Subject Area:

Percutaneous transluminal angioplasty for isolated infrapopliteal arterial occlusive disease in diabetic patients with critical limb ischemia

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Percutaneous transluminal angioplasty for isolated infrapopliteal arterial occlusive disease in diabetic patients with critical limb ischemia

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Abstract

Background
Critical limb ischemia (CLI) is considered the most severe stage of peripheral artery disease. Patients with CLI typically have the disease affecting multiple levels (i.e. aortoiliac, femoropopliteal, and infrapopliteal). CLI due to isolated infrapopliteal arterial disease is commonly seen in patients with long-standing diabetes mellitus, chronic kidney disease, or the elderly. Endovascular treatment of infrapopliteal arteries has been considered a primary approach for revascularization in CLI.

Objective
The aim of this study was to evaluate the efficacy of percutaneous transluminal angioplasty (PTA) for isolated infrapopliteal arterial occlusive disease in diabetic patients with CLI.

Patients and methods
This prospective study included 20 diabetic patients with CLI in 28 limbs due to isolated infrapopliteal arterial occlusive disease who underwent infrapopliteal PTA between January 2017 and January 2019 in Mataria Teaching Hospital, Cairo, Egypt.

Results
The study was conducted on 20 diabetic patients, 12 (60%) men and eight (40%) women. Their age ranged between 54 and 76 years with a mean age of 65 years. Successful recanalization was achieved in 23 (82.1%) limbs. Reintervention was needed in five (17.9%) limbs and it was successful in four limbs. The follow-up period ranged from 6 to 18 months with the mean overall follow-up being 12.5 months. The primary patency rate and secondary patency rate were, respectively, 78.3 and 80% at 1 year. The limb salvage rates after 1 year were 75%. Mortality rate after 1 year was 10%.

Conclusion
PTA is effective and the preferred procedure for revascularization and limb salvage in diabetic patients with CLI due to isolated infrapopliteal arterial occlusive disease.

Keywords: Angioplasty, critical limb ischemia, isolated infrapopliteal angioplasty, isolated tibial angioplasty

Introduction
Critical limb ischemia (CLI) is considered the most severe stage of peripheral artery disease (PAD), being associated with a very high risk of major amputation, cardiovascular events, and death [1]. A mortality rate of about 20% within 6 months after the diagnosis and 50% after 5 years has been reported [2]. The excessive mortality rate may be due to
systemic cardiovascular diseases, including coronary artery
disease and cerebrovascular arterial disease [3].

According to the Inter-Society Consensus for the Management of PAD (TASC II), CLI is defined by the presence of ischemic rest pain, ulceration, or gangrene because of an arterial occlusive disease. CLI is considered in case of ischemic rest pain with ankle pressure less than 50 mmHg or a toe pressure less than 30 mmHg and in patients affected by foot ulcers or gangrene by an ankle pressure less than 70 mmHg, a toe systolic pressure less than 50 mmHg, or TcPO₂ less than 30 mmHg [4].

Infrapopliteal arterial occlusive disease with or without concomitant inflow disease is a leading cause of CLI. CLI is due to a multilevel arterial disease in the majority of cases. Adequate rates of limb salvage can be achieved in patients undergoing multilevel interventions for CLI compared with isolated tibial interventions. Patients with isolated tibial disease appear to have a higher incidence of limb loss secondary to more extensive distal disease [5].

Infrapopliteal arterial disease or ‘below-the-knee’ arterial disease is commonly seen in patients with long-standing diabetes mellitus, chronic kidney disease, or in the elderly. This arterial bed consists of relatively small caliber vessels, which are often calcified and associated with extensive disease [6].

The treatment of CLI due to tibial vessel occlusive disease remains a challenge for vascular surgeons particularly in diabetic patients, who represent the majority of CLI patients [4]. Diabetes mellitus is one of the strongest predictors of peripheral arterial occlusive disease and a significant risk factor for the progression of asymptomatic disease or claudication into CLI [7].

