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Original Article

Endovascular reconstruction of popliteal and infrapopliteal arteries for limb salvage and wound healing in patients with critical limb ischemia – A retrospective analysis

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ABSTRACT

Background: Advancement in endovascular techniques has led to rapid growth in endovascular revascularization, and it has emerged as a treatment for critical limb ischemia (CLI). Clinical effectiveness of revascularization has been frequently judged by vessel patency and limb salvage, but there is paucity of reports on outcomes of the wound. We present a retrospective analysis of immediate angiographic and 3-month clinical outcome of patients who underwent endovascular reconstruction of popliteal and infrapopliteal arteries for CLI.
Methods: All patients who underwent endovascular reconstruction of popliteal and/or infrapopliteal arteries for CLI and >70% stenosis on digital subtraction angiography between March 2010 and November 2014 and had a clinical follow-up of at least 3 months were selected for analysis.
Results: 34 patients underwent endovascular reconstruction. 9 patients (26%) underwent only POBA and remaining 25 (74%) underwent additional stenting. 13 patients (38%) had multiple segmental revascularization. 24 patients (71%) had successful vessel recanalization. Linear flow to foot in at least one artery could be achieved in 20 patients (59%) post revascularization. Successful wound healing occurred in 11 (35%) patients with an additional 7 (21%) patients showing clinical improvement in their wounds. Limb salvage was achieved in 33 patients (97%) at 3-month follow-up.
Conclusion: Endovascular revascularization of popliteal and infrapopliteal arteries is a feasible, safe, and effective procedure for the treatment of CLI. Normal inflow and outflow with at least one of the three infrapopliteal vessels being patent is essential for adequate healing of chronic ulcers and prevention of major amputation.

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1. Introduction

Critical limb ischemia (CLI) occurs, when arterial blood flow to the part or entire foot is markedly reduced, in most cases as a result of progressive obstructive atherosclerosis.[1] Although surgical bypass has long been considered the gold standard treatment for CLI patients, its use is limited by absence of suitable conduits, advanced age, and presence of comorbidities, resulting in high morbidity and mortality rates.[2] Advancement in endovascular techniques and technology has led to rapid growth in endovascular revascularization of popliteal, tibial, peroneal, and pedal arteries, and it has emerged as a treatment for CLI secondary to popliteal and infrapopliteal artery stenosis/occlusion.[3] Clinical effectiveness of endovascular revascularization has been frequently judged by vessel patency and limb salvage, but still there is a paucity of reports on outcomes of the wound.[1] We present a retrospective analysis of immediate angiographic and 3-month clinical outcome of patients who underwent endovascular reconstruction of popliteal and infrapopliteal arteries for CLI.

2. Methods

All patients who underwent endovascular reconstruction of popliteal and/or infrapopliteal arteries for CLI and >70% stenosis on digital subtraction angiography between March 2010 and November 2014 and had a clinical follow-up of at least 3 months were selected for analysis. CLI was defined as >2 weeks of rest pain or ulcer/gangrene attributable to peripheral arterial disease. Serum creatinine value was determined before and after the procedure. A nephroprotection protocol was used in all nondialyzed patients with baseline creatinine above 1.3 mg% (N-acetylcysteine 600 mg twice a day and Trimetazidine 35 mg twice a day, both given orally for 5 days). Patients were preloaded with 600 mg of clopidogrel, 60 mg of prasugrel, or 180 mg of ticagrelor 1 h prior to the procedure.

Percutaneous transluminal angioplasty (PTA) was performed under local anesthesia through contralateral puncture of the common femoral artery, and vascular access was accomplished using 7 F Introducer Sheath (Cordis Corporation, Florida, USA). If obstructions were present at duplex scanning in the contralateral iliac or common femoral artery, the arterial puncture was performed through an antegrade puncture of ipsilateral common femoral artery. 7500 U bolus of heparin was administered intra-arterially at the beginning of the procedure and ACT was maintained above 250 s. A double length (300 cm; Cougar XT, Medtronic USA) 0.014-in. guide wire was used to cross the lesion.

