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Predictors of restenosis after popliteal angioplasty in patients with chronic limb threatening ischemia

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Abstract
Purpose: To evaluate factors associated with restenosis after angioplasty of popliteal artery lesions in patients presenting with chronic limb threatening ischemia.
Methods: A prospective non-randomized study between from August 2018 to December 2020 conducted on 25 patients presenting with chronic limb threatening ischemia and having popliteal artery atherosclerotic occlusive disease (median age 65.52 (±8.35) years). Plain balloon angioplasty was done and patients were followed for 6 months. The primary outcomes were the primary patency and predictors of restenosis.
Results: The primary patency at 6 months was 64%. Restenosis after angioplasty was associated with the presence of multilevel disease (p=0.036), presence of complete total occlusion (p=0.003), and subintimal angioplasty (p=0.005). Other studied variables weren't associated with patency loss.
Conclusion: Angioplasty of popliteal atherosclerotic disease is feasible and has accepted short term primary patency rate. The presence of multilevel disease, popliteal complete occlusion, and the use of subintimal angioplasty were associated with lower primary patency after 6 months.

Keywords: Popliteal angioplasty, patients, chronic limb threatening ischemia

Introduction
Endovascular interventions are the first-line management strategy in patients with chronic limb threatening ischemia including patients with chronic total occlusions and long lesions [1]. This is attributed to its less invasive nature with lower perioperative morbidity and mortality compared to open reconstruction of peripheral arterial disease [2]. The popliteal artery is infrequently involved in patients with chronic limb threatening ischemia. Popliteal lesions were detected in 8.8% of atherosclerotic lesions in 417 diabetic patients presenting with critical limb ischemia [3]. Isolated popliteal lesions were reported in 0.98% of patients presenting with peripheral arterial disease [4]. Angioplasty of popliteal artery atherosclerotic lesions are challenging due to the unique biomechanical properties including compression, flexion and twisting which may increases the risk of stent deformation or fracture and affect vessel patency [5]. Restenosis is the Achilles' heel after peripheral endovascular interventions and no endovascular modality completely abolish the development of restenosis [6]. The aim of this study was to evaluate factors associated with restenosis after angioplasty of popliteal artery lesions in patients presenting with chronic limb threatening ischemia.

Patients and Methods
This is a prospective non-randomized study done on 25 patients with chronic limb threatening ischemia at the Vascular and Endovascular Surgery Department, Tanta University during the period from August 2018 to December 2020. Patients who had successful Percutaneous transluminal with plain balloon angioplasty for popliteal lesions were followed for 6 months. Patients presenting with claudication were excluded from the study as well as patients with unsalvageable foot due to extensive infection, patients with poor distal run off, and patients presenting with acute ischemia.
Informed consent was taken from all the recruited patients in the study. The study has been approved by the Research Ethics Committee of Tanta Faculty of Medicine (32547/9/18). All steps of the study follow the Helsinki declaration [7].

Clinical assessment of the patients included analysis of symptoms as regarding onset, course and duration, determination of atherosclerotic risk factors including diabetes mellitus, hypertension, hyperlipidemia and smoking, evaluation of pulse status and measurement of ankle brachial pressure index (ABPI). Clinical staging was done using Rutherford classification [8] and The Society for Vascular Surgery Wound Ischemia Foot Infection (SVS-WIFI) classification [9].

Laboratory investigations included complete blood picture, renal function tests, fasting and post-prandial blood sugar, liver function tests, lipid profile, high sensitivity C- reactive protein and coagulation profile including clotting and bleeding times, prothrombin time, concentration and International Normalized Ratio (INR).

Duplex scanning was done to detect site and length of the lesion, associated proximal lesions, pattern of arterial waveform and flow velocity proximal and distal to the lesion. Computed tomographic angiography was done to evaluate patency of the proximal arterial tree, site, character and length of the lesion, presence and severity of calcification and the status of the distal run-off vessels. After CT angiography, the TASC II stage [10] and Global Limb Anatomic Staging System (GLASS) stage [11] were determined for each patient.

