occurred after manual compression and closure device were separately calculated and the results were compared to demonstrate if the closure device use is accompanied by reduced number of puncture site complication.

Technical success rate was calculated based on successful revascularization observed at the end of the procedure. Protocol success rate was calculated based on procedures that had been fully accomplished as OPAP. Conversion rate was defined as the percentage of patients included in the study and in whom it was necessary to convert their stay from the SSU to the standard hospital stay. Readmission rate was calculated as the percentage of patients discharged as OPAP and readmitted to the hospital in the 10-days following the procedure.

Quantitative variables were expressed as mean  $\pm$  standard deviation (SD) and ranges. Qualitative variables were expressed as raw numbers, proportions and percentages. Chi<sup>2</sup> test was used to search for differences between groups. A *P*-value < 0.05 was considered to indicate significance.

## Results

### Patients and lesion distribution

Of the 574 originally retrieved patients, 76 were excluded and 498 patients were ultimately included (Fig. 1). There were 305 men and 193 women, with a mean age of mean  $66 \pm 10$  (SD) years (range: 37–90 years). The most frequent associated risk factor was hypertension (276/498 patients; 55.4%) and the most frequent associated vascular comorbidity was coronary disease (95/498 patients; 19.1%). Clinical

**Table 1** Characteristics of 498 patients who underwent peripheral transluminal angioplasty for peripheral arterial disease.

Variables	n (%)
<i>Gender</i>	
Male	305/498 (61.2)
Female	193/498 (38.8)
<i>Hypertension</i>	276/498 (55.4)
<i>Hyperlipidemia</i>	244/498 (48.9)
<i>Smoking habitus</i>	225/498 (45.2)
<i>Diabetes mellitus</i>	102/498 (20.4)
<i>Obesity (Body mass index &gt; 30)</i>	41/498 (8.2)
<i>Coronary disease</i>	95/498 (19.1)
<i>Cerebrovascular disease</i>	14/498 (2.8)
<i>Renovascular disease</i>	7/498 (1.4)
<i>Symptoms</i>	
Fontaine I	6/498 (1.2)
Fontaine II	448/498 (90.0)
Fontaine III	27/498 (5.4)
Fontaine IV	17/498 (3.4)
<i>Target lesions</i>	
Aorto-iliac	473/873 (54.2)
Femoropopliteal	388/873 (44.4)
Infrapopliteal	12/873 (1.4)
<i>Antiplatelet therapy</i>	498/498 (100)

indication for revascularization was claudication (454/498 patients; 91.2%) and critical limb ischemia (44/498 patients; 8.8%). Patients' demographic is summarized in Table 1.

A total of 654 procedures were performed in 498 patients to treat 873 target lesions that included 654 de novo stenoses (74.9%), 67 in stent stenoses (7.7%), 142 de novo occlusions (16.3%) and ten stent occlusions (1.1%). Three hundred ninety-eight patients (398/498; 79.9%) underwent one procedure. Lesions were predominantly aorto-iliac lesions (473/873; 54.2%).

## Procedure details

All procedures were done under local anesthesia. In 81% of procedures (529/654) vascular success was obtained through the common femoral artery and in 11.7% of procedures (77/654) bilateral vascular access was performed. A 6-F sheath was used in 80.7% of procedures (528/654) and a 5F sheath in 7.9% of procedures (52/654). Closure device was used in 55.3% of procedures (362/654), with a success rate of 99.2% (359/362). In 40.5% of procedures (265/654) the hemostasis of puncture site was achieved by manual compression.

Percutaneous angioplasty alone was performed in 17.3% of target lesions (148/857) while 82.7% (709/857) had stent placement. In 1.8% (16/873) PTA failed. Thus, the technical success rate was 98.2%. In the majority of procedures (72.5%, 474/654) one level lesion was treated. Multilevel treatment was performed in 27.5% of procedures (180/654). In 19% of procedures (124/654) both limbs were treated.

As described before, the protocol success was evaluated based on a successful OPAP. The protocol success rate was 98.2% (642/654) of procedures with unexpected conversion in 12 patients (conversion rate of 1.8%). The majority of the converted procedures (8/12) were due to major complications, 3 patients due to minor complications, and one patient for a medical problem unrelated to the procedure.