PTA was performed with standard angioplasty balloons (2–15 cm in length; 2–10 mm in diameter) selected to match the length of the lesion and the diameter of the artery. Balloon size selection was based on the visual estimate of the size of the vessel. Balloon inflation pressures ranged from 4 to 16 atmospheres and were repeated routinely two to three times (for at least 60 s) at the same segment. A variety of balloon catheters (Maverick Monorail-Boston Scientific, Ireland; Admiral xTreme – Invatec, Italy; and Amphirion Deep – Invatec, Italy) were used.

Stents used were either bare metal stents (BMS) (Prozeta PS, Vascular Concepts, Bangalore, India) and drug eluting stents (DES) (Pronova, Vascular Concepts, Bangalore, India; Biomime Aura, Meril, Brussels, Belgium), or self expanding stents (Complete SE, Medtronic Inc, Minneapolis, USA). All popliteal/infrapopliteal lesions were stented only if >30% residual stenosis or flow limiting dissection occurred following plain balloon angioplasty and associated inflow (ileal/femoral) lesions were also stented.

Dual oral antiplatelet therapy with aspirin (150 mg/day) and clopidogrel (75 mg/day), prasugrel (10 mg/day) or ticagrelol (90 mg/day) was continued long term (at least 1 year) and the duration of treatment was life-long for aspirin.

Vessel recanalization was considered successful when direct flow was obtained in the treated vessel, with no significant residual stenosis along the whole artery. Wound healing was considered successful when the index wound got completely healed within 3-month follow-up. In patients presenting with rest pain without foot ulcer, the disappearance of pain was considered limb salvage successful. In patients with foot ulcers, we considered limb salvage successful when the plantar stand was maintained, even when achieved by a tarsal-metatarsal amputation. Any above-the-ankle amputation was considered a failure.

3. Results

34 patients underwent endovascular reconstruction of popliteal and infrapopliteal arteries for CLI between March 2010 and November 2014 (Table 1). Mean age was 65 years (range 43–84 years) and majority (97%) had diabetes. 8 patients (24%) had coronary artery disease, and 3 (09%) had associated LV dysfunction (LVEF <40%). 31 patients (91%) had an ulcer, while 3 patients (9%) presented with rest pain.

Obstructions of >70% of vessel diameter were present in the infrapopliteal arteries in all patients except two ($n = 32$, 94%). 15 patients (44%) had lesions affecting all 3 infrapopliteal

Table 1 – Clinical and demographic characteristics of patients.

Variable	Study subjects ($n = 34$)
Age	
40–60	15 (44%)
61–75	16 (47%)
>75	3 (09%)
Men	22 (65%)
Women	12 (35%)
Diabetes mellitus	33 (97%)
Smoking	2 (06%)
Coronary artery disease	8 (24%)
LV dysfunction	3 (09%)
Baseline high creatinine (>1.3 mg%)	9 (26%)
Rest pain	3 (09%)
Ulcer	31 (91%)
Gangrenous ulcer	9 (26%)
Prior toe amputation	8 (24%)

Table 2 – Segmental location of lesions.

Segmental location	No. of patients $n = 34$ (%)
Exclusively in infrapopliteal arteries	13 (38%)
Exclusively in popliteal artery	2 (06%)
Popliteal and infrapopliteal arteries	9 (27%)
Femoropopliteal and infrapopliteal arteries	10 (29%)

Table 3 – Number of segments treated.

No. of segments treated[a]	No. of patients $n = 34$ (%)
One	21 (62%)
Two	10 (29%)
Three	3 (09%)

[a] Femoral, popliteal, and/or infrapopliteal segments.

arteries. Associated popliteal lesions were present in 15 patients (44%), and femoral lesions were present in 10 (29%) patients (Table 2). Two patients had lesions confined to the popliteal artery. 26 patients (76%) had occlusive lesions and 20 occlusions (39%) had lesion length >100 mm. 19 patients (56%) had calcific vessels. 8 patients (24%) had diffusely diseased plantar arch.

