Feasibility and outcome of endovascular management of atherosclerotic chronic total occlusion of the popliteal artery

Original Article

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ABSTRACT

Background: Endovascular interventions are well-established for treating femoropopliteal diseases. However, there is still a lack of data for isolated popliteal artery diseases.

Aim: We aim to evaluate the safety, efficacy, and midterm patency of endovascular intervention for isolated popliteal artery disorders.

Patients and Methods: This is a prospective nonrandomized cohort study on 23 patients presenting with critical limb ischemia and subjected to revascularization at the Vascular and Endovascular Surgery Department, Kasr Elainy Hospital, Nile Health Insurance Hospital, from November 2020 to November 2022.

Results: The disease involved the popliteal artery only in five (21.7%) patients. The popliteal disease was associated with infrapopliteal disease in 18 (78.3%) patients. The P1 segment was involved in eight (34.7%) patients, the P2 segment in 16 (69.5%) patients, and the P3 segment in 14 (60.8%) patients. Technical success was 100%. Lesion crossing was done intraluminally in 18 (78.3%) cases, while subintimal angioplasty was done in five (21.7%) cases. Subintimal angioplasty had a lower primary patency than intraluminal crossing (*P=0.007*). The lesion length ranged from 2 to 14 cm (mean 7.59±6.4). Longer lesions (≥5 cm) were associated with lower primary patency than shorter lesions (≤4.9 cm) (*P=0.048*). No mortality occurred during or within 30 days of the procedure. The limb salvage rate was 93.5% during the study period. Restenosis of the target lesion occurred in five patients after 6 months. The primary patency rate was 91.5% at 1 month, 86.9% at 3 months, and 82.1% at 6 months.

Conclusion: Endovascular intervention for popliteal artery disease in critical limb ischemia patients is a safe and effective procedure that has good short-term results regarding technical success, patency, and limb salvage rates.

Key Words: Angioplasty, atherosclerosis, critical limb ischemia, endovascular intervention, popliteal artery disease.

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INTRODUCTION

The popliteal artery is the continuation of the superficial femoral artery as it exits Hunter's canal in the distal medial thigh. It travels behind the knee and divides into the anterior tibial artery and tibioperoneal trunk, which subsequently divides into the peroneal artery and posterior tibial artery (together, the so-called trifurcation)[1].

Atherosclerosis is found to be the most important factor causing worldwide morbidity and mortality and the leading cause of popliteal artery occlusion or stenosis[2].

The pathogenesis of atherosclerosis is well-established. Excessive release of cellular mediators occurs due to endothelial damage, leading to fibrotic plaque formation, with subsequent calcification, ulceration, fracture, or hemorrhage causing limitation of blood flow[3]. Smoking, old age, diabetes, hyperlipidemia, male sex, hypertension, and positive family history are all significant risk factors for atherosclerosis[4].

According to the severity and the progress of the disease, there are a wide range of clinical manifestations. Intermittent claudications can occur more in cases with a single-level disease, while a multilevel disease can be manifested with worse ischemic presentations such as rest pain and tissue loss[5].

In cases with popliteal diseases manifested by claudication pain and critical limb ischemia, endovascular interventions have been widely used, and many places recognize endovascular interventions as the first-line method for complicated cases as in cases of complete femoropopliteal chronic occlusions[6].

Endovascular intervention have shown good results for femoropopliteal lesions; however, there is still a lack

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of data in cases with isolated obstructive popliteal artery disorders. The popliteal artery is known for its special characteristics, making it remarkably different from the superficial femoral artery, as it shows marked mobility between its fixed proximal and distal ends, and it is under continuous biomechanical power due to the movement of the knee joint. Therefore, the popliteal artery is traditionally considered a no-stent zone[1].

The novel interwoven nitinol (Supera Tm, Peripheral Stent System, Abbot vascular) stent has been shown to enhance strength, flexibility, and fracture and kink resistance, and it conforms well to the femoropopliteal arteries with joint movements[7].

So, this study aims to assess the safety, efficacy, and midterm patency of the endovascular method for obstructive popliteal artery disorders.

PATIENTS AND METHODS:

Study design

This is a prospective nonrandomized study that was done on a cohort of 23 patients presenting with critical limb ischemia and subjected to revascularization at the Vascular and Endovascular Surgery Department, Kasr Elainy Hospital, Nile Health Insurance Hospital, from November 2020 to November 2022.

Inclusion criteria

Patients presenting with rest pain or tissue loss (gangrene, ulcer) due to chronic atherosclerotic popliteal artery occlusion with or without infrapopliteal disease.

Exclusion criteria

(1) Patients with acutely thrombosed popliteal artery.

(2) Patients with thrombosed popliteal artery aneurysm.

(3) Patients with popliteal entrapment syndrome.

(4) Patients with cystic adventitial disease.

(5) Patients with impaired renal function.

(6) Children, pregnant women, and mentally disabled patients.

(7) Arteritis, autoimmune, and thrombo-angitis obliterans.

Consent:

A detailed explanation of the procedure, its indications, methods, risks, and outcomes were given to the patient to obtain his informed consent for the procedure.

Methodology in details

All patients were subjected to the following protocol:

(1) Preprocedural work up:

(a) Full history taking:

(i) Personal history: it included age, sex, and smoking habits.

(ii) Present history: this included:

(1) Symptomatology of the patients: rest pain or presence of ulcer or gangrene including onset, course, and duration of the lesion.

(b) Complete general and local examination:

(i) General examination: an examination was done to assess the vital signs and the cardiological status.