## Perprocedural complications

Ten complications (1.5%, 10/654), including 6 major (0.9%) and 4 minor (0.6%) complications, were observed in 10 patients during the 654 procedures. Major complications consisted of four inadvertent intraprocedural distal embolizations and two iatrogenic non-targeted vessel flow-limiting dissections of iliac arteries. Minor complications included one focal dissection of the target lesion, two stent fractures and one hemorrhage from anterior tibial artery.

## Post-procedural complications

Seventeen complications (2.6%, 17/654) including 8 major (1.2%, 8/654) and 9 minor (1.3%, 9/654), were observed in 17 patients in the 6 hours of observational time. Complications included ten puncture site related complications (4 major and 6 minor complications), two patients with active hemorrhage of the psoas muscle (major complication), two patients who suffered from vagal reflex (minor complication group I), one patient who had retroperitoneal hemorrhage with no active bleeding (major complication), one patient with femoral artery occlusion (puncture site) detected post-procedure (major complication) and one patient with abdominal wall hematoma (minor complication group II).

Regarding puncture site complication (pseudoaneurysm and hematoma) four major and six minor complications were observed. No closure device was used in all major complications. Three closure devices were used in the six minor complications observed. In total, the incidence of puncture site complication associated with closure device was 0.8% (3/362) compared to 2.6% (7/265) with manual compression per procedure ( $P=0.07$ ). Concerning the size of the sheath, all but 3 complications (24/27; 88.9%) occurred

**Table 2** Characteristics of procedures in 498 patients who underwent peripheral transluminal angioplasty for peripheral arterial disease.

Variables	n (%)
<i>Balloon angioplasty alone</i>	148/857 (17.3)
<i>Stenting procedures</i>	709/857 (82.7)
<i>Sheath size</i>	
4F	12/654 (1.8)
5F	52/654 (7.9)
6-F	528/654 (80.7)
7F	21/654 (3.2)
8-F	2/654 (0.3)
<i>Puncture site hemostasis</i>	
Closure device	362/654 (55.3)
Manual compression	265/654 (40.5)
<i>Complication<sup>a</sup></i>	
Major	14/654 (2.1)
Minor	13/654 (2.0)
<i>Conversion rate</i>	12/654 (1.8)
<i>Readmission rate following 10 days</i>	4/654 (0.6)

<sup>a</sup> Complications include per procedure complications and complications occurring during the six hours following procedure.

with the 6-F sheath and three complications (unrelated to puncture site) occurred using the 5F and 7F sheaths. Among patient who had bilateral groin puncture, only one complication (1/27) was observed (vagal malaise). Among the 27 patients with complication, 70.4% (19/27) had one lesion treatment per procedure while seven and one patients underwent two and three target lesions treatment, respectively.

Four patients were readmitted in the 10-days period following discharge (0.6%, 4/654 of the whole procedures). One patient was hospitalized during the week after the procedure because of acute ischemia of the other side lower limb. The second patient on the day 8 post-procedure consulted the emergency department for an inguinal hematoma managed by conservative measures. One patient consulted on the day 2 post-procedure for groin hematoma due to arteriovenous fistula that required surgical repair that was classified as major complication. The last patient consulted on the day 7 post-procedure for groin hematoma due to arteriovenous fistula that was thrombosed by manual compression. Characteristics of procedures are summarized in [Table 2](#).

## Follow-up

Three-, six- and twelve-month follow-up was available for 566, 522 and 494 target lesions in 337, 300 and 285 patients, respectively. Two patients died within twelve-month follow-up. At 3-, 6- and 12-month follow-up, 4, 10 and 54 restenosis were detected which among them 0, 6 and 50 patients benefited from revascularization, respectively. The long-term follow-up could be documented for 386 target lesions with a follow-up ranging from 12 to 164 months while no follow-up data could be collected for 247 patients. Also, 20 patients

died during this period. In long-term follow-up, 79 restenosis were detected which 67 of them benefited from revascularization. The 5-year restenosis rate was 20.5% (79/386 lesions).