In patients with diabetes, the risk of PAD is 3–4 folds higher and it tends to be more aggressive than in patients without diabetes. The need for a major amputation is 5–10 times higher in diabetics than in nondiabetics. This is due to sensory neuropathy and decreased resistance to infection [4].

In diabetic patients with ischemic foot ulcer(s), the underlying vascular disease is widespread in the lower limb arteries and is particularly severe in arteries below the knee. On the basis of these observations, a consensus statement from the American Diabetes Association recommends PAD screening with an ABI every 5 years in patients with diabetes [8].

Goals of CLI treatment are relief from rest pain, healing of ischemic ulcers, prevention of limb loss, improvement of patient function and quality of life, and prolonged survival. The aim of the intervention is to obtain at least one, but preferably two or even three, patent crural vessels down to the distal foot [4]. Endovascular opening of more than one artery in favorable cases is associated with better wound healing rates [9].

Endovascular revascularization is an established first-line revascularization strategy for most patients presenting with CLI and infrapopliteal arterial occlusive disease. The Bypass Versus Angioplasty in Severe Ischemia of the Leg study suggested that if the anatomy is convenient for angioplasty, primary percutaneous transluminal angioplasty (PTA) might be an appropriate first therapy even if the patient is a good candidate for bypass [10].

AIM OF THE STUDY
The aim of this study was to evaluate the efficacy of PTA for isolated infrapopliteal arterial occlusive disease in diabetic patients with CLI.

PATIENTS AND METHODS

Study design
This is a prospective study.

The study was approved by the Ethics Board of Vascular Surgery Department, Mataria Teaching Hospital, Cairo, Egypt.

Study population
The participants included 20 diabetic patients with CLI due to isolated infrapopliteal arterial occlusive disease.

Study venue
Mataria Teaching Hospital.

Study duration
The study was conducted in 2017 and 2018 with a follow-up period of up to 18 months.

Inclusion criteria
(1) Diabetic patients with CLI (Rutherford categories 4–6) [10].
(2) Clinically palpable popliteal pulse.
(3) Evidence of significant isolated infrapopliteal arterial occlusive disease by a high-quality duplex ultrasound or computerized topographic angiography (CTA).
(4) Patients with generally adequate state of cardiac, respiratory, and renal conditions that allow the procedure.

Exclusion criteria
(1) Patients with multilevel arterial lesions, that is, aortoiliac, femoropopliteal combined with infrapopliteal PAD.
(2) Inevitable amputation.
(3) Acute on top of chronic ischemia.
(4) Buerger’s disease.
(5) Patients with creatinine more than 2 mg/dl.
(6) End-stage renal disease patients.
(7) Poor general condition (decompensated heart failure, stroke, and bed ridden).

Preoperative assessment
Patients underwent full history taking and detailed vascular examination. Patients had routine laboratory investigations including blood sugar, lipid profile, liver and kidney functions, and arterial duplex examination (Fig. 1).

Lower limb ischemia severity was hemodynamically assessed by the ankle peak systolic velocity (APSV). APSV is the mean of the peak systolic velocities measured across distal
tibial arteries (anterior and posterior tibial arteries) at the ankle level (Figs. 2–4). APSV strongly correlates with the ankle–brachial index and with the toe-brachial index whenever those can be reliably measured. An APSV of less than 25 cm/s indicates severe ischemia [11]. APSV is not affected by vessel calcification and can be measured in the presence of toe gangrene or amputation and can be measured during arterial duplex scanning of the lower limbs [12].

CTA was done for some patients but it was not routine, because all patients had normal femoral and popliteal pulses. Multidetector row CT angiography is a noninvasive imaging test in the evaluation of patients with PAD. Although CTA is currently the modality of choice in patients with intermittent claudication, its most important drawback is the limited lumen evaluation of extensive calcified arteries. CTA appears to be clinically less valuable in CLI because of extensive crural artery calcifications in diabetic patients [13].

Data were collected including age, sex, risk factors for peripheral arterial disease, for example, ‘smoking, diabetes, or hyperlipidemia,’ serum creatinine level, patient complaint: ‘gangrene, ulcer, or rest pain.’

