

Assessment of the Outcome of the Infragenicular Balloon Angioplasty for Limb Salvage in Patients with Critical Lower Limb Ischaemia (CLI)

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Abstract: Aim: The aim of this study was to evaluate the results of percutaneous transluminal balloon angioplasty in patients suffering from infragenicular arterial diseases in patients with critical lower limb ischaemia. **Patients and methods:** From March 2008 to June 2011, 32 patients with critical lower limb ischaemia (40 infragenicular lesions) were treated by percutaneous transluminal balloon angioplasty, clinical results and patency were evaluated by means of symptoms assessment, Ankle Brachial Pressure Index (ABPI) and duplex scanning at discharge and at 1, 3, 6, 12 and 24 months after angioplasty. **Results:** 40 lower limb arterial lesions (Infragenicular) in 32 patients presented with critical lower limb ischaemia were treated by balloon angioplasty, the age of the patients range from 50 to 72 years (mean age 61 years), the period of follow up range from 12 to 24 months, the primary patency rates were 95%, 87.5%, 80%, 70% and 65% at 1 month, 3 months, 6 months, 12 months and 24 months respectively, while the limb salvage rates were 95%, 95%, 90%, 85% and 80% at 1 month, 3 months, 6 months, 12 months and 24 months respectively. **Conclusion:** Primary infragenicular balloon angioplasty for limb salvage in patients presented with critical lower limb ischaemia represents an efficacious method to improve wound healing if present and to improve rest pain taking into consideration the fragile nature and co-morbidities in such patients.

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1. Introduction

Atherosclerotic occlusive disease of the infragenicular arteries is increasingly recognized as a major contributor to CLI^{1,2}.

Critical limb ischaemia occurs when the blood flow to the leg is insufficient to maintain the metabolic requirement of the tissue in the resting state, it is usually categorize 4-6 of the Rutherford classification^{3,4}.

Rest pain, ulceration and gangrene of the foot or distal extremity indicate CLI, untreated critical limb ischaemia most commonly leads to amputation⁵.

For most vascular surgeons tibial lesions represent the most challenging territory for angioplasty either because of clinical considerations as usually most of these patients are suffering from critical lower limb ischaemia with a high potential for limb loss⁶.

The therapeutic efficacy of Percutaneous Transluminal Angioplasty (PTA) has not been clearly defined⁷.

For this category of fragile patients world over, the features of the disease/ morbidity, involving extended inflammation and tissue loss, make them somewhat reluctant to undergo revascularization^{8,9}.

However, increasing contemporary reports are to date proposing primary angioplasty as a feasible procedure in most patients with optimal clinical results¹⁰⁻¹².

Studies of PAT in CLI have involved very heterogeneous patient populations and this limits our

knowledge of the value of PTA in particular patient subsets^{13,14}.

Many of the published studies included diabetic and non diabetic patients, different clinical presentations of ischaemia (claudication, rest pain and tissue loss) and PTA of the above- the- knee or below- the- knee vessels performed in the same setting^{15,16}.

2. Patients and Methods

From March 2008 to June 2011, 32 patients presented with 40 infragenicular arterial lesions treated with Percutaneous Transluminal Angioplasty (PTA), the patients included in this study with the following parameters (1) Critical lower limb ischaemia (Rutherford categorize 4,5,6). (2) Infragenicular arterial lesions with collateral distal refilling of at least one of the foot vessels. (3) Absence of concomitant supragenicular significant (> 30%) arterial lesions, all patients included in this study were subjected to full medical history, clinical examination and investigations including haemodynamic assessment of the lesions by measurement of the Ankle- Brachial Pressure Index (ABPI), duplex scanning and conventional arteriography to estimate the (lesion site, lesion type whatever stenosis or occlusions, calcified lesions and the status of run off vessels).

A total of 32 patients (26 males and 6 females) ranging in age from 50 to 72 years (mean age 61 years).

Patient demographic data including risk factors were collected as follow: 20 patients were diabetics, 18 patients had ischaemic heart disease, 20 patients were smokers, 16 patients were hypertensive and 16 patients had a high profile lipid, clinical criteria including Rutherford category at base line and during follow up were collected and analyzed. Lesion morphological criteria including lesion severity (occlusion or stenosis) and length were recorded.

The procedure was done under local anaesthesia in a vascular surgery room with a mobile c-arm with vascular imaging capabilities, procedural tools were invariably, a 6-f introducing sheath, a 4-f angiographic catheter (vertebral, cordis), 0.035 hydrophilic guidewire (terumo) and 0.014 guidewire, long tibial balloons (amphirion deep, invatec), stents when needed (chromis deep, invatec), the puncture site was inspected before discharge and the ABPI was measured within 24 hours of angiography and compared with the procedural value. Immediate technical success was defined as residual angiographic stenosis of < 30% of the target lesion with an inline flow in at least one tibial vessel down to the foot. Postprocedure, any minor amputations needed were to be done within 48 hours of the procedure, together with recording of peri-procedural adverse events.