3.1. *Endovascular revascularization*

9 patients (26%) underwent only plain old balloon angioplasty (POBA). Remaining 25 patients (74%) underwent stenting; 19 (76%) of whom had dissection of the artery while 6 (24%) had >30% residual stenosis post POBA. 10 patients (40%) who underwent stenting required POBA for revascularization of other segments.

13 patients (38%) had multiple segmental revascularization (Table 3). Details of location of lesions, proportion of patients who underwent endovascular revascularization, and successful vessel recanalization achieved in individual arteries are shown in Table 4. Overall 44 stents were deployed: 22 in infrapopliteal, 13 in popliteal, and 9 stents in femoral arteries. Majority (26 stents, 59%) were DES, 3 (7%) were BMS, and 15 (34%) were self expanding stents. 24 patients (71%) had successful vessel recanalization in all treated arteries following endovascular revascularization. Linear flow to foot in at least one infrapopliteal artery could be achieved in 20 patients (59%) post revascularization.

3.2. *Endovascular revascularization for femoral lesions*

All 10 patients who had associated lesions in femoral segment underwent revascularization to improve inflow. 8 patients (80%) underwent successful PTA and stenting. All ($n = 9$) were self-expandable stents. Remaining 2 patients (20%) underwent femoropopliteal bypass surgery with Gore-Tex graft as a part of hybrid revascularization.

3.3. *Endovascular revascularization for popliteal lesions*

All 17 patients with popliteal lesions underwent endovascular revascularization with successful vessel recanalization. 5 patients (29%) underwent POBA and 12 patients (71%) underwent stenting. 4 patients had lesions involving mid (P 2) segment, behind knee joint of which 2 underwent stenting and remaining 2 underwent POBA. 7 DES and 6 self expanding stents were deployed in popliteal artery.

3.4. *Endovascular revascularization for infrapopliteal lesions*

Out of 32 patients with infrapopliteal lesions, 25 patients (78%) underwent endovascular revascularization for infrapopliteal lesions. 15 patients (60%) had successful vessel recanalization. In remaining 10 patients (40%), linear flow to the foot could not be established post revascularization due to distal diffuse disease despite revascularization in proximal segments of same vessel.

14 patients (54%) underwent stenting of which 2 underwent across ankle joint (1 in dorsalis pedis and 1 in distal posterior tibial artery). 5 patients (36%) had additional POBA done. 11 patients (44%) had only POBA as their revascularization mode. 19 DES and 3 BMS were deployed in infrapopliteal arteries.

15 patients (44%) had lesions in all 3 infrapopliteal arteries. In this subset, establishment of uninterrupted flow to foot in at least one vessel (Fig. 1) was achieved in 9 patients (61%), two vessels in 2 patients (13%), and all three in 1 patient (7%). In 1 patient (7%), in spite of revascularization, linear flow could not be achieved at the foot due to diffusely diseased distal anterior tibial artery. In remaining 2 patients (13%), only popliteal and femoral endovascular revascularization was done in view of totally occluded and diffusely diseased infrapopliteal vessels; one patient also had associated renal dysfunction.

In 6 patients with single vessel runoff, 4 (67%) underwent successful revascularization to index vessel with reestablishment of linear flow to foot.

Table 4 – Endovascular revascularization and successful vessel recanalization in individual arteries.

Artery	No. of patients	Endovascular revascularization (%)	Successful vessel recanalization (%)
Superficial femoral	10	8 (80%)	8 (100%)
Popliteal	17	17 (100%)	17 (100%)
Anterior tibial	24	17 (71%)	12 (71%)
Tibioperoneal	8	3 (37%)	1 (33%)
Posterior tibial	24	11 (46%)	6 (55%)
Peroneal	17	3 (18%)	2 (67%)
Dorsalis pedis	2	2 (100%)	2 (100%)