The morphology of infrapopliteal lesions was evaluated in each vessel regarding the number, length of the lesion and whether it is occlusion, stenosis, or there is no distal runoff.

A written informed consent for the procedure and the study was taken from all patients.

Technique
Preprocedure preparation
Antiplatelet drugs, statins, and antihypertensive drugs were administered to reduce cardiovascular events in all patients, to prevent periprocedural complications, and to increase postprocedural patency rates. Aggressive blood glucose control is done in all patients to reach glucose levels as close to normal as possible. In patients who were receiving metformin, metformin was stopped at the time of the procedure and for 48 h after the procedure, and if renal function was normal at 48 h, metformin was restarted. Good hydration with normal saline for 6 h before and after the procedure.

Procedure
Antegrade ipsilateral femoral artery access using a 6 Fr sheath under local or spinal anesthesia. An intra-arterial bolus of 5000 IU of unfractionated heparin was given. Baseline selective arteriograms of the whole limb are obtained to have a baseline to compare with the final result. A 4 Fr Bern catheter is positioned at the level of the popliteal bifurcation, and superselective DSA is performed. A 6 Fr, 55 cm long sheath enough to reach the distal popliteal artery is used in some cases for support (VISTA BRITE TIP; Cordis, Cordis, Miami, Florida, USA).

Lesions were passed with a 0.035 hydrophilic guide wire or with a 0.018 hydrophilic guide wire if there is significant arterial calcifications to avoid subintimal passage of the wire. In some cases, we used a guide wire in conjunction with a support catheter (0.035 or 0.018 Rubicon Support Catheter; Boston Scientific) or a short- and low-profile coaxial catheter balloon to cross the lesion.

After crossing the lesion, dilation is effected using low-profile balloons with a diameter of 2.5–3 mm and a length of 40–200 mm. Following balloon angioplasty, completion angiography was performed with the guide wire remaining across the lesion. Technical success was achieved if the residual stenosis is less than 30%.

Nitroglycerine (100–300 µg) was administered routinely, selectively into the infrapopliteal arteries according to
the systemic blood pressure, to prevent vasospasm. When multiple stenosis or occlusions were noted in infrapopliteal arteries, the aim of the intervention is to obtain at least one, but preferably two or even three, patent crural vessels down to the distal foot.

Debridement of extensive gangrene was mostly performed immediately after the end of the angioplasty procedure when it was successful.

Postprocedure medication

The patients were given dual antiplatelet therapy for 6 months after PTA. Check renal function 48 h after the procedure.

The interventions done for all patients were analyzed identifying the dilated vessels, the amount of dye used, technical success, and the presence of palpable pulse or triphasic Doppler signals immediately following intervention.

Follow-up

The follow-up period ranged from 6 to 18 months. Before the patient’s discharge and after 1 week, and then at 1, 3, 6, 12, and 18 months after the procedure. All patients were evaluated with full history taking, general and local examination, and duplex ultrasound.

On clinical examination we looked for the following:
(1) Partial or complete wound healing.
(2) Absence of rest pain.
(3) Absence of tissue necrosis and gangrene.

The outcome for all patients was assessed focusing on the following end points:
(1) Technical success.
(2) Clinical success (wound healing and disappearance of rest pain).
(3) Follow-up for primary patency at 1, 3, 6, 12, and 18 months.
(4) Secondary patency.
(5) Limb salvage and mortality.

Results

Patient characteristics and comorbidities

During the study period, 20 patients underwent PTA for 28 limbs. The baseline characteristics of the study patients are shown in Table 1.

Rutherford clinical categories of treated patients

Most of the patients of the study were categorized as Rutherford 5 as shown in Table 2.

Clinical categories of clinical categories.

Angiographic characteristics of the study patients

Angiographic findings of the study patients are shown in Table 3.

PTA outcomes

Angioplasty short-term and long-term outcomes of the study patients are shown in Table 4.

Complications

Complications occurred in three patients. One case of tibial artery thrombosis, which was treated by intra-arterial thrombolysis and two cases of retroperitoneal hematoma which were treated conservatively.