(ii) Local examination: meticulous assessment of both lower limbs. Pulse examination was done to document the location and quality of the pulses on both sides.

(iii) Examination of the ulcers, gangrenes, and spread of infections were noted. All patients were classified using the Rutherford classification, Fountaine classification, SVS – wound, ischemia, and foot infection (WIFI) classification regarding the wound status, degree of ischemia, and the presence of infection. Global Limb Anatomic Staging System (GLASS) stage was determined for each patient according to his femoropopliteal and infrapopliteal grades.

(c) Investigations:

(i) Routine laboratory investigations.

(ii) ECG (to detect any cardiac problems such as rhythm abnormalities).

(iii) Ankle–brachial pressure index (ABPI) measurement.

(iv) Imaging:

(1) Duplex scanning.

(2) Plain radiograph foot (if there is ulcer or osteomyelitis).

(3) Chest radiograph: it was performed to evaluate the general condition of the patients, especially smokers and those with hypertension and cardiac troubles.

(4) Echocardiography: it was done to evaluate cardiac patients regarding the ejection fraction.

Angiography:

Computed tomographic angiography was done to detect:

(5) The condition of the proximal arterial tree.

(6) The site of the lesion.

(7) Character of the lesion, length, calcifications.

(8) Distal run-off.

(2) Procedural technique:

Medications

Contrast materials

The contrast media was Ultravist (Iopromide), which is a nonionic low-osmolar contrast material.

Other drugs used

(1) Xylocaine 2% was used for infiltration as a local anesthetic at the puncture site.

(2) Saline 0.9%/heparin (500 ml saline+5000 IU heparin) was used to flush the sheath, catheters, and balloons all through the procedure.

(3) Intravenous heparin to prevent thrombosis just after sheath insertion (5000 U).

Steps of the endovascular procedure

Positioning

All the patients were operated in the supine position. Preparation and sterilization of site of access with povidone–iodine 10%.

Anesthesia

All cases were performed under local infiltration anesthesia (10 ml of xylocaine 2% at the puncture site) with continuous monitoring of the patient's vital data during the steps of the procedure.

The access

The ipsilateral contralateral femoral artery was punctured against the femoral head in all cases except one case in which the contralateral femoral artery was accessed. No retrograde access was needed in any case.

Assessment of the lesion

The level of arterial occlusive disease was determined by diagnostic angiography. The popliteal artery was divided into three anatomical segments: P1 begins where the artery crosses the femur and ends at the proximal edge of the patella; P2, from the edge of the patella to the center of the knee joint space; and P3, from the knee joint space to the origin of the anterior tibial artery.

Chronic total occlusion was diagnosed when no intraluminal antegrade flow was observed in the angiogram (Fig. 1).

Fig. 1: Digital subtraction angiography showing complete occlusion of P2+P3 segments of the popliteal artery.

The guide wires and catheters

The guide wires used for lesion crossing were either Radifocus Guide Wire M Standard Type 0.035-inch×260 cm (TERUMO Cardiovascular Systems Corp., Ann Arbor, Michigan, USA) supported by a 4 F Bernstein Impress Diagnostic Peripheral catheter (Merit medical) or V-18 control wire 0.18 inch×300 cm (Boston Scientific, Natick, Massachusetts, USA) supported by Rubicon supporting catheter (Boston Scientific). Digital subtraction angiography and "road" mapping technique were obtained as needed to aid in the assessment and crossing of the lesion.

Angioplasty: the endovascular approach to the lesion was either transluminally or subintimally. The transluminal approach: transluminal crossing of the lesion was attempted. Subintimal angioplasty: if the transluminal approach was not possible, subintimal angioplasty with angled 0.035-inch hydrophilic coated guide wire creating a subintimal plane according to the standard method described by Bolia and colleagues. As the wire was advanced, a loop was formed at the tip of the guidewire supported by a 4 F Bernstein catheter (Fig. 2). Distal to the lesion, the wire was directed to reenter the lumen of the artery. Reentry was tried just distal to the lesion to preserve the branches of the artery and to minimize the length of the dissected artery. Reentry was confirmed by advancing the catheter over the guidewire beyond the point of reentry and performing angiography (Fig. 3)[8].

Fig. 2: Crossing popliteal lesion using a 0.035-inch guidewire and a Bernstein catheter.

Fig. 3: Angiography of the infrapopliteal vessels through a Bernstein catheter after successfully crossing a popliteal lesion.

The recanalized segment was ballooned using appropriately sized balloons (4 or 5 mm in diameter in reference to the vessel diameter assessed by duplex ultrasonography) with an inflation time of 2 min and ballooning pressure from 6 to 12 atm (Fig. 4).

The aim was to achieve in-line flow to the foot via one of the tibial vessels. The popliteal lesion was dilated using Admiral Xtreme PTA Balloon Catheter OTW 0.035-inch (Medtronic, Minneapolis, Minnesota, USA), Pacific Plus PTA Balloon Catheter OTW 0.018 inch (Medtronic). A Supera stent 4.5 mm and 5.5 mm (Abbott Vascular Inc., Redwood, California, USA) was used when there was residual stenosis or flow-limiting dissection. Elastic recoil DCB balloons were used when it was available and there was no need for stenting (IN.PACT DCB, Medtronic Inc., Santa Rosa, California, USA).

Fig. 4: Balloon angioplasty of a lesion in the P1 segment of the popliteal artery. Note the waist of the balloon in (a), which disappeared in (b).