Procedural technique: ipsilateral common femoral artery access was obtained after local infiltration anesthesia of the puncture site and under complete anti septic precautions. The guide wires used for lesions were crossed using either Radifocus® Guide Wire M Standard Type 0.035-inch X 260 cm (TERUMO Cardiovascular Systems Corp, Ann Arbor, Michigan) or V-18 control wire™ 0.18-inch X 300cm (Boston scientific, Natick, Massachusetts). Rubicon supporting catheter (Boston scientific, Natick, Massachusetts) was used to support the wire and aid in lesion crossing. If crossing the lesion through transluminal approach was not possible, sub-intimal lesion crossing with angled 0.035-inch hydrophilic coated guide wire was attempted. Re-entry was confirmed by advancing the catheter beyond the re-entry point, aspirating blood and performing angiography. The lesion was ballooned using a plain balloon of appropriate size (4 or 5 mm in diameter according to the reference vessel diameter measured by duplex ultrasonography). The balloon used was either Admiral™ Xtreme™ PTA Balloon Catheter OTW 0.035 inch (Medtronic, Minneapolis, Minnesota) or Pacific™ Plus PTA Balloon Catheter OTW 0.018 inch (Medtronic, Minneapolis, Minnesota). The inflation time was 120 seconds and inflation pressure from 6 to 12 atm. The target was to provide in-line flow to the foot through a patent tibial vessel. Technical success was defined as lesion dilatation with ≤ 30% residual stenosis and absence of flow-limiting dissections.

After the procedure, Patients were examined for puncture site complications. The ABPI was measured and compared with the pre-procedural value. Duplex ultrasound was performed to measure flow velocities. Patients were prescribed Aspirin 100 mg daily, Cilostazol 100 mg twice daily and Naftidrofuryl 200 mg three times daily after the procedure. were also prescribed after the procedure. Follow-up was conducted after 1 week, and then after 1, 3 and 6 months and consisted of clinical evaluation and duplex ultrasonography. Clinical evaluation included distal pulse status, ABPI measurement, assessment of wounds healing, limb salvage or amputation (minor or major). Restenosis was suspected if there was a change in pulse status or decreased ABPI by ≥ 0.015. Restenosis was confirmed by duplex ultrasonography if peak systolic velocity ratio was ≥ 2. Primary patency was defined as freedom from >50% restenosis or occlusion based on duplex ultrasonography.

Statistical methods

The patients' data were analyzed using Statistical Package for Social Science (SPSS) Version 26.0, SPSS, Chicago, IL, USA). Numeric variables were presented as mean and standard deviation, while categorical variables as number and percentage. Student t test was used to compare means for numeric data, and chi-square or Fisher's exact tests for categorical variables. P-value ≤ .05 was considered significant.

Results

The study was conducted on 25 patients who presented with chronic limb threatening ischemia and popliteal artery atherosclerotic disease. Baseline patients' characteristics are listed in Table 1.

Table 1: Patients' Characteristics

Male	14 (56%)
Mean age, years	65.52 (±8.35)
Smoking	10 (40%)
Hypertension	11 (44%)
Hyperlipidemia	8 (32%)
Diabetes Mellitus	16 (64%)
Coronary artery disease	9 (36%)
Run-off vessels	
1	16 (64%)
2	8 (32%)
3	1 (4%)
Other arterial segments involved	
Iliac	1 (4%)
SFA	5 (20%)
SFA + Infragenicular	3 (12%)
Infrageniclar	7 (28%)
Isolated popliteal	9 (36%)
Part of popliteal artery involved	
P1 only	4 (16%)
P2 only	4 (16%)
P3 only	2 (8%)
P1 + P2	1 (4%)
P2 + P3	10 (40%)
P1 + P2 + P3	4 (16%)
TASC	
B	6 (24%)
C	9 (36%)
D	10 (40%)
GLASS stage	
1	4 (16%)
2	9 (36%)
3	12 (48%)
Stenosis versus occlusion	
Stenosis	12 (48%)
Occlusion	13 (52%)
Lesion length (cm)	7.88±7.1
run-off vessels	
1	16 (64%)
2	8 (32%)
3	1 (4%)

