Peroneal Artery Angioplasty As a Single Runoff Vessel for Foot Revascularization in Patients with Critical Limb Ischemia

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ABSTRACT

Introduction: *Prevention of major amputation in critical limb ischemia is arguably the most important goal and is based on the capability for restoring and maintaining straight-line tibial arterial blood flow to the foot. The main objective of below-knee limb salvage angioplasty is to restore a direct straight-line flow to the foot through a native tibial artery and is usually attempted by selecting, whenever possible, the anterior tibial artery for ischemic forefoot lesions and the posterior tibial for calcaneal lesions. If neither the anterior nor the posterior tibial artery can be treated, the alternative treatment may consist of providing direct flow along the peroneal artery. The aim of this study is to assess the clinical and haemodynamic outcomes of peroneal artery angioplasty as a single runoff vessel for foot revascularization in patients with critical limb ischemia.* ***Methods:*** *Between September 2014 and January 2016, we enrolled 23 patients in our prospective clinical study with critical lower limb ischemia having the peroneal artery as a single runoff vessel to the foot. Our patients were treated by endovascular balloon dilatation of the peroneal artery. Our primary end points were primary, assisted primary, secondary patency, and limb salvage rate at 12 months, while secondary end points were procedure related complications, and major adverse cardiovascular events.* ***Results:*** *Data was obtained for 23 patients presenting with critical limb ischemia with 46.8% of patients presenting with rest pain (Rutherford category 4), and 56.5% of patients presenting with minor tissue loss (Rutherford category 5). Peroneal artery angioplasty as a single vessel was attempted in all patients with a mean duration of follow up of 1 year post intervention. Using the Kaplan-Meier survival curves, our primary patency rate was 63.2%, assisted primary patency rate was 81%, secondary patency rate 100%, Limb salvage rate was 91.3%.* ***Conclusion:*** *This study successfully demonstrates a durable 1 year primary, assisted primary, and secondary patency rates as well as limb salvage rate together with good clinical, and haemodynamic outcome. Therefore, in patients with critical limb ischemia, peroneal artery angioplasty as a single vessel runoff to the foot is essential and sufficient to improve their clinical outcomes and limb salvage rate.*
Keywords: *Angioplasty; critical limb ischemia; peroneal; single runoff*

INTRODUCTION

Critical limb ischemia (CLI) usually occurs secondary to severe multilevel peripheral arterial disease. Prevention of major amputation in critical limb ischemia is arguably the most important goal and is based on the capability for restoring and maintaining straight-line tibial arterial blood flow to the foot.[1]

Revascularization by bypass surgery or endovascular therapy plays an important role in preventing major amputation, improving the quality of life, and prolonging survival in patients with critical limb ischemia. Although bypass surgery has been the standard method of revascularization because long-term patency can be achieved, this approach also can be difficult for certain patients because of poor surgical targets, lack of suitable conduits, advanced age, and presence of multiple comorbidities. Endovascular therapy also offers the advantages of local anesthesia and shorter hospital stay. The objective of below-knee limb salvage angioplasty is to restore in-line flow to the foot arches whenever possible.[2]

Few data are available regarding procedural and limb salvage outcomes of endovascular treatment for infrapopliteal occlusions. Infrapopliteal lesions could be recanalized with a high rate of success using standard guidewire techniques and that successful treatment would be associated with acceptable limb salvage rate.[2]

A direct straight-line flow to the foot through a native tibial artery is usually attempted selecting, whenever possible, the anterior tibial artery for ischemic forefoot lesions and the posterior tibial for calcaneal lesions. If neither the anterior nor the posterior tibial artery can be treated despite several crossing attempts, the alternative treatment may consist of providing direct flow along the peroneal artery.[3]

The peroneal artery is relatively spared from the terminal stages of atherosclerosis and is often the last tibial vessel to become occluded in diabetics or end-stage vascular disease.[4] The peroneal has multiple collaterals that supply the pedal arteries via anterior perforating and posterior communicating branches.[5]

The aim of this study was to assess the technical success, clinical and haemodynamic outcomes of peroneal artery angioplasty as a single runoff vessel for foot revascularization in patients with critical limb ischemia.