Completion angiography

Postprocedure angiography was then performed to assess the technical success, presence of dissection, or vessel recoil and flow to the foot. After completion of the procedure, withdrawal of the sheath was done with manual compression followed by the application of compressive dressing to the puncture site for 8 h. The patient remained in bed for 8 h following the procedure.

Immediate postprocedure care

Patients were examined for puncture site complications. The ABPI was measured to be compared with the preprocedural value. A duplex scan was performed for each patient the next day of the procedure after removing the groin compressive dressing. The patient's postoperative hospital stay ranged from 1 to 5 days.

Postprocedure medications

(1) Aspirin 100 mg was prescribed for patients after the procedure. Dual antiplatelet therapy in the form of Aspirin 100 mg and clopidogrel in a daily dose of 75 mg was prescribed for those who had stenting to be given for 6 months.

(2) Cilostazol 100 mg twice daily and naftidrofuryl 200 mg three times daily were also prescribed after the procedure.

(3) Antibiotics were used in cases with signs of infection.

Follow-up

Follow-up consisted of clinical evaluation and duplex ultrasonography on day 1, after 1 week, and then after 1, 3, 6, 9, and 12 months.

(1) Clinical follow-up:

(a) Evaluation of distal pulses.

(b) Assessment of wounds and ulcer healing.

(c) ABPI evaluation.

(2) Radiological follow-up.

Duplex imaging to detect

(1) The presence of restenosis (and its degree) or reocclusion.

(2) The type of the blood flow pattern.

(3) The velocity of the blood flow.

Angiography

Computed tomographic angiography was done if restenosis or reocclusion was detected on a duplex study to evaluate the possibility of reintervention. Patients were evaluated for technical success (defined as successful dilatation of the lesion with <30% residual stenosis in the absence of flow-limiting dissections and arterial perforation of the treated segment), primary patency [defined as freedom from significant restenosis (>50% as indicated by a peak systolic velocity ratio ≥2) or occlusion based on DUS evaluation], primary-assisted patency (defined as freedom from significant restenosis after endovascular reintervention for a lesion with >50% restenosis), freedom from the target lesion revascularization (TLR), clinical success (defined as complete wound healing), major amputation of the target limb, overall survival and freedom from major adverse cardiovascular events defined as cardiovascular death, myocardial infarction, or ischemic stroke.

Statistical methods

Statistical presentation and analysis of the present study were conducted using the mean, SD, paired t test, and χ^2 tests by SPSS software statistical computer package version 20 (SPSS Inc, USA).

Privacy: it was maintained by identification of the patients by coded numbers to identify research participants, and all the private data of the patients, such as name, address, and phone number or even photos, did not appear in the research.

Ethical Committee approval

The Cairo Faculty of Medicine's Research Ethics Committee has accepted the project (MD-356-2020). Every stage of the research adheres to the Helsinki Declaration[9].

RESULTS:

A total of 23 patients were included in our study who presented with critical lower limb ischemia due to popliteal artery atherosclerotic disease. The data obtained from those patients was as follows.

Patients' characteristics

Age distribution

Patients' ages ranged from 49 to 80 years, with a mean of 64.6±8.34 years.

Sex distribution

There were 17 (73.9%) males and six (26.1%) females.

Risk factors

Thirteen (56.5%) patients were smokers; medical comorbidities included diabetes mellitus in 16 (69.5%) patients, hypertension in 15 (65.2%) patients, coronary heart disease in nine (39.1%) patients, and hyperlipidemia observed in nine (39.1%) patients. No patients had renal impairment.

Clinical presentation

In this study, all patients presented with ischemic ulcers or gangrene. The extent of tissue loss was limited to the toes in 14 (60.8%) patients, involving the forefoot in five (21.7%) patients, and involving the heel in two (8.57%) patients. Two (8.57%) patients had leg ulcers.

Ankle–brachial pressure index evaluation

The preintervention mean ABPI was 0.44±0.114 (range, 0.3–0.65).

The characteristics of the lesion

The part of the popliteal artery involved

According to the lesion location in the popliteal artery, nine (39.1%) patients had lesions in P2+P3 segments, four (17.4%) patients had lesions in the P2 segment only, four (17.4%) patients had lesions in the P1 segment only three (13%) patients had lesions in all segments of the popliteal artery. Two (8.7%) patients had lesions in the P3 segment only, and one (4.3%) patient had lesions in the P1+P2 segments. Accordingly, the P1 segment was involved in eight (34.7%) patients, the P2 segment in 16 (69.5%) patients, and the P3 segment in 14 (60.8%) patients.

Other arterial segments involved in association with popliteal artery disease

In five (21.7%) patients, the disease involved the popliteal artery only. The popliteal disease was associated with infrapopliteal arterial disease in 16 (79.3%) patients (Fig. 6).

The length and characteristics of the lesion

The lesion length ranged from 2 to 14 cm (mean, 7.59±6.4). The lesion was less than 5 cm in seven (30.4%) patients, between 5 and 10 cm in 10 (43.4%) patients, and more than 10 cm in six (26.1%) patients. In patients with popliteal lesions continuous with infragenicular lesions, the popliteal-infragenicular lesion was considered as one lesion. The popliteal lesion was a complete total occlusion in 23 (100%) cases and it involved the popliteal trifurcation in eight (34.7%) cases, while the trifurcation was free of disease in 15 (65.2%) cases.

Global Limb Anatomic Staging System

According to GLASS, femoropopliteal disease grade 4 in 23 (100%) patients.