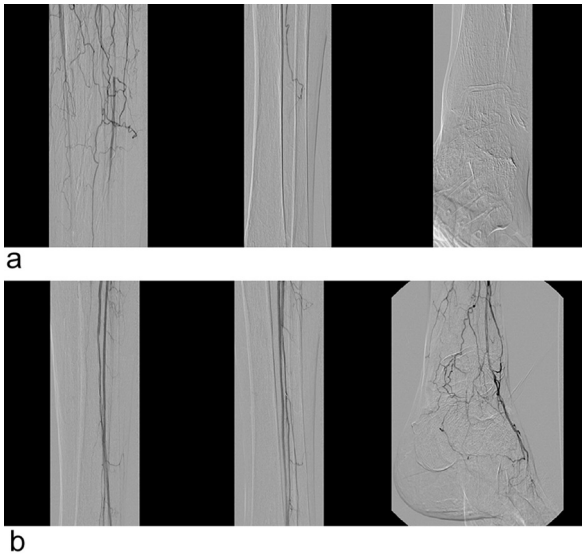

Fig. 1 – (a) Complete occlusion of all 3 infrapopliteal arteries in a patient with CLI. (b) Linear flow to the foot in at least one infrapopliteal artery (anterior tibial artery) after PTA.

Majority ($n = 10$, 83%) of the femoropopliteal occluded lesions (Table 5) were treated by endovascular revascularization. 2 patients underwent femoropopliteal grafting as a part of hybrid revascularization. Only 7 infrapopliteal occluded lesions (18%) were treated by endovascular revascularization (Fig. 2). Majority of the infrapopliteal occluded lesions could not be opened in view of calcific long segment occlusions and distal diffuse disease; nevertheless, linear flow to the foot was maintained by opening up nonoccluded, stenotic parallel artery or via naturally patent parallel artery.

Of the 9 patients with high baseline creatinine, creatinine stabilized without dialysis in 7 patients. 2 were already on hemodialysis. 1 patient, who had a normal creatinine before procedure had a transient rise in creatinine after PTA requiring hemodialysis temporarily. In the absence of complications, hospital stay was 3 days.

3.5. *Clinical follow-up at 3 months*

Wound care with debridement and regular dressings post revascularization were sufficient to achieve successful wound healing in 11 (35%) patients with an additional 7 (21%) patients showing clinical improvement in their wounds. 12 (39%) patients had to undergo planned amputation. 11 had minor amputations (9 had toe amputation and 2 had trans metatarsal amputation) and one had major amputation (below knee). All minor amputations were performed 2–7 days (mean of 3 days) after index PTA out of which 8 (73%) were having preexisting gangrene and rest 3 (27%) had intractable local infection. The patient who underwent major amputation (45 days after PTA) had persistent nonhealing gangrenous ulcer with diffusely diseased infrapopliteal arteries and only popliteal lesion could be successfully tackled. One patient had persistent nonhealing ulcer but had good flow up to dorsalis pedis on arterial doppler at 3 months; he had uncontrolled diabetes mellitus. 2 patients underwent skin grafting. Resolution of ischemic rest pain occurred in all 3 patients who presented with rest pain. Limb salvage was achieved in 33 patients (97%) at 3-month follow-up.

4. Discussion

With the increasing prevalence of diabetes mellitus and greater life expectancy, the incidence of peripheral artery disease, especially CLI is progressively rising.[4] CLI is an advanced disease marked by the development of rest pain, ischemic ulceration, or gangrene and is associated with a high amputation and mortality rate.[5] CLI generally occurs in diabetics with extensive atherosclerotic disease of the below-the-knee vessels. Most have associated lesions in iliac, femoral, and popliteal arteries.[6] Even with aggressive local wound care, patients who do not undergo revascularization often progress to amputation with the likelihood of amputation increasing as the ankle-brachial index decreases.[7] In patients who do not undergo an attempt at revascularization, CLI caused major amputation in 73% of the patients with rest pain and in 95% of the patients with tissue loss at 1 year.[8] The optimal treatment for CLI is prompt revascularization, but careful planning is required, as patients often have multilevel disease and limited options for revascularization.[9]

Preventing major amputation in CLI is arguably the most important goal and is predicated on the ability to restore and maintain linear arterial flow to the foot.[10] For that the inflow consisting of iliofemoral arteries and outflow via the popliteal and at least one infrapopliteal artery should be near normal along with a healthy plantar arch. Options for revascularization include surgery, endovascular intervention, and 'hybrid therapy' – a combination of surgical and endovascular therapy.

