Role and outcome of endovascular procedures in patients with buerger's disease with critical lower limb ischemia

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Objective
To assess the effectiveness, feasibility, and safety of endovascular intervention in patients who presented with Buerger's disease with infrainguinal critical lower limb ischemia.
Patients and methods
This is a prospective study that was conducted on 52 patients who presented with Buerger's disease who underwent percutaneous transluminal angioplasty. Clinical outcomes and limb salvage rates were reported at 1, 3, and 6 months following the intervention.
Results
The study was conducted on 52 patients, comprising 50 males and two females. The age varied between 25 and 55 years. The clinical outcome showed 73.1% technical success by endovascular intervention, with 53.8% patency rate after 1 month (P=0.001) and 86.3% limb salvage rate (P<0.022).
Conclusion
Endovascular treatment of patients with Buerger's disease is an effective, safe, and feasible method and shows high limb salvage rates and clinical improvement.

Keywords:
Buerger's, disease, endovascular intervention, limb salvage, vasculitis

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Introduction

Buerger's disease (thromboangiitis obliterans) is an inflammatory vascular disease that affects small-sized and medium-sized vessels and leads to vascular obstruction. The prognosis of patients with Buerger's disease regarding loss of the limbs is significantly higher than that for those with diabetes, atherosclerosis, or other types with vasculitis [1]. Recently, the only proven method for prevention of development and progressing of that disease and also decreasing the amputation rate is complete stoppage of smoking of cigarettes or other tobacco products [2]. With the development of endovascular procedures for peripheral arterial diseases, some investigators documented the effect of an endovascular intervention for patients with Buerger's disease who presented with lower limb ischemia. Endovascular procedures such as the angioplasty of below-knee occlusions produce good limb salvage rate and lower mortality and morbidity [3]. The endovascular management in cases with Buerger's disease is usually difficult and technically challenging owing to the presence of the lesions in the distal segments of the vessels and compromised distal run-off of the foots, so to extend the endovascular procedure until the foot (foot arch and dorsalis pedis) becomes obligatory to have a higher technical success rate [4].

Patients and methods

This is a prospective study that included 52 cases that presented with critical lower limb ischemia with infrainguinal occlusive disease. Informed consent was applied to all patients before any intervention.

Inclusion criteria

All cases that presented with Buerger's disease, with ages between 25 and 55 years, and clinically having an infrainguinal occlusive disease were included.

Exclusion criteria

Patients who presented with diabetes, hyperlipidemia, hypertension, cardiac patients, source of embolism, dead limbs, acute thrombotic ischemia, trauma, and aneurysms were excluded from our study.

All cases were subjected to full history taking and full physical and radiological examination. All patients underwent rheumatological assessment for activity of the disease. Full explanation of the intervention,

methods, indications, complications, and outcomes was done, and an informed consent also was signed by all included cases.

Criteria for selection of the patients for endovascular intervention were as follows: patients who presented with critical lower limb ischemia in the form of tissue loss or rest pain; patients not in active phase, which is guided by erythrocyte sedimentation rate/C-reactive protein and rheumatological assessment; and ankle–brachial index below 0.35 and PSV below 30 cm/s.

Endovascular intervention

Preprocedure preparation

All patients were admitted to the hospital at least for 24–48 h before the procedure and monitoring of the medical condition of patients and disease activity. Proper hydration was ensured by adequate fluid intake the day before the procedure. A loading dose of clopidogrel 300 mg was given the night of the procedure, which was to be continued postprocedurally at a maintenance dose of 75 mg daily.

The procedure

Access: the approach for lower limb intervention was through an ipsilateral antegrade puncture of the common femoral artery for femoropopliteal disease and infrapopliteal disease.

Angiography: thereafter, a bolus of 5000 IU of unfractionated heparin was administered. An initial angiogram was done to confirm the preprocedure Duplex and to determine the morphology of the lesion and the plan of treatment.

A 0.035, 0.018, or 0.014-inch guide wire was used and cross the lesion either transluminally or subintimal followed by balloon dilatation of the arteries (diameters: 2.5, 3, 4, 5, and 6 mm, and lengths 100–150 mm).