Infrapopliteal disease grade 0 was present in five (21.7%) patients, grade 1 in eight (34.7%) patients, grade 2 in four (17.4%) patients, grade 3 in four (17.4%) patients, and grade 4 in two (8.7%) patients. One (4.3%) patient had stage I (according to GLASS), eight (34.7%) patients had stage II, and 14 (60.8%) patients had stage III.

Wound, ischemia, and foot infection classification

According to wound grading, four (17.4%) patients had grade 1, 14 (60.8%) patients had grade 2, and five (21.7%) patients had grade 3. Regarding ischemia, five (21.7%) patients had grade 1, 12 (52.1%) patients had grade 2, and six (26.1%) patients had grade 3. Grade 0 foot infection was present in 13 (56.5%) patients, grade 1 in three (13.1%) patients, grade 2 in four (17.4%) patients, and grade 3 in three (13.1%) patients.

The estimated risk of amputation at 1 year, according to WIFI classification, was very low in one (4.3%) patient, low in two (8.6%) patients, moderate in seven (30.4%) patients, and high in 13 (56.5%) patients.

Preprocedural duplex

The mean peak systolic velocity at the ankle was 19.35±7.83 cm/s (range, 10–38 cm/s). It was measured in either the posterior tibial or the anterior tibial artery at the ankle level. In six patients, both the anterior and posterior tibial arteries were patent at the ankle level. In these six patients, the higher velocity was recorded. Thus, the peak systolic velocity was measured in the posterior tibial artery in 15 (64.5%) patients and the anterior tibial artery in eight (34.7%) patients.

The results of the technique

The length of the procedure and hospital stay

The mean length of the procedure was 45.6±13.6 min (range, 25–75 min) and the mean length of hospital stay was 2.7±1.15 days (range, 1–5 days).

Technical success

In this study, all cases showed technical success. Intraluminal lesion crossing was performed in 18 (78.2%) patients, while the remaining five (21.8%) patients underwent subintimal angioplasty.

Radiation time and contrast volume

The mean radiation time was 14.8±5.01 min (range, 8–25 min) and the mean contrast volume was 54±13.9 ml (range, 35–80 ml).

The need for stenting

In 11 patients, stenting was required. In five patients, a Supera stent was put in the whole popliteal artery (P1, P2, and P3 segments), with a diameter of 5.5 mm and a length of 150 mm. In three patients, a Supera stent was put in segments P1 and P2 of the popliteal artery, with a diameter of 5.5 mm and a length of 120 mm. In the last three patients, a Supera stent was put in segments P2 and P3 of the popliteal artery with a diameter of 4.5 mm and a length of 120 mm. The indication for stenting was vessel recoil in eight patients and flow-limiting dissection in three patients.

The run-off status

Three vessel run-offs were present in only five (21.7%) cases, while two vessel run-offs were present in eight (34.7%) cases, and one vessel run-off was present in 10 (43.4%) cases. The posterior tibial artery was a target run-off in 13 patients, the peroneal artery in eight patients, and the anterior tibial in 12 patients.

Procedural complications

Four (12.9%) patients were complicated with hematoma in the access site. They underwent conservative management (Figs 5, 6). Three (9.6%) patients had infragenicular vessel spasms that needed intraarterial injection of nitroglycerine (Tridil) with a dose of 100–400 µg and frequent assessment of blood pressure. In one patient, wire perforation occurred in a branch of the anterior tibial artery, which was treated with temporary balloon occlusion and external compression.

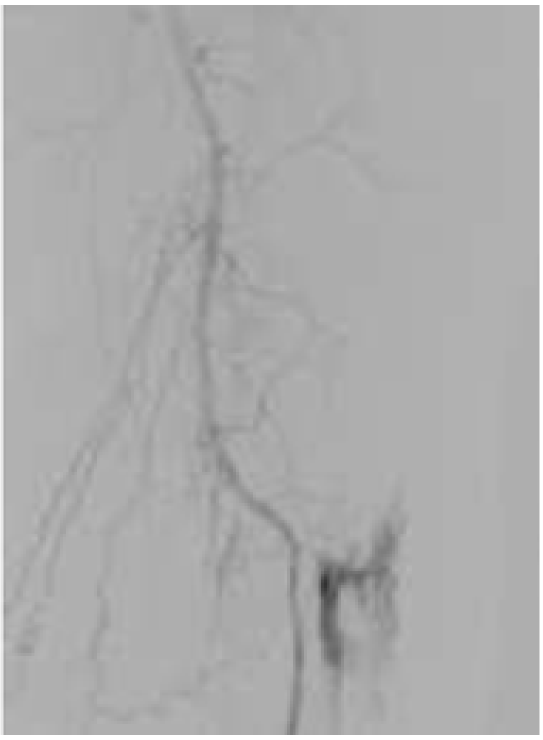

Fig. 5: Perforation in a branch of the anterior tibial artery

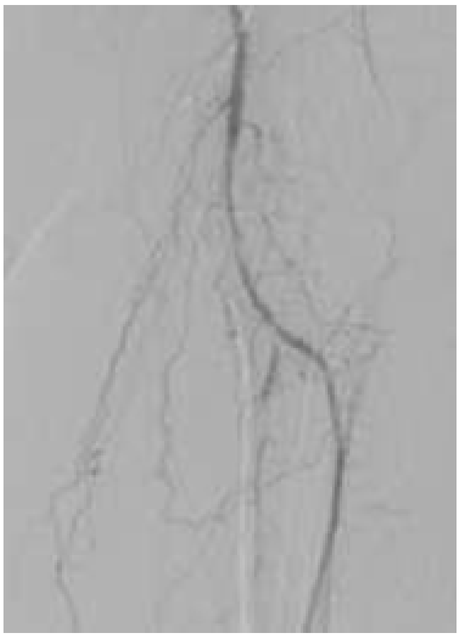

Fig. 6: Sealing of the perforation after temporary balloon occlusion and external compression.