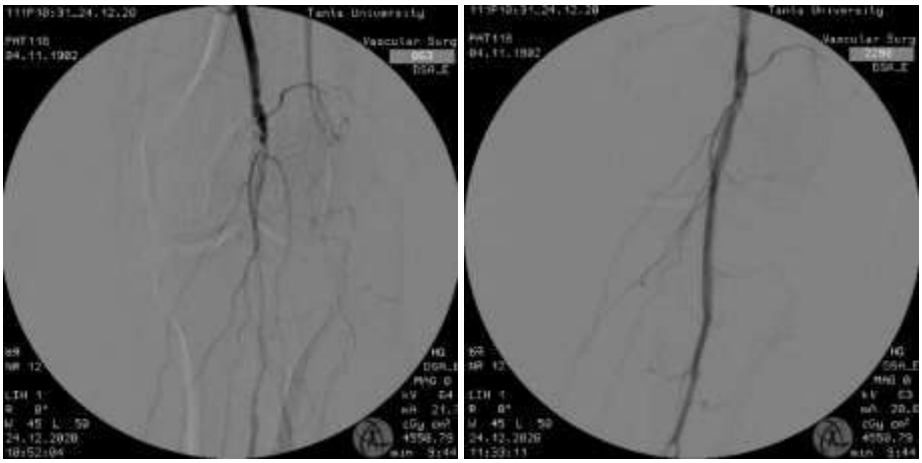
The mean length of the procedure was 44.2±13.2 minutes and the mean length of hospital stay was 2.88±1.2 days. In this

study, all interventions were technically successful. Lesion crossing was done intraluminally in 17 cases (68%), while subintimal angioplasty was done in 8 cases (32%). The mean radiation time was 14.82±4.9 minutes, and the mean contrast volume was 52.6±13.3 ml. Access site hematoma occurred in 4 patients (16%). All of them were treated conservatively. Spasm of infragenicular vessel was observed in 3 cases (12%) and was treated with intra-arterial injection of Nitroglycerine with a dose of 100–400 µg of with close monitoring of blood pressure. The mean peak systolic velocity increased from 19.35±7.83 cm/sec before the procedure to 86.7±19.4 cm/sec after the procedure. The increase in PSV was statistically significant (p<0.0001). Restenosis of the target lesion occurred in 9 patients (36%) after 6 months. In 2 patients, restenosis occurred within the first month after the procedure. In 3 patients, restenosis was observed between 1 and 3 months. In the remaining 4 patients, restenosis occurred was observed between 3 and 6 months. In the current study, we found that sex, smoking, DM, hypertension, coronary heart disease, and hyperlipidemia had non-significant associations with primary patency rate. Multilevel disease with involvement of popliteal as well as another arterial segment was significantly associated with restenosis. Also, Restenosis was significantly associated with popliteal artery occlusion, and using subintimal angioplasty.

Table 2: Risk factors of primary patency loss.

Variable	*P* value
Male	0.325
Smoking	0.536
Hypertension	0.219
Hyperlipidemia	0.533
Diabetes Mellitus	0.593
Coronary artery disease	0.126
Isolated popliteal versus multilevel disease	0.036*
P1 involvement	0.326
P2 involvement	0.648
P3 involvement	0.253
Reference vessel diameter	0.374
TASC II stage	0.276
GLASS stage	0.417
Stenosis versus occlusion	0.003*
Lesion length (≥ 5cm)	0.145
run-off vessels	0.382
Intraluminal versus subintimal	0.005*

TASC, Transatlantic society consencus; GLASS, Global limb anatomic staging system; P1, from the adductor hiatus to the superior border of the femoral condyle; P2, from the superior border of the femoral condyle to the joint line; P3, from the joint line to the bifurcation of the popliteal artery.