In cases with thrombolytic therapy, after adequate flushing with heparinized saline, a 5-Fr 90 cm length Fountain infusion system with Squirt 83 (Merit Medical Systems Inc., California, USA), with an infusion segment length of 50 cm, was advanced over the guide wire. The guide wire was exchanged for the Merit occluding wire which was intended (according to the manufacturer's instruction for use) to occlude the end hole of the catheter; therefore, the infused thrombolytic agent, tissue–plasminogen activator (Alteplase) (dose 58 million IU), exited the catheter only through its side holes (inside the thrombus). Correct placement of the catheter and occluding wire was checked radiographically. Sheath and infusion catheter were secured in position by skin silk suture followed by injection of the loading dose of thrombolytic drug (10 ml). Then those patients were monitored at intensive or intermediate care units in which 1 ml of this thrombolytic drug was given every 1 h. Heparinized saline also was given in the sheath through a syringe pump at a rate of 300 U every hour over 24 h.

Arteriography was done 24 h after injection of the thrombolytic drug to assess the need for balloon dilatation. Successful recanalization of the vessels was assessed by direct flow through the treated vessels with or without distal pulses.

Intraprocedural complications such as spasm and dissection either flow limiting or nonflow limiting were treated. In case of spasm, tridil 5 mg/ml (1 ml diluted in 10 ml saline) was injected directly to the artery.

Procedure outcomes

The outcomes were evaluated for every patient immediately after procedure and 1, 3, and 6 months postoperatively. Immediate evaluation was done by angiography and clinical evaluation of pulses, warmth, and capillary refilling. Follow-up was done regarding clinical reassessment and imaging study. Success of the interventions was assessed by the following:

(1) Angiographical success, which means good flow with lower than 30% residual stenosis at the narrowest part of the treated artery.
(2) Clinical success by regaining the distal pulsation.
(3) Clinical improvement in the form of warmth, good capillary refilling, rest pain relief, healing of the ulcers, or minor amputation.

Postprocedure care

The arterial sheath was routinely removed 2–3 h after the procedure. Digital compression was done for 15–20 min. Mobilization was delayed for 12–24 h. Fluids and N-acetylcysteine (600 mg) were given. Successful cases were discharged on the second day of a treatment on clopidogrel 75 mg/day and aspirin 150 mg/day.

Results

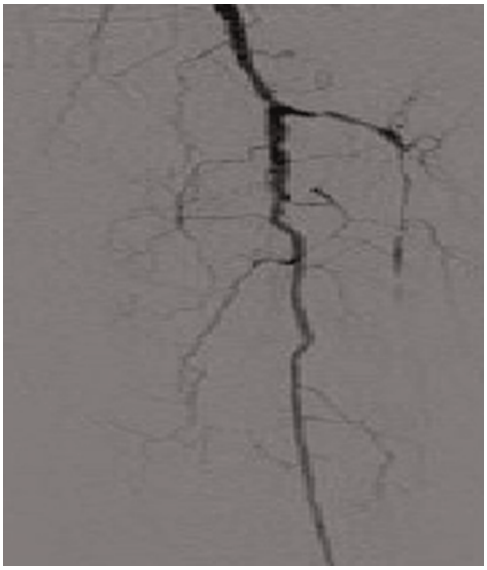
This is a prospective study that included 52 patients who presented with Buerger's disease to the vascular

outpatient clinic in Cairo University Hospitals. All patients included had critical lower limb ischemia and underwent percutaneous transluminal angioplasty (PTA) after fulfilling the selection criteria. The study included 50 (96.2%) males and two (3.7%) females, with ages between 25 and 55 years (mean age, 36.72 years). All the cases were heavy cigarettes smokers (P=0.001). Most of the cases were Rutherford category IV (42%), followed by category VI (31%) and category V (27%). Regarding anatomical characteristics, the study included 52 patients, comprising 30 (57.7%) patients with right lower limb lesion and 22 (42.30%) patients with left lower limb lesion. Of the presented patients, 52 limbs were included, comprising six (11.50%) femoral lesions, 21 (40.40%) popliteal lesions, 40 (76.90%) anterior tibial lesions, 42 (80.8%) posterior tibial lesions, and 29 (55.80%) peroneal lesions (Figs 1–4). According to the details of endovascular procedure, all the 52 cases underwent angioplasty. Eight of our patients received catheter-directed thrombolysis 24 h before the angioplasty. In 46