One patient died after 2 months of the procedure due to cerebral ischemic stroke. The patient had controlled blood pressure, and he was on dual antiplatelet.

Postprocedural duplex exam

The mean peak systolic velocity showed significant improvement after the operation, with a mean of 86.7±19.4 cm/s after the operation from a preoperative mean peak systolic velocity of 19.35±7.83 cm/s (*P<0.0001*).

Minor amputation and wound debridement

Minor amputation or surgical debridement after the angioplasty procedure was done in 23 patients. Toe amputation was done in 13 patients. Forefoot amputation was done in five patients, and wound debridement was done in five patients.

The follow-up

The follow-up was conducted after 1 week, then after 1, 3, 6, 9, and 12 months. One patient developed a cerebral stroke and died after 2 months of the procedure. Another two patients had a below-knee amputation due to the progression of foot infection and systemic toxemia during the first month after the procedure.

Primary patency

Restenosis of the target lesion occurred in five (17.2%) patients. In one patient, restenosis was observed after 1 month. In three patients, restenosis was observed after 3 months. One of these patients had recurrent symptoms such as delayed wound healing and gangrenous edges of the wound. Patency was restored by angioplasty and stenting with Supera stent, diameter (5.5 mm), and length

(150 mm). In the fifth patient, restenosis occurred after 6 months. The primary patency was evaluated after 1 month in 23 patients and after 3, 6, 9, and 12 months in 20 patients because two patients had major amputations during the first month, and one patient died after 2 months.

The overall primary patency rate was 91.5% at 1 month, 86.9% at 3 months, 82.1% at 6 months, 77.1% at 9 months, and 72.1% at 12 months (Fig. 7).

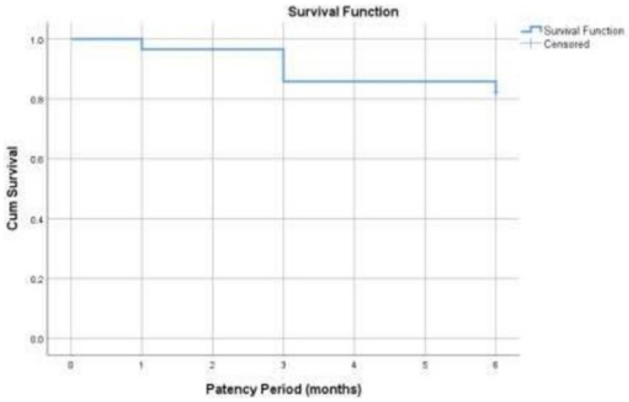

Fig. 7: Kaplan–Meyer curve of the primary patency at 6 months.

Association of the characteristics of patients to the primary patency

In this study, the primary patency rate at 12 months of follow-up was not significantly affected by hypertension, diabetes mellitus, coronary heart disease, smoking, sex, or hyperlipidemia.

Association of the characteristics of lesions to the primary patency

Lower primary patency was significantly associated with the presence of long lesions, TASC II D lesions, subintimal angioplasty, and in patients with multilevel disease in whom the popliteal lesion was continuous with infragenicular disease (Tables 1-4).

Lesions longer than 5 cm were associated with more loss of primary patency when compared with shorter lesions (≤4.9 cm) (*P=0.048*). TASC II D lesions had lower primary patency. Also, subintimal angioplasty had lower primary patency than intraluminal angioplasty (*P=0.007*).

When the popliteal lesion was continuous with an infrapopliteal disease, the primary patency was lower than the isolated popliteal artery lesion (*P=0.033*). The presence of occlusion, involvement of any popliteal artery segment, presence of lesion involving the popliteal bifurcation, and presence of only one patent run-off vessel all had a nonsignificant association with patency rates. GLASS grade 4 in the femoropopliteal segment, GLASS grades in infrapopliteal segments, and GLASS stages all had a nonsignificant association with patency rates.

Table 1: Association of the level of the lesion and the primary patency in 12 months

	Primary patency [*n* (%)]			
Variables	Positive	Negative	Total	*P* value
Isolated popliteal	5 (100)	0	5 (25)	0.033
Multilevel continuous	3 (50)	3 (50)	6 (30)	
Isolated popliteal	5 (100)	0	5 (25)	1
Multilevel discrete	10 (83.3)	2 (16.7)	12 (60)	
Multilevel continuous	3 (50)	3 (50)	6 (30)	0.14
Multilevel discrete	10 (83.3)	2 (16.7)	12 (60)	

Table 2: Association of the involved segment of the popliteal artery and the primary patency in 12 months

	Primary patency [*n* (%)]			
Variables	Positive	Negative	Total	*P* value
Involvement of P1 segment				
Involved	6 (75)	2 (25)	8 (40)	1
Not involved	13 (86.6)	3 (23.4)	15 (75)	
Involvement of P2 segment				
Involved	12 (75)	4 (25)	16 (80)	0.29
Not involved	7 (100)	0	7 (35)	
Involvement of P3 segment				
Involved	11 (78.5)	3 (21.5)	14 (70)	0.12
Not involved	7 (100)	0	7 (35)	