In our series of 34 patients with CLI, majority (56%) had lesions affecting multiple segments of which 68% underwent

Table 5 – Outcome of occluded lesions.

	Superficial femoral artery ($n = 4$)	Popliteal artery ($n = 8$)	Anterior tibial artery ($n = 12$)	Tibioperoneal artery ($n = 3$)	Posterior tibial artery ($n = 16$)	Peroneal artery ($n = 8$)
POBA		3 (38%)	1 (9%)		2 (12%)	
PTA + Stent	2 (50%)	5 (62%)	1 (9%)	2 (67%)	1 (6%)	
Hybrid	2 (50%)					
Unable to cross wire			3 (25%)		1 (6%)	
Medical management			7 (57%)	1 (33%)	12 (76%)	8 (100%)

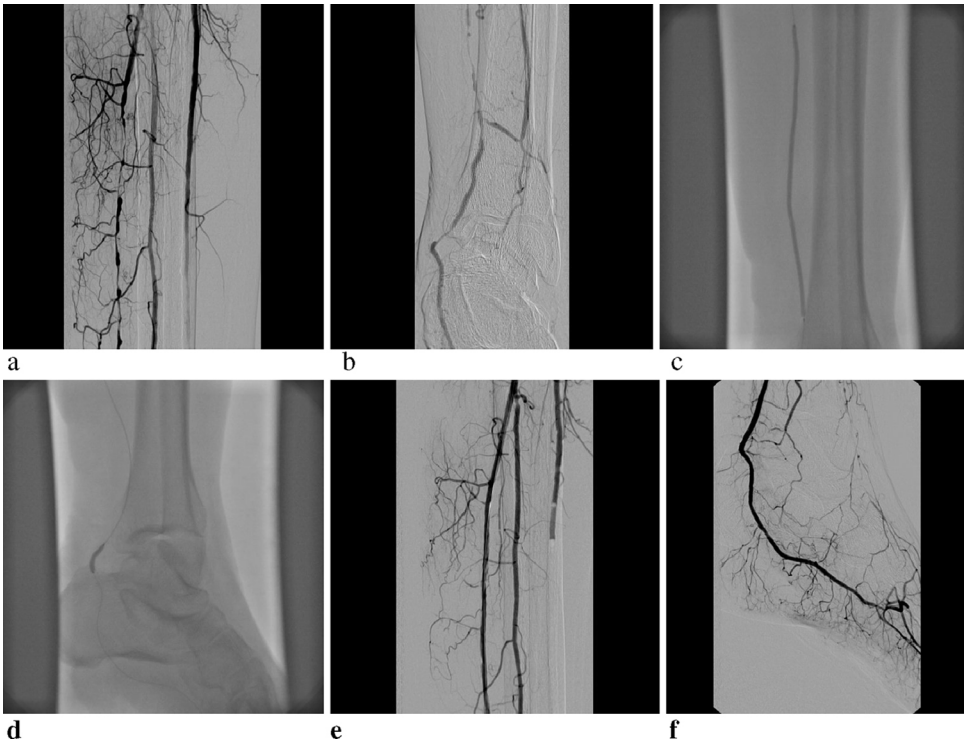

Fig. 2 – Endovascular revascularization performed for posterior tibial artery with multiple stenosis and occlusions. (a and b) Multiple stenosis and occlusions of posterior tibial artery. (c) Angioplasty with 2.5 mm × 120 mm long balloon (Amphirion Deep – Invatec, Italy). (d) Angioplasty with 2.5 mm × 15 mm balloon (Maverick Monorail-Boston Scientific, Ireland). (e) Post angioplasty showed good flow without residual stenosis/flap. (f) Plantar arch flow maintained via posterior tibial artery.

multisegmental endovascular revascularization. All inflow lesions were successfully opened; 2 required hybrid therapy as inflow lesions were not amenable for endovascular revascularization. Majority (59%) of our patients achieved linear flow to the foot in at least one artery following endovascular revascularization. Ideally all lesions in outflow need to be addressed, but may not be feasible in all patients due to associated comorbidities such as renal insufficiency and/or LV dysfunction. Only femoropopliteal lesions were tackled in 3 of our patients due to associated comorbidities. Diffuse disease and long segment chronic total occlusions also limit complete revascularization.