PATIENTS AND METHODS

Between September 2014, and January 2016, 23 patients with critical lower limb ischemia were prospectively enrolled in our study conducted at Ain Shams University hospitals. Our Inclusion criteria were patients presenting with critical limb ischemia (Rutherford categories 4, and 5) due to infragenicular atherosclerotic arterial disease with the peroneal artery as a single target vessel for foot revascularization. Exclusion criteria were patients presenting with critical limb ischemia (Rutherford category 6) with major tissue loss extending above the transmetatarsal level, patients who have patent anterior tibial or posterior tibial artery amenable for bypass surgery or angioplasty, patients presenting with acute thrombotic events, patients with associated significant lesions in the femoropopliteal or iliac arterial segments, or patients with known intolerance to contrast agents.

Clinical presentation was determined according to Rutherford - Baker scale of severity of peripheral arterial disease for chronic lower limb ischemia as specified by the Society for Vascular Surgery/American Association for Vascular Surgery reporting standards. Computed tomography angiography (CTA) was done to assess the infragenicular arterial system and to describe the peroneal artery lesion characteristics (stenosis/occlusion), and length. Our protocol to guard against contrast induced nephropathy was intravenous administration of 0.9% saline at a rate of 0.5-1ml/kg/hr for 12 hours before and after the procedure.

All procedures were performed in an operating room suite with vascular imaging capabilities. Arterial access was gained under local infiltration anesthesia through an antegrade ipsilateral common femoral artery 6Fr sheath, followed by intravenous administration of sodium heparin at a dose of 100 IU/Kg. Selective infragenicular angiography was performed through a diagnostic angiographic angled tip catheter (BERN, Imager™, Boston scientific corporation, USA) placed at the level of the popliteal artery using non-ionic contrast media (Ultravist®300, Bayer) diluted with 0.9% saline at a ratio of 1:1 to visualize the infragenicular arterial system.

Traversing the peroneal artery lesion was achieved by the aid of a hydrophilic angled tip guidewire 0.035 inch (Radiofocus® Glidewire® Terumo corporation, Japan) or a 0.018 inch steerable guidewire (V-18 Control™, Boston scientific corporation, USA) with the support of an angiographic angled tip catheter (BERN, Imager™, Boston scientific corporation, USA) or a straight support catheter (Rubicon™, Boston scientific corporation, USA). After traversing the diseased peroneal arterial segments, the angiographic catheter or the support catheter was advanced to the distal end of the peroneal artery and used to do a control angiography to visualize the terminal peroneal artery branches. Balloon dilatation was attempted using either (Admiral Xtreme™ Balloon dilatation catheter, Medtronic, USA) over the 0.035 inch guidewire or (SterlingTM Balloon dilatation catheter, Boston scientific corporation, USA) over the 0.018 inch guidewire. The choice of angioplasty balloons diameter and length was tailored according to the patient's angiographic anatomy and lesion's morphology. Completion angiography was performed to confirm satisfactory foot revascularization through the anterior perforating and posterior communicating branches (Figure 1).