Table 3: Association of characteristics of lesions and the primary patency in 12 months

	Primary patency [*n* (%)]			
Variables	Positive	Negative	Total	*P* value
Length of the lesion				
1–4.9 cm	7 (100)	0	7 (35)	0.048*
≥5 cm	9 (69.2)	4 (30.8)	13 (65)	
Stenosis	0	0	0	
Occlusion	14 (70)	6 (30)	20 (100)	0.134
Involvement of popliteal bifurcation				
Present	4 (57.1)	3 (42.9)	7 (35)	0.075
Absent	11 (86.6)	2 (13.4)	13 (65)	
Intraluminal crossing	15 (93.7)	1 (6.3)	16 (80)	0.007*
Subintimal angioplasty	1 (25)	3 (75)	4 (20)	
Run-off vessels				
1 vessel	7 (52.2)	3 (100)	10 (60.7)	0.196
2 vessels	8 (39.1)	0	8 (32.1)	
3 vessels	5 (8.7)	0	5 (7.1)	

Table 4: Association of the Global Limb Anatomic Staging System and TASC classification and the primary patency in 12 months

	Primary patency [*n* (%)]			
Variables	Positive	Negative	Total	*P* value
TASC classification				
B	0	0	0	
C	0	0	0	0.007*
D	7 (35)	13 (65)	20 (100)	
GLASS femoropopliteal				
Grade				
2	0	0	0	0.429
3	0	0	0	
4	16 (75)	5 (25)	20 (100)	
GLASS stage				
I	1 (5)	0	1 (5)	
II	7 (100)	0	7 (35)	0.405
III	9 (75)	3 (25)	12 (60)	

GLASS, Global Limb Anatomic Staging System.

Assisted primary patency

In five patients who had restenosis, no intervention was needed as there was no recurrence of symptoms. Except for one patient who had recurrent symptoms, patency was restored by angioplasty and stenting with Supera stent, diameter (5.5 mm) and length (150 mm). The assisted primary patency was 100% at 3 and 6 months post-reintervention, reocclusion occurred 9 months post-reintervention, and the patient needed no intervention as he was asymptomatic and had complete wound healing.

Ankle–brachial pressure index follow-up

Immediately postangioplasty, the ABPI mean was improved to 0.88±0.102. When it was evaluated during the follow-up period, it was 0.85±0.085) after 1 month, (0.82±0.112) after 3 months, and 0.75±0.187 after 6 months. The ABPI significantly improved immediately after the procedure and after 1, 3, and 6 months when compared with the preprocedural value (*P<0.0001*). ABPI mean was 0.93 in five patients, 0.89 in nine patients, and 0.87 in six patients.

Limb salvage

Twenty (86.9%) limbs were salvaged during the study period. Two patients had limb loss, which occurred in the first month due to progression of infection despite successful revascularization. These two patients had a high risk of amputation according to WIFI classification; one patient had severe infection with systemic manifestation (TLC count 20 000, fever) and infective gangrene involving the sole of the midfoot and heel. Grade 2 ischemia with ABPI 0.41, the other patient had grade 3 ischemia with ABPI 0.31, severe infection at midfoot, and extensive ulceration. The amputation rate in patients who had a high risk of amputation according to WIFI classification (WIFI stage IV) was 15.3%.

Wound healing

Complete ulcer healing within 6 months was observed in 19 (87%) patients (16 of them during the first 3 months and three between the third and the sixth month), whereas incomplete healing occurred in one (6.5%) patient.

DISCUSSION

Endovascular treatment of peripheral arterial disease is continuously improving with increasing technical success, even in complex cases. Popliteal artery atherosclerotic disease is one of the most challenging anatomical locations due to its unique biomechanical properties, which increase the risk of stent deformation or fracture and, thus decreased patency[10].

Many studies evaluated different endovascular modalities for treating popliteal artery atherosclerotic disease. Most of these studies included patients with intermittent claudication as well as patients with critical limb ischemia. In the present study, all patients had critical limb ischemia and were treated with balloon angioplasty and bailout stenting if the results after angioplasty were unsatisfactory. The patient demographics were almost similar in this study and the study by Semaan and colleagues regarding smoking and the presence of diabetes (56.5 and 69.5% for smoking and diabetes, respectively, in this study versus 41 and 66% in their study). However, they had more patients with hypertension and hyperlipidemia (65.2 and 39.1% for hypertension and hyperlipidemia, respectively, in this study vs. 92.8 and 69.6% in their study)[3].

In this study, patient demographics and atherosclerotic risk factors did not have a significant association with the primary patency rate. Soga *et al*.[11] found that the primary patency after popliteal angioplasty was lower in patients with increased BMI (HR: 0.9, $P=0.02$) and in patients with anemia (defined as a hemoglobin <11 g/dl) (HR: 2.1, $P=0.04$).