## Discussion

The present study demonstrates the safety, feasibility and efficacy of endovascular procedures in patients with disabling lower limb PAD as outpatient without compromising the clinical outcomes. Traditionally, patients undergoing PTA and/or stenting for chronic lower extremity PAD were hospitalized for overnight observations to prevent an eventual complication which could compromise desired outcomes. While numerous large studies regarding outpatient percutaneous coronary intervention demonstrated the safety and feasibility of this method [11–13], the large studies in the field of interventional radiology are less pronounced. Although different studies have attempted to demonstrate the feasibility and safety of outpatient percutaneous revascularization in patients with PAD [7,9,14–17], the majority of studies have been focused on highly selected patients such as excluding the patients with critical limb ischemia or previous lower limb vascular surgery. However, what was revealed was that in almost every situation, complications occur during the procedure or during the 6 hours observation period, and therefore the outpatient approach will not alter the outcomes [8,9,16,18]. In addition, a high patient satisfaction rate of PTA in outpatients was also reported [6]. The routine protocol for lower limb PTA and/or stent placement in our hospital since 2005, based on institutional experience, was mainly an outpatient protocol. All patients aged between 30 and 90 years, regarding less the past history of lower limb vascular operation, lesion severity as revealed by angiography, and technical difficulty, under the appropriate medical condition, are routinely included in this protocol.

Today, owing to technical progress, a dramatic increase in technical success and a striking reduction of procedure complications rate has been achieved. In our study, on a lesion basis, a technical success rate of 98.2% (857/873) was observed, similar to those of other researchers [19,20] and greater to the 82% reported by Mesbahoskui et al. [21]. Because of heterogeneity in reporting complications in prior studies, our study was based on the CIRSE complication classification. According to this classification, 14 major and 13 minor complications were reported with an overall rate of complications of 4.1%, similar to those of other studies [16,17,19]. The conversion rate reported by different studies shows a large range from 0 to 20% [6,14,22]. In the present study, outpatient protocol could be accomplished in 98.2% of procedures. Although, previous literature demonstrated the safety of percutaneous revascularization in hospitalized patients with critical limb ischemia [23–25], the majority of studies dealing with outpatient protocol excluded this group of patients. Considering that the study population was comprised of all patients with lower limb arterial disease, including patients with critical limb ischemia (8.8%), our results confirm the feasibility of the

OPAP regarding the severity of arterial disease. In our study, the readmission rate during 10 days post-procedure was 0.6% (4/654) consistent with those of other reports [16,20].

While bilateral groin puncture is believed to be associated with a greater incidence of puncture site related complications, it was performed in 11.7% of procedures with no puncture site complication. Of interest, a 6-F introducer sheath was used in the majority of the procedures (80.7%) and associated with 24/27 complications (88.9%). Complications were not observed in procedures performed with 8-F introducer sheath but the 8-F introducer was used in only two procedures. Although previous studies reported a lower complication rate associated with closure device when compared to manual compression, particularly with Angio- [20,26–31], the results of present study are not consistent with previous reports. Our findings are supported by recent results reported by Spiliopolous et al. who reported a non-significant difference between complications related to manual compression and closure device [19]. Furthermore, as recently reported by Shukla et al. ultrasound-guided femoral low angle arterial access technique followed by 10 minutes manual compression and ambulation after 2 hours seems to be a safe approach to prevent puncture site related complications [32].

Although the goal of this study was to demonstrate the feasibility and safety of OPAP, data regarding 5-year follow-up could be obtained. We found that most restenosis/reocclusion happened during the first year following the procedure, indicating that recurrence rate decreases with time.

In addition to technical advantages observed with endovascular treatment of PAD on outpatient basis, OPAP appears cost-effective by comparison with the traditional surgical or endovascular inpatient admission [20,33]. OPAP is associated with higher turnover of hospital beds, decrease in patients' charges and reduce the time to return back to normal activity for the patient. Taken together, this procedure can lead to a reduction in financial burden imposed on the patient and society. Furthermore, the satisfactory enquiry provided by previous studies demonstrates a high patient's satisfaction rate [6,22].

This study has two limitations. Firstly, the retrospective review of patient's history, which can alter the patients demographic and procedure related information's as well as collecting the follow-up data, especially to obtain a full long-term follow-up. However, the primary objective was rather to evaluate the feasibility and safety of the OPAP than long-term treatment outcome. The second limitations relates to the long period of inclusion with the use of different techniques and technologies over the last decades even all procedures were done by the same team. However, the population included in this study was selected based on the OPAP criteria and is not representative of the general population.

In conclusion, the present study strongly supports the safety and feasibility of OPAP for PTA in patients with PAD regardless to the severity and complexity of arterial lesions. The proposed protocol is effective with very low conversion and complication rates, encouraging a wide use of such protocol in routine practice.

## Disclosure of interest

The authors declare that they have no competing interest.

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