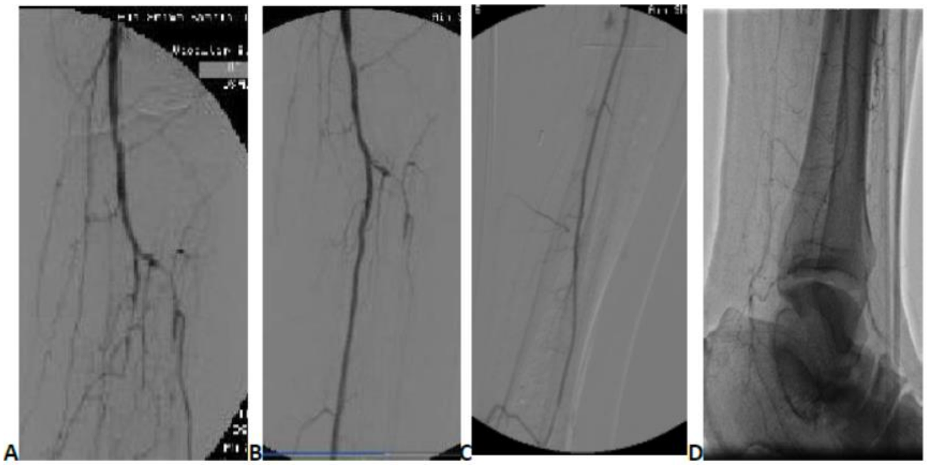


Fig. 1: (A) Peroneal artery occlusion before intervention, (B) Peroneal artery post dilatation, (C) Mid segment peroneal artery, (D) lower segment peroneal artery giving branches to the terminal posterior tibial and dorsalis pedis

Immediately after the procedure the patient was kept on therapeutic low molecular weight heparin (Enoxaparin sodium) according to body weight at a dose of 1mg/Kg subcutaneous injection every 12 hours for 2 days, Clopidogril 300mg loading dose followed by 75mg daily for 6 months, and aspirin 75mg daily indefinitely. Technical success was defined as in-line peroneal artery flow to the foot without any residual stenosis >30%, or any evidence of flow-limiting dissection, acute occlusion, or distal embolization.

Postoperative follow up was done immediately post procedure and at 1,3,6,9, and 12 months thereafter. Clinical and haemodynamic outcomes were defined according to the American Heart Association (AHA) classification which combines the Ankle-Brachial index (ABI) and Rutherford-Baker scale of severity of peripheral arterial disease for chronic lower limb ischemia (Figure 2).

Grade	*Clinical description*
3	Markedly improved; ABI > 0.9 and no ischemic symptoms
2	Moderately improved; ABI increase > 0.1 but not normal, and increase by one category
1	Minimally improved; ABI increase 0.1 but not normal, or increase by one category
0	No change
−1	Mildly worse; no category decrease or ABI increase < 0.1
−2	Moderately worse; one category worse or unexpected minor amputation
−3	Markedly worse; more than one category worse or unexpected major amputation

ABI, Ankle-brachial index.

Fig. 2: American Heart Association guidelines for clinical improvement

Duplex ultrasound was performed during the follow up period, if there was any evidence of deterioration of clinical outcomes, looking for a peak systolic velocity ratio >3.0, or visible narrowing >50% of the peroneal artery flow lumen. CT angiography (CTA) was only done in such a case where there was clinical deterioration together with duplex findings suggesting restenosis or occlusion. The decision for repeated intervention was based on the recurrence of symptoms and signs of CLI and the aforementioned duplex and CTA criteria of restenosis or occlusion.

Our primary end points were primary patency, assisted primary patency, and secondary patency of the treated arterial segment as well as limb salvage rate. Primary patency refers to the interval from the time of the original intervention until any intervention designed to maintain or re-establish patency is performed. Assisted primary patency is patency of the endovascular intervention achieved with the use of any additional procedures, as long as occlusion of the primary treated site has not occurred. Secondary patency is patency obtained with the use of an additional procedure after occlusion occurs.

Our secondary end points were local procedure related complications, and major adverse cardiovascular events (MACE).

The wound care regimen through surgical debridement was performed at each outpatient visit as indicated. If the wound appeared infected with signs of inflammation, systemic antibiotics were administered. Once the infection was cleared, routine wound care was resumed. Wound healing was considered poor when the wounds were noted to be failing to improve by 4 weeks from revascularization, or if they were noted to be worsening, or if they progressed to major amputation. Major amputation was accounted for on the basis of any amputation above the tarso-metatarsal (Lisfranc's) level.