Popliteal artery disease may be isolated or associated with diseases in another arterial segment. In the present study, isolated popliteal disease was present in 21.7% of cases. Popliteal artery disease was related to infrapopliteal disease in 78.3%. In a study by Semaan and colleagues, isolated popliteal lesions were present in 21% of patients. In patients with multilevel disease, superficial femoral artery disease was the most common to be associated with popliteal disease (80%)[3]. All popliteal artery lesions in the present study were due to chronic atherosclerotic occlusions and not due to acute thrombotic ischemia. Dosluoglu *et al*.[12] evaluated patients presenting with claudication or critical limb ischemia due to isolated popliteal artery thrombotic occlusions and suggested using rheolytic thrombectomy before percutaneous transluminal angioplasty and selective stenting of those patients. The more commonly involved part of the popliteal artery in this series was the P2+P3 lesion (39.1%), the P1 segment-only lesion was involved in 17.4%, while P2 segment only lesion was involved in 17.4%, and the whole popliteal artery was diseased in 13%. In a study by Spiliopoulos *et al*.[13] the P2 segment-only lesion was the most frequently encountered (32.6%), followed by P1+P2 lesion (21.7%). The P2+P3 lesion was encountered in only 13% of cases.

In this study, there was a significant improvement in ABPI after the procedure. The mean ABPI improved from 0.44±0.114 before the intervention to 0.88±0.102 after angioplasty. In a study by Cui and colleagues, they reported improvement of ABPI from 0.49±0.11 to 0.92±0.14 after angioplasty of popliteal artery atherosclerotic disease was reported ($P<0.01$).

In a study by Jahnke and colleagues the baseline ABPI improved from 0.71±0.2 to 0.94±0.21 after popliteal angioplasty. After 3 months, the ABI mean was 0.83±0.33, and after 6 months, it was 0.92±0.21. The higher preprocedural ABPI in the study by Jahnke *et al*.[14] is because most of their patients (80%) had intermittent claudication, and multilevel disease was present in 28% of patients. However in the present study, all patients had critical limb ischemia.

In a study by Rastan and colleagues, the mean ABI increased significantly after popliteal angioplasty from a baseline of 0.67±0.42 to 0.98±0.35 after the procedure. The ABI in their study remained improved considerably after 6 and 12 months compared with the baseline as it measured 0.93±0.39 after 6 months and 0.93±0.32 after 1 year ($P=0.0001$)[15].

In this study, stenting was used as a bailout when the results after balloon angioplasty were unsatisfactory; stenting of popliteal lesions was needed in the popliteal artery in 11 patients.

In a study by Soga *et al*.[11], bailout stenting was performed in 15 (16.6%) out of 90 lesions. In a study by Steinkamp *et al*.[16], 44 (50%) patients had major dissections after popliteal balloon angioplasty. Most of these dissections were treated with repeated balloon dilation, and only 12 (13.6%) patients required stents.

In the present study, restenosis of the target lesion occurred in 17.2% of cases during 6 months of follow-up. Clinical reocclusion is defined as the regression of the ABPI to the preintervention status. In a study by Atar and colleagues, clinical reocclusion was observed in 23/27 (85.2%) of their patients within 1 year (average 4.8±2.4 months). This difference may be due to the increased disease burden of the patients in their study, as multilevel disease was present in 92% of their patients[17]. However, multilevel disease (tibial disease) was present in 79% of this study. Spiliopoulos *et al*.[13] reported restenosis in 15.8, 40.9, and 45.8% of their patients at 1, 2, and 3 years, respectively. TLR-free interval in their series was 90.5, 79.0, and 74.1% at 1, 2, and 3 years, respectively.

In this study, the overall primary patency rate was 91.5% at 1 month, 86.9% at 3 months, and 82.1% at 6 months. The assisted primary patency was 100% at 3 and 6 months. Primary patency after 1-year and 5-year for popliteal lesions was found to be 75.5 and 56.2%, respectively. In the study by Soga *et al*.[11], lower primary patency was associated with residual stenosis after angioplasty (*P=0.04*) and smaller reference vessel diameter (*P=0.05*). In a study by Jahnke *et al*.[14], lesion patency after angioplasty was reported to be 90.8, 79.8, and 66.7% after 3, 6, and 9 months of follow-up, respectively.

In a study by Abdul Raouf and colleagues, a primary patency rate of 57.4±6.7% at 2 years of popliteal angioplasty was reported. Primary-assisted patency rate was 86.3±4.8 and 79.1±5.9% at 1 and 2 years, respectively. Their study included patients with intermittent claudication as well as patients with critical limb ischemia. Primary patency rate was higher in patients with intermittent claudication (87.0±7.0%) than in those with critical limb ischemia (38.2±10.8%) (*P=0.0006*) at 2 years. The primary patency rate was higher in patients with TASC type A lesions (73.0±7.6%) than types B and C lesions (40.40±13.4%) (*P=0.09*). Also, the lower and middle popliteal arteries had better patency (77.6±8.1%) than the upper popliteal artery (41.5±9.1%) (*P=0.03*). However, the number of patent run-off vessels, stenosis compared to occlusion, and lesion length did not appear to affect the primary patency rate[18].

In Semaan and colleagues study, the 1-year primary patency of 65.7% was observed after popliteal angioplasty. The secondary patency rate after 1-year was 82.8%. In their study, predictors of restenosis were target lesion length (<3 cm vs. >6 cm; odds ratio: 0.26; *P=0.007*) and the presence of total occlusion (odds ratio: 0.39; *P=0.02*)[15]. Primary patency after popliteal artery angioplasty was found to be 89, 82, and 73% at 3, 6, and 12 months, respectively[3].

In Cui and colleagues study, the 1-year primary patency and primary-assisted patency rates were reported to be 75.2 and 82.4%, respectively. Popliteal artery restenosis occurred in 23.8% of patients. The presence of a long lesion (≥10 cm) was a significant risk factor for loss of primary patency (hazard ratio, 5.35, *P=0.029*), and the presence of a stent in the P3 segment was associated with primary patency loss (hazard ratio, 5.62, *P=0.029*). The presence of chronic total popliteal occlusion, critical limb ischemia, the number of run-off vessels, and subintimal angioplasty were not significantly associated with primary patency loss[19].