The optimal strategy for infrapopliteal disease has not been clearly defined. 1-year restenosis rate after balloon angioplasty of long lesions in below-the-knee arteries may be as high as 70%.[11] Given its safety and clinical effectiveness, balloon angioplasty is generally preferred as a standard treatment for patients with infrapopliteal disease.[12] As a suboptimal (or ''bail-out'') treatment, stent implantation is currently reserved for some cases, such as significant recoil, flow-limiting dissection, or residual stenosis after balloon angioplasty.[4] In our series, 54% had stenting done for infrapopliteal lesions after PTA. Recently, with the advancement in stent material and design, primary bare metal stent and drug-eluting stent implantation have been used as an alternative therapy to treat infrapopliteal disease in selected patients.[10,13] Drug eluting balloons are increasingly being used, but could not be used in our patients as it was not commercially available during study period. Drug-eluting balloons compared with PTA strikingly reduced 1-year restenosis (27% versus 74%), target lesion revascularization (18 versus 43%), and target vessel occlusion (17% versus 55%) in the treatment of below-the-knee lesions in diabetic patients with CLI.[12]

In a recent study involving popliteal lesions, provisional stenting as part of a plain balloon angioplasty strategy was found to have equivalent 1-year patency (67.4% versus 65.7%).[14] In our series, out of 17 patients, 12 (71%) underwent stenting in the popliteal artery after PTA.

An attempt at a foot salvage procedure should take place after a revascularization procedure has been performed if possible.[15] The level of adequate circulation, extent of infection, if any, and remaining function of the foot are factors considered when choosing the level of a foot salvage procedure. A waiting period of at least 3 days has been suggested; this allows for sufficient time for the restoration of perfusion and for demarcation to occur.[15] All minor amputations in our series were performed as part of foot salvage procedure and were done at a mean of 3 days after index PTA.

O'Brien-Irr et al. in their analysis of 106 infrainguinal interventions for CLI reported wound healing rate of 50% with a mean healing time of 7 months.[16] 78% of patients who achieved prompt healing did so by 2 months. Limb salvage was 83% at 2 years in patients with tissue loss. This was comparable to our results; successful healing of the index wound occurred in 35% of patients (additional 21% showing clinical improvement) with a limb salvage rate of 97% at 3

months. However, it is acknowledged that direct comparisons in wound healing rates between studies is complicated by differences in patient mix, local wound care standards, wound duration prior to intervention, etc.[2]

In the presence of CLI, limb salvage depends on successful revascularization.[17] The goal of acute treatment is to perfuse the ischemic limb and allow healing.[6] Additional perfusion is necessary to heal the ulcer, but once it heals, the skin viability can be maintained even though the treated artery gets re-occluded.[18] Also slow restenosis of the treated artery allows time to form new collateral circulation.[19] When no pain is present or wound healing has occurred in CLI patients, a possible delayed closure of the treated vessel may not always be clinically relevant.[20] If restenosis of the treated lesion occurs at a later date, the wound generally will not recur in the absence of recurrent injury.[6] Similarly amputation is not synonymous with failure of revascularization; in some, revascularization is performed with the aim of limiting the extent of amputation and promoting wound healing after amputation.[21]

5. Conclusion

Endovascular revascularization of popliteal and infrapopliteal arteries is a feasible, safe, and effective procedure for the treatment of CLI. Immediate angiographic outcome was good and 3-month wound healing/limb salvage rates were high. Despite advances in management of wound care (growth factors and novel approaches to stimulating wound healing), management of vascular disease in patients with CLI is an important consideration. Normal inflow and outflow with at least one of the three infrapopliteal vessels being patent are essential for adequate healing of chronic ulcers and prevention of major amputation. Associated comorbidities may hamper complete revascularization. The need for a multidisciplinary team to provide good foot care is also essential.

Conflicts of interest

The authors have none to declare.

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