RESULTS

Data was obtained for 23 patients (23 limbs) who underwent peroneal artery angioplasty during the study period. Demographic and clinical features of the study group are shown in (Table 1). The group consisted of 19 (82.6%) males with a mean age of 63.5 years (range: 50-76) and a high incidence of associated ischemic heart disease in 16(69.5%) patients. Diabetes mellitus was also present in 20(86.9%) patients, hypertension in 11(47.8%) patients, smoking in 14(60.8%) patients, chronic kidney disease in 5(21.7%) patients of our study group.

According to Rutherford - Baker scale of severity of peripheral arterial disease for chronic lower limb ischemia, 10 (46.8%) patients were treated for rest pain (category 4), while 13 (56.5%) patients suffered from minor tissue loss, non-healing ulcer, or focal gangrene (category 5), as shown in (Table 2).

According to the Trans-Atlantic Inter-Society Consensus Classification of Infrapopliteal Disease (TASC), all our patients were classified as TASC D (tibial or peroneal occlusions longer than 2�cm, or diffusely diseased tibial or peroneal vessels).

Lesion characteristics are shown in (Table 3), with diffusely diseased or multiple stenotic segments of the peroneal artery accounting for seven (30%) of limbs treated, while occluded peroneal artery accounting for 16(70%) of limbs treated with a mean occlusion length of 10.5 cm (range 3-15 cm).

Regarding the technical procedure details, immediate technical success was achieved in 100% (23 patients). Crossing the lesions was successful in a transluminal fashion in all seven patients with diffusely diseased or stenotic peroneal artery using the V-18 ControlTM guidewire. In the remaining 16 patients with peroneal artery occlusion, crossing the lesion was initially attempted using the V-18 ControlTM guidewire in a transluminal fashion and was successful in 12 patients. In the remaining four patients with unsuccessful transluminal passage, a subintimal guidewire passage was gained using the 0.035 inch Terumo Glidewire®. Subsequent dilatation was done either by the SterlingTM over the wire balloon dilatation catheter over the V-18 ControlTM guidewire or by the Admiral Xtreme™ Balloon dilatation catheter over the 0.035 inch Terumo Glidewire®.

We had two cases of minor peroneal artery perforations by the V-18 ControlTM guidewire during attempted transluminal passage through total occlusions and these perforations sealed nicely after successful guidewire passage and dilatation without consequences.

Clinical success, according to the AHA classification (Table 4), at 1 month showed that 16 patients (70%) had grade 2 improvement, while seven patients (30%) had grade 1 improvement. Furthermore, during the rest of the follow up period, the AHA clinical improvement showed eight patients with deterioration of clinical condition at 3, and 6 months and this clinical deterioration was further proved by duplex and CTA findings showing >50% re-stenosis of the treated peroneal artery segment in four patients and total occlusion of the treated peroneal artery segment in another four patients. Those patients were subsequently subjected to re-intervention in order to maintain or re-establish peroneal artery patency. Remarkably, the four patients who had total re-occlusion were those who were treated by the subintimal guidewire passage technique.

Minor amputations and wound debridement were attempted in 13 patients who presented with tissue loss, non-healing ulcers, or focal gangrene. Complete wound healing was achieved in 11 of these patients at the end of the study period with the remaining two patients requiring below knee amputation at 3 months follow up due to spreading infection despite the presence of a patent treated peroneal artery segment by duplex with no evidence of restenosis or occlusion.

Over the follow-up period of 12 months, there were only 2 minor groin haematomas which resolved spontaneously, and three major adverse cardiovascular events (MACE) that resulted in myocardial infarction in two patients and cerebrovascular stroke in another patient as shown in (Table 5).

Kaplan-Meier curves were used to demonstrate our patency rates and limb salvage rate. Our primary patency rate of the target treatment segment (peroneal artery) was 63.2% (Figure 3). Assisted primary patency was 81% (Figure 4). Secondary patency was 100% (Figure 5). Our limb salvage rate was 91.3% at 12 months (Figure 6).