Figure 1

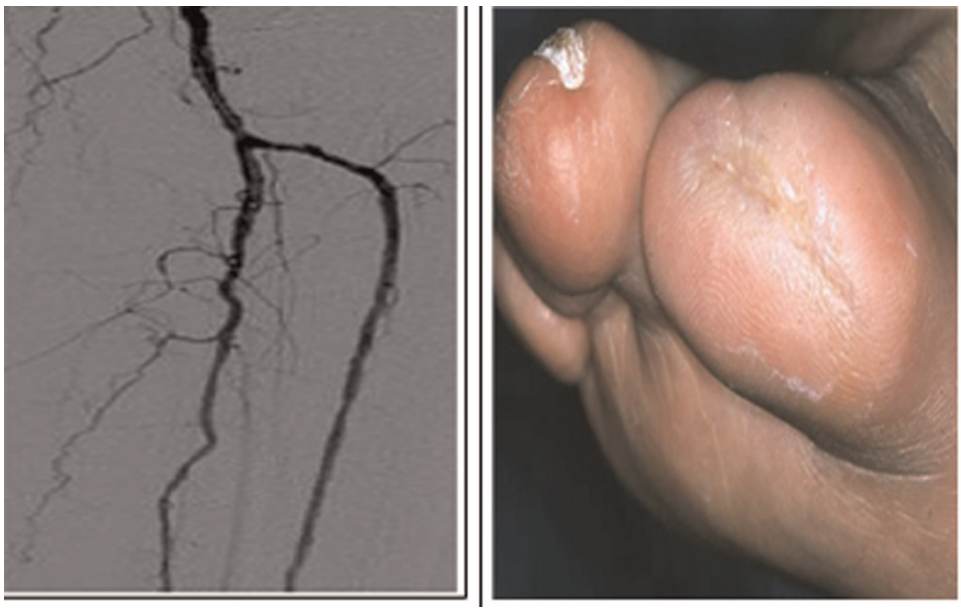
Gangrene.

Figure 2



AT occlusion. AT, anterior tibial.

Figure 3



After ATA balloon dilatation. ATA, anterior tibial artery.

Figure 4

Healing of the wound after 6 months.

cases, balloon dilation was used and seven cases were failed.

All the procedures were done by inserting 6 Fr sheath in the ipsilateral groin with an antegrade femoral approach. The wires used for crossing the lesions were 0.035 inch (61.50% of cases). The 0.018 wire was used in 36.50% of cases and the 0.014 in 7.70% of cases. Following the intervention, 73.10% of cases had patent vessels, and 26.90% failed. No stents were deployed in femoral, popliteal, or tibial arteries. There were no minor or major complications during or after the interventions. Regarding follow-up of the patency rates, the patency rates were classified into primary and secondary patency rates. The primary patency rate is defined as the duration after the primary intervention in which the artery remained patent and need no other intervention. Secondary patency rates are defined as the period of patency following successful reintervention. Assisted primary patency rate is the period of patency following successful reintervention by endovascular interventions. In this study, primary patency rate at 1 month was 28 (53.8%) and secondary patency rate was two (3.8%), with assisted primary patency rate of 0; after 3 months, the primary patency rate was 17 (32.7%) and secondary patency rate was two (3.8%), with assisted primary patency rate was four (7.7%); and after 6 months, the primary patency rate was 11 (21.15%) cases, and assisted primary patency was five (9.8%) cases and the secondary patency rate was three (5.9%) patients (Table 1).

Table 1 Follow-up of the patency rates in patients who underwent endovascular procedures

	1 month [*n* (%)]	3 months [*n* (%)]	6 months [*n* (%)]	*P* value
Primary patency	28 (53.8)	17 (32.7)	11 (21.15)	0.008
Assisted primary patency	0	4 (7.7)	5 (9.8)	0.006
Secondary patency rate	2 (3.8)	2 (3.8)	3 (5.9)	0.368

Regarding clinical improvement, after 1 month, the rate of clinical improvement was 61.5%. The cases that showed worsening in their clinical course were 17.30%. The patients who were stable in their course were 11 (21.15%) patients. After 3-month follow-up, the clinical improvement was 49.20%. The cases that showed worsening in their clinical course were 17 (32.70%) patients and patients who were stable in their course were 11 (21.15%) patients.