A B

Fig 1: A: Angiography showing complete occlusion of P2 and P3 segments of popliteal artery. B: Patent popliteal artery after balloon angioplasty.

Discussion

The popliteal artery is subjected to significant biomechanical forces including axial compression, bending, and twisting with knee movement. During Knee flexion, tortuosity occurs in the upper part of the artery with development of one or more acutely angled curves. This makes this arterial segment a unique vascular territory [12]. Restenosis after angioplasty is frequently associated with recurrence of symptoms and the need for reintervention. Multiple factors were evaluated in different studies to be associated with arterial restenosis and loss of patency after angioplasty. Identification of these variables may aid in selecting endovascular tools (i.e., Drug coated balloons) that aim to reduce the incidence of restenosis in these patients. In the current study, patients with chronic limb threatening ischemia were followed after plain balloon angioplasty. The presence of multilevel disease (p=0.036), presence of complete total occlusion (p=0.003), and subintimal angioplasty (p=0.005) were significantly associated with restenosis after angioplasty.

Cui *et al*. reported 1 year primary and primary-assisted patency rates to be 75.2% and 82.4%, respectively. Popliteal artery restenosis occurred in 23.8% of patients. In thier study, the presence of long lesion (≥10 cm) was a significant risk factor for loss of primary patency (hazard ratio, 5.35, P = .029), also the presence of a stent in P3 segment was associated with primary patency loss (hazard ratio, 5.62, P = .029). Other variables such as the presence of chronic total occlusion, the presence of critical limb ischemia, subintimal angioplasty and the number of runoff vessels were not found to be associated with patency loss [13]. Spiliopoulos *et al*. reported restenosis after angioplasty of isolated popliteal artery disease to occurr in 15.8, 40.9, and 45.8% at 1, 2 and 3 years, respectively. popliteal artery occlusion was the only independent predictor of restenosis (HR 5.3; p = 0.02) [4]. In a study by Schillinger *et al*., restenosis occurred in 39% of after 1 year of angioplasty of femoropopliteal lesions. Restenosis was associated with ≥30% residual stenosis after angioplasty (odds ratio 3.6, p=0.001) and baseline C-reactive protein levels (odds ratio 4.2, p=0.02) [14]. Soga *et al*. reported lower primary patency after popliteal angioplasty in patients with anemia (defined as a hemoglobin < 11 g/dl) (HR: 2.1, p = 0.04), and in patients with increased body

mass index (HR: 0.9, p = 0.02) [15]. In a study by Siablis *et al*. on patients treated with subintimal angioplasty for long femoropopliteal chronic total occlusions, restenosis was associated with increased legion length (≥20 cm) (HR 4.55; 95% CI 1.41–14.29, p = 0.011) and with presentation with critical limb ischemia (HR 2.78; 95% CI 1.25–6.67, p = 0.03) [16]. Laxdal *et al*. treated 103 patients with above-knee femoropopliteal disease. The primary patency rate after 1-year was 48%. Inferior primary patency was found in diabetic patients (p = 0.038), patients with elevated D-dimer levels (≥.0.5 mg/l) (p = 0.019), and patients with occlusions (p = 0.026), and patients not on aspirin therapy (p = 0.043) [17]. Dohi *et al*.- using drug coated angioplasty- treated 281 popliteal lesions. Variables associated with restenosis were critical limb ischemia presentation (p=0.02), severe dissection after procedure (p=0.04), and Reference vessel diameter (p=0.02) [18]. The impact of distal runoff vessels on primary patency after angioplasty is a matter of controversy with some studies showing a negative impact of poor runoff on primary patency [19, 20], while others doesn't [13].

Conclusion

Angioplasty of popliteal atherosclerotic occlusive disease is feasible and has accepted short term primary patency rate. The presence of multilevel disease, popliteal complete occlusion, and the use of subintimal angioplasty were associated with lower primary patency after 6 months.

Conflict of Interest

Not available

Financial Support

Not available

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