Table 1. Demographic data

Characteristics	**N (%)**
Age	Mean 63.5 (50-76)
Gender Male Female	 19 (82.6%) 4(17.4%)
Ischemic Heart disease	16(69.5%)
Diabetes	20(86.9%)
Hypertension	11(47.8%)
Smoking	14(60.8%)
Chronic kidney disease	5(21.7%)

Table 2. Clinical presentation according to Rutherford classification

Rutherford category	N (%)
Ischemic rest pain (category 4)	10(46.8%)
Minor tissue loss (category 5)	13(56.5%)

Table 3. Peroneal artery lesion characteristics

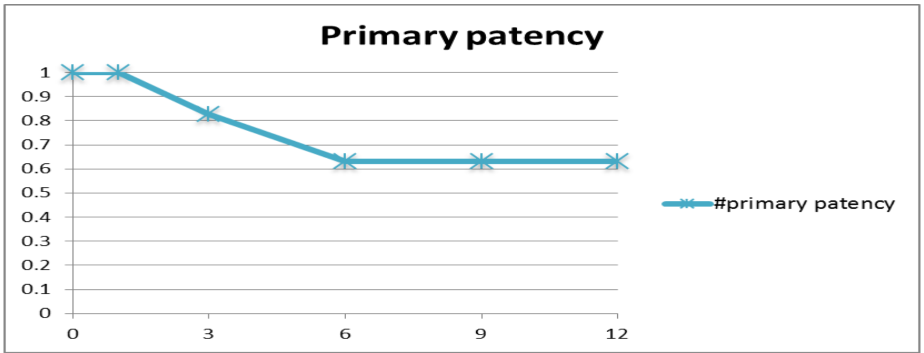
Lesion	**N (%)**
Diffusely diseased or multiple stenotic segments	7(30%)
Occlusions Mean occlusion length (range)	16(70%) 10.5cm (3-15)

Table 4. AHA clinical improvement after intervention

AHA clinical improvement	**1 month n**	**3 months n**	**6 months n**	**9 months n**	**12 months n**
+3 points	0	0	0	0	0
+2 points	16	13	15	18	18
+1 point	7	4	2	3	3
No improvement	0	0	0	0	0
Worse (-1 point)	0	4	4	0	0
Worse (-2 points)	0	0	0	0	0
Worse (-3 points)	0	2	0	0	0
Total number of patients followed	23	23	21	21	21

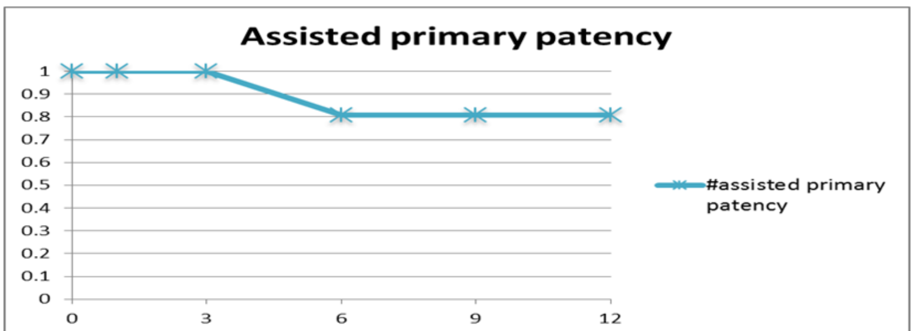
Table 5. Minor complications and MACE

	N (%)
Minor complications	2(8.7%)
MACE Myocardial infarction Stroke Death	2(8.7%) 1(4.3%) 0(0%)