After 6-month follow-up, the clinical improvement was 46.20%. The cases that had worsening in clinical course were 14 (26.9%) patients. The patients who were stable in their course were 12 (23.50%) patients.

The total limb salvage rate after 1 month was 51 (98%) patients, after 3 months was 48 (92.3%) patients, and after 6 months was 45 (86.5%) patients. Of 52 patients, seven underwent major amputation: one (1.9%) after 1 month, three (5.76%) after 3 months, and three (5.76%) after 6 months.

Discussion

Buerger's disease, also called thromboangiitis obliterans, is a nonatherosclerotic, inflammatory, segmental, nondestructive episodic and occlusive disease of unknown etiology affecting small-sized and medium-sized distal vessels and nerves [5]. The aggressive involvement of distal segment of the vessels makes open surgical intervention technically challenging, with lower patency rates and low feasibility [6].

Recent interventions, such as endovascular procedure, increase the questions around the success of conservative management (smoking cessation). In 2010, Talwar and Choudhary [7] did PTA with smoking cessation of 22 patients, where major amputation rate was 0 and the minor amputation rate was 4.5% (one case), which was done in the toes. However, in spite of the good short-term results and lower amputation rate, the long-term

results and healing of the ischemic ulcers still remain unclear.

Surgical procedure is another option for revascularization if the distal segment of the artery is patent and good for doing an anastomosis. However, because of aggressive involvement and affection of arteries and veins with absence of distal vasculature, making open surgical procedure rare to be done and difficult. It was reported that only 4 patients with Buerger's disease (1.77%) among 225 were suitable and underwent open surgical procedure in a 1-year follow-up in a study by Modaghegh *et al.* [8,9], but it was reported less than 10% in other studies [9].

At the same time, primary patency rate was recorded as low as to be ~33.3% at the third-year follow-up in another study [10].

All patients included in this study had critical lower limb ischemia and underwent PTA.

The total limb salvage rate after 1 month was 51 (98%) patients, after 3 months was 48 (92.3%) patients, and after 6 months was 45 (86.5%) patients.

Of 52 patients, seven underwent major amputation: one (1.9%) after 1 month, three (5.76%) after 3 months, and three (5.76%) after 6 months.

After 1 month, the rate of clinical improvement was 61.5% but worsening clinical course was present in 17.30% and the patients who were stable in their course were 11 (21.15%) patients. After 3-month follow-up, the clinical improvement was 49.20%. The cases that showed worsening in their clinical course were 17 (32.70%) patients. The patients who were stable in their course were 11 (21.20%) patients. After 6 months, the clinical improvement was 46.20%. The cases that showed worsening in their clinical course were 14 (26.9%) patients. The patients who were stable in their course were 12 (23.50%) patients.

Graziani *et al*. [4] assessed the safety and the efficacy of endovascular management in 17 cases with 20 limbs with CLI (all the cases were below the knee). In this study, they reported technical success rates of ~95%, and limb salvage rate was 100% during the period of follow-up (23 months), with clinical improvement in 16 limbs of the 20 limbs without mortality or complications.

Yuan *et al.* [11] reported a technical success rate of ~100% after endovascular procedures in nine Buerger's disease cases with femoral arterial obstruction with angioplasty alone without stenting. Similar to our study, none of our cases needed stent deployment.In a study by Kawarada *et al.* [12], they managed 20 cases with 20 lower limbs and five upper limbs presented by critical limb ischemia (in 15 limbs) and claudication (in 10 limbs). They used angioplasty and different wire crossing techniques to supply direct blood to the distal arterial segments. In 21 limbs, they tried different types of wire crossing techniques such as subintimal and intraluminal angioplasty together to pass the nonatherosclerotic lesions but a single technique in four limbs [12].

Parallel to the previous study, we tried also multiple crossing techniques together in most of the cases by using new guide wires and crossing technologies.

Recently, a comparative study reached the conclusion of endovascular procedure being an acceptable method for salvage of the limbs when open surgical revascularization is not available [13].

In another study, angioplasty of above-the-knee vessels was successfully done with clinical improvement in all nine cases presented with critical limb ischemia, involving femoral and/or iliac arteries and infrapopliteal vessels [12].

Recently, other endovascular procedures such as radiofrequency ablation and intraarterial injection of thrombolytic drugs have been mentioned in cases with Buerger's disease [14].

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Conflicts of interest
There are no conflicts of interest.

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