According to Spiliopoulos *et al*.[13] the only independent predictor of restenosis was the presence of popliteal artery occlusion (hazard ratio 5.3; *P=0.02*).

In the present study, patients having popliteal lesions continuous with the infrapopliteal disease had lower primary patency than isolated popliteal artery lesions (*P=0.033*). Long lesions (≥5 cm) had lower primary patency rates than short lesions (*P=0.048*), and subintimal angioplasty had lower primary patency than intraluminal crossing (*P=0.007*). The presence of occlusion, involvement of the P3 segment, presence of lesion involving the popliteal bifurcation, and presence of only one patent run-off vessel all had a nonsignificant negative effect with patency rates.

The results of the present study were comparable to other studies in which other endovascular modalities were used in the treatment of popliteal artery disease. In a study by Rastan and colleagues, directional atherectomy was used to treat patients with popliteal artery occlusive disease. The 1-year primary patency rate was 75.0%, which was better in patients presenting with intermittent claudication than those presenting with critical limb ischemia (78.2 vs. 67.5%, respectively). Secondary patency was 93.2% (95.1% in patients with intermittent claudication and 88.5% in patients with critical limb ischemia; *P=0.237*). The limb salvage rate in their study was 100%[15].

In a study by Stavroulakis and colleagues, the results of DCB angioplasty and directional atherectomy were compared in patients with isolated popliteal artery lesions. The 1-year primary patency rate was higher in the directional atherectomy group than in the DCB angioplasty group (82 vs. 65%; *P=0.021*). Freedom from TLR in both groups was 94 versus 82%, respectively (*P=0.072*)[20].

In a study by Dohi and colleagues, drug-coated balloon angioplasty was used in patients with popliteal artery disease. The 12-month primary patency was 77.4%. The worst patency rates were observed in patients in whom the lesion extended from the superficial femoral artery to the infrapopliteal arteries (57.8% at 12 months). The 12-month freedom from TLR was 84.1%[21].

In a study by San Norberto and colleagues, the results of Supera stent implantation in popliteal atherosclerotic lesions were evaluated. The primary patency after 12, 24, and 36 months was 89, 72, and 70%, and primary-assisted patency was 93, 87, and 85%, respectively. They found that TASC II D lesions were associated with a higher rate of stent occlusion (*P=0.041*)[22]. Another study by Scheinert and colleagues evaluating Supera stents in popliteal lesions reported 6- and 12-month primary patency rates of 94.6 and 87.7%, respectively. The secondary patency rate was 97.9 and 96.5%, respectively[23]. In the present study, 11 patients needed stenting with Supera stent with a primary patency rate of 100% at 3 and 6 months, 90.9% at 9 months, and 81.8% at 12 months. Freedom from reintervention was 95.7% at 3, 6, and 12 months.

Semaan and colleagues reported that the limb salvage rate was 91.3% at 12 months. Freedom from reintervention after popliteal angioplasty was reported at 3, 6, and 12 months to be 91, 84, and 76%, respectively, with a limb salvage rate of 97% at 1 year[3]. Spiliopoulos *et al*.[13] reported limb salvage rate was 95.4, 95.4, and 88.1% at 1, 2, and 5 years, respectively. Amputation-free survival rate at 12 months of 92.1% and limb salvage rate of 94.6% at 12 months.

Complete wound healing within 6 months was observed in this study in 87% with a mean healing time of 2.7±1.5 months, whereas incomplete healing occurred in 4.4% of patients and major amputation in 8.6%. In a study by Atar and colleagues on elderly patients with popliteal atherosclerotic disease, complete wound healing occurred in 11 (55%) of 20 patients with a mean healing time of 4.45±2.16 months. In their study, improvement in the wound status but incomplete healing was noticed in five (25%) of 20 patients. In their study, the limb salvage was 74% after 1 year compared to 93.5% in the present study[17].

In this study, the limb salvage rate in patients who had clinical stage IV according to WIFI classification was 89.5%. The limb salvage rate was 100% in patients presenting with WIFI stages I, II, or III. Similar results were reported by Darling and colleagues, who had a limb salvage rate of 100% in WIFI stage I patients, 96% in stage II and three patients, and 79% in stage IV patients[24]. Minor complications occurred in the present study as groin hematoma in four (12.9%) patients. All were treated conservatively. Spasm of infrainguinal vessels was observed in three (9.6%) cases and was treated with an intraarterial injection of nitroglycerine (Tridil) with a dose of 100–400 μg with close monitoring of blood pressure. In one patient, wire perforation occurred in a branch of the anterior tibial artery and was treated with temporary balloon occlusion and external compression. Major amputation was required in two (8.7%) cases, both were below-knee amputations. The mortality rate was 4.3%.

CONCLUSION

(1) Endovascular intervention for popliteal artery disease in critical limb ischemia patients is a safe and effective procedure that has good short-term results regarding technical success, patency, and limb salvage rates.

(2) Careful follow-up is essential to detect restenosis and the need for repeated intervention.

(3) Patients with long lesions (≥5 cm), subintimal angioplasty, and popliteal lesions with continuous infrapopliteal disease had lower primary patency and thus needed close follow-up and duplex surveillance.

CONFLICT OF INTEREST

There are no conflicts of interest.

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