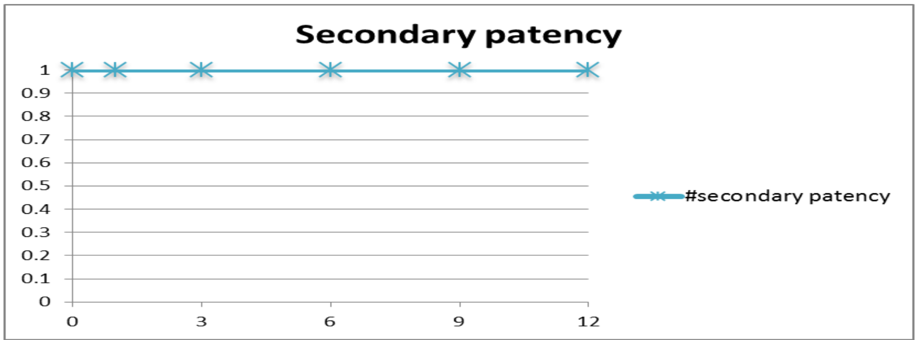
period	#risk	#censored	#stenosis or occlusion	#survived	#primary patency
0	23	0	0	23	1
1	23	0	0	23	1
3	23	0	4	19	0.826086957
6	17	2	4	13	0.631713555
9	13	0	0	13	0.631713555
12	13	0	0	13	0.631713555

Fig. 3: Kaplan Meier curve for primary patency



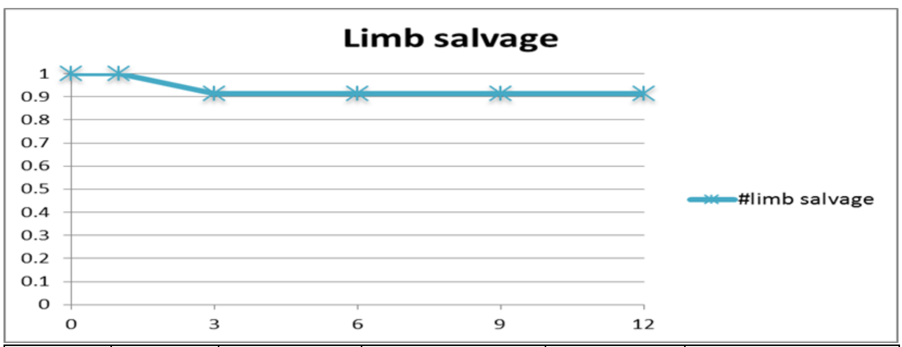
period	#risk	#censored	#occlusion	#survived	#assisted primary patency
0	23	0	0	23	1
1	23	0	0	23	1
3	23	0	0	23	1
6	21	2	4	17	0.80952381
9	17	0	0	17	0.80952381
12	17	0	0	17	0.80952381

Fig. 4: Kaplan Meier curve for assisted primary patency



period	#risk	#censored	#re-occlusion	#survived	#secondary patency
0	23	0	0	23	1
1	23	0	0	23	1
3	23	0	0	23	1
6	21	2	0	21	1
9	21	0	0	21	1
12	21	0	0	21	1

Fig. 5: Kaplan Meier curve for secondary patency



period	#risk	#censored	#re-occlusion	#survived	#secondary patency
0	23	0	0	23	1
1	23	0	0	23	1
3	23	0	2	21	0.913043478
6	19	2	0	19	0.913043478
9	19	0	0	19	0.913043478
12	19	0	0	19	0.913043478

Fig. 6: Kaplan Meier curve for limb salvage

DISSCUSION

One of the major conflicts between interventionists and vascular surgeons is the "Angiosome concept". The angiosome directed revascularization concept has gained popularity as an approach to improve limb salvage, whereby the target vessels for revascularization are chosen based on the angiosome in which the wound is located. An angiosome is a three-dimensional anatomic block of tissues fed by a specific artery. Although arterial connections exist between angiosomes, the angiosome theory posits that superior results can be achieved by revascularizing the vessel that directly feeds an angiosome in the region where there is tissue loss.