Table 1: Characteristics of the study patients

<table>
<thead>
<tr>
<th>n (%)</th>
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<tbody>
<tr>
<td>Number of patients</td>
</tr>
<tr>
<td>Number of treated limbs</td>
</tr>
<tr>
<td>Number of treated arteries</td>
</tr>
<tr>
<td>Age (years) (mean±SD)</td>
</tr>
<tr>
<td>Male sex</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Active smoking</td>
</tr>
<tr>
<td>History of tobacco</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
</tr>
<tr>
<td>Previous stroke</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
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</tbody>
</table>

Table 2: Clinical categories of the study patients

<table>
<thead>
<tr>
<th>n/N (%)</th>
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</thead>
<tbody>
<tr>
<td>Rutherford category 4</td>
</tr>
<tr>
<td>Rutherford category 5</td>
</tr>
<tr>
<td>Rutherford category 6</td>
</tr>
</tbody>
</table>
Our results in terms of primary patency rate and secondary patency rate are higher than those reported by Romiti et al. [18]. In their meta-analysis study including 30 studies (2557 cases) published between 1990 and 2006, dealing with PTA performed for infrapopliteal lesions, a primary patency rate of 58% and a secondary patency rate of 74% at 1 year have been reported.

Our results are consistent with other studies such as that of Tartaglia et al. [19] and Ryu et al. [20]. Tartaglia et al. [19] reported that the primary patency rate and secondary patency rate were 67 and 83% at 1 year for 101 diabetic patients who underwent infrapopliteal angioplasty for CLI. Ryu et al. [20] reported that among the 82 patients with CLI who underwent infrapopliteal angioplasty, the primary patency rate was 70.7% at 1 year.

The incidence of limb salvage in this study was 75%, at 1 year. These results in terms of limb salvage can be considered comparable to those reported by Fernandez et al. [21], who reported that the limb salvage rate in his group of isolated tibial disease was 74.8% at 12 months. Our result is lower than that reported in the literature. Romiti et al. [18] reported that the limb salvage rate was 85% at 1 year. Giles et al. [22] and Tartaglia et al. [19] reported that the limb salvage rate was 84% at 1 year.

Although the present study is a prospective study, some limitations can be identified. This study is a single-center experience with a relatively small study population with a short-term follow-up period. Further multicenter studies with large numbers of patients and with long-term follow-up periods are required to confirm the current results.

**DISCUSSION**

Revascularization is the first-line treatment for CLI. Revascularization may be surgical through bypass or by endovascular techniques. There is still an open debate on the first-line strategy between open surgery and endovascular revascularization in diabetic patients. The decision is related to many factors: morphology of the lesions, arterial disease distribution, health status of the patient, comorbidities, presence of foot ulcer, and foot infection and local expertise [14]. PTA has shown good results in terms of limb salvage, feasibility, and complications, especially for infrapopliteal lesions [15]. Even if bypass is characterized by a long-term patency, angioplasty can be performed in patients not suitable for bypass due to the presence of several comorbidities, reduced life expectancy, unavailability of veins, absence of landing zone for distal bypass, and foot infection in the site of potential anastomosis. Angioplasty does not require general anesthesia and usually shows few contraindications in patients with active comorbidities [16]. PTA remains the most appropriate treatment modality for infrapopliteal disease, even with severe disease and suboptimal runoff [17].

In this study, 20 diabetic patients with CLI in 28 limbs due to isolated infrapopliteal arterial disease underwent infrapopliteal angioplasty to demonstrate the efficacy of angioplasty alone on this type of arterial disease and to demonstrate its effect on wound healing and limb salvage. The primary patency rate and secondary patency rate were, respectively, 78.3 and 80% at 1 year. The limb salvage rates after 1 year were 75%. Mortality rate after 1 year was 10%.

**CONCLUSION**

PTA is effective and the preferred procedure for revascularization and limb salvage in diabetic patients with CLI due to isolated infrapopliteal arterial disease.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

**REFERENCES**