The angiosome concept is widely accepted by interventionists to improve outcomes, and some retrospective studies conducted by Neville et al[6], and Lida et al[7] have reported that the outcomes of angiosome-oriented endovascular therapy were better than those of indirect treatment. However, many vascular surgeons may criticise their results, because vascular surgeons believe that the blood supplied by bypass graft anastomosed to one foot artery is sufficient to fill the entire foot regardless of the angiosome.[8]

In bypass surgery, Azuma et al[8] in a study comparing direct and indirect foot revascularization bypass surgery, concluded that the angiosome concept seems unimportant in the field of bypass surgery. Sidawy et al[9] demonstrated no significant differences between the 6-year patency rates of bypasses to the peroneal artery compared with bypasses to the anterior or posterior tibial artery. Darling et al[10] similarly showed no differences in the 5-year patency of bypasses to the peroneal artery compared with those to the dorsalis pedis artery.

In Endovascular therapy, Dosluoglu et al[11] showed that there was no statistically significant difference in the 12-month primary patency or limb salvage of patients with peroneal artery only runoff compared with those with anterior or posterior tibial single-vessel runoff. Similarly, Abularrage et al[12] found that patients with critical limb ischemia and peroneal artery only runoff (PAOR) have similar long-term outcomes compared with non-PAOR patients. Furthermore, patients with critical limb ischemia and single vessel runoff can achieve excellent limb salvage with close surveillance and aggressive reintervention.

Our results, compares nicely to these two landmark studies with our primary patency for peroneal artery revascularization at 12 months 63.2%, assisted primary patency 81%, and limb salvage rate 91.3%. Dosluoglu et al[11] had a primary patency for peroneal artery revascularization at 12 months 73%, assisted primary patency 89%, and limb salvage rate 80%. Similarly, Abularrage et al[12] had a primary patency for peroneal artery revascularization at 12 months 61%, assisted primary patency 94%, and limb salvage rate 87%.

In our study, 86.9% of patients were diabetic and this relatively high incidence correlates with Abularrage et al[12] study where diabetic patients constituted 69% of its patients. This is probably attributed to the effect of diabetes on the infrapopliteal vasculature as it is a significant risk factor for peripheral arterial disease.

In our study, two patients had a major below knee amputation 3 months after intervention. It is worth mentioning that amputation was indicated in those two patients because of extensive spreading infection despite patent treated peroneal artery. Remarkably, those two patients were end stage renal disease (ESRD) and dialysis dependent. This association between poor outcome and ESRD is supported by Lida et al[7] who adopted the fact that CLI patients with ESRD commonly present with long diffuse arteriosclerotic disease below the knee. Similarly, Azuma et al[8] highlighted the poorer outcomes in patients who are having an indirect below the knee surgical bypass not directly related to the angiosome affected, and postulated that the severe arterial disease associated with ESRD has probably involved the connecting arterial network between tibial vessels.

Finally, Norihiro et al[13] in their study concluded that the achievement of double vessel inflow to the wound by double tibial artery revascularization positively affects wound healing, particularly in severe CLI patients. On the other hand, other study by Rafael et al[14] concluded that it is not necessary to treat the largest number of arteries possible in CLI patients. Instead, the most amenable artery for endovascular procedures should be treated to improve limb salvage and secondary patency rates. Also another study by Jeremy et al[15] concluded that a multiple vessel intervention does not improve outcomes when compared to a single vessel intervention following infrapopliteal angioplasty for CLI.

Specific angiosome vessel should be considered when selecting target arteries. However, it is often difficult to recanalize below the knee vessels based on the angiosome concept. Thus, in these cases, interventions should focus on vessels that are easy to treat and should establish one straight-line flow to the pedal arch, regardless of the angiosome concept.

In conclusion, among patients with critical limb ischemia, peroneal artery angioplasty as a single vessel runoff to the foot is essential and sufficient to improve their clinical outcomes and limb salvage rate.

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