The patients were evaluated at 1, 3, 6, 12 and 24 months following the procedure for:- 1. Sustained clinical improvement based on Rutherford upward categorical shift with absence of rest pain and/ or progressive tissue healing. 2. Haemodynamic outcome based on pulse volume recording (PVRs). 3. Freedom from major amputation. The ABPI was recorded at each visit, if clinically warranted, duplex scanning or arteriography were done.

3. Results

In this study between March 2008 to June 2011, 40 infragenicular arterial lesions in 32 patients (26 males and 6 females) presented with critical lower limb ischaemia were treated with percutaneous transluminal balloon angioplasty, the age of the patients at the time of angioplasty range from 50 to 72 years with mean age 61 years, the period of follow up range from 12 to 24 months, 32 patients included in this study 26 males "81.2%" and 6 females "18.8%" with a remarkable association of diabetes in 20 patients "62.5%", smoking in 20 patients "62.5%", Ischaemic Heart Disease (IHD) in 18 patients "56.2%", hypertension in 16 patients "50%" and hyperlipidaemia in 16 patients "50%". Table (1) summarizes the patient's demographic data and risk factors.

The patient's clinical criteria at the time of angioplasty according to Rutherford category 4 (rest pain) was in 6 patients and Rutherford category 5 (minor tissue loss) was in 16 patients and Rutherford category 6 (major tissue loss) was in 10 patients.

The peroneal artery was the most commonly treated artery in 18 limbs (45%), the posterior tibial artery in 12 limbs (30%), while the anterior tibial artery in 10 limbs (25%), the stenosis treated in 22 lesions (55%) with mean stenotic length 8cm, while the occlusion treated in 18 lesions (45%) with mean occlusion length 10 cm.

The technical characteristics of the procedure regarding guidewire passage plane through the lesion were determined by the operator according to the guidewire- lesion interaction under fluoroscopic guidance, out of 40 procedures, 30 "75%" of the lesions were treated by a transluminal approach and 10 "25%" of the lesions were treated by a subintimal approach, the stents were used in 4 lesions due to occlusive dissection or ostial residual stenosis, 3 of which in the tibio- peroneal segment and one in the anterior tibial artery.

The technical success rate was 92.5%, technical failure occurred in 3 lesions due to inability to cross a highly calcified total occlusion and femoro- distal bypass was done one week after intervention.

There were 2 cases of post procedure groin haematoma that did not required any special treatment and 2 cases of myocardial infarction during the first week after the procedure, 2 patients underwent major amputation (one below knee and one above knee) the first after 5 months of the procedure and the second after 18 months, one patient escaped during the period of follow up at 12 months after the procedure.

Two patients died, one patient 2 months after the angioplasty and the other at 14 months after the angioplasty, so the patient survival rate was 93.8%. During the period of follow up, there is a clinical improvement based on Rutherford upward categorical shift with absence of rest pain and / or progressive tissue healing.

Also long occlusion (>5cm) showed lower patency rates than short occlusion (< 5cm), so the primary patency rates in short occlusion (13 lesions) were 69.2% at one year 69.2% at two years, while the primary patency rates in long occlusion (5 lesions) were 60% and 40% at one and two years respectively .

The risk factors affect the patency rate, so the primary patency rate was higher in non diabetics, non smokers, non hypertensive, -ve history of hyperlipidaemia and -ve history of ischaemic heart disease.

The primary patency rates were 95, 87.5, 80, 70 and 65% at 1, 3, 6, 12 and 24 months respectively, while the limb salvage rates were 95, 95, 90, 85 and 80% at 1, 3, 6, 12 and 24 months respectively.

Criteria of success and failure

- Technical success is defined as restored patency of the vessel with an angiographic residual diameter stenosis of < 30% of the target vessels

with an inline flow in at least one tibial vessel down to the foot.

- Clinical success is defined as some combination of symptomatic improvement and objective haemodynamic success.
- Haemodynamic success is defined as an increase in the ABPI of more than 0.10.
- Haemodynamic failure occurred if the ABPI declined or the rise was < 0.10 or if the stenosis or occlusion occurred confirmed by duplex scanning or arteriography.

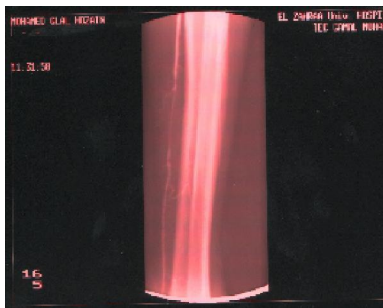
Table (1): Patient's demographic data and risk factors.

Variables	Number of patients "32"	%
Gender:		
Males	26	81.2%
Females	6	18.8%
Diabetes	20	62.5%
Smoking	20	62.5%
- X smokers	12	37.5%
-Current smokers	8	25%
Ischaemic Heart Disease	18	56.2%
Hypertension	16	50%
Hyperlipidaemia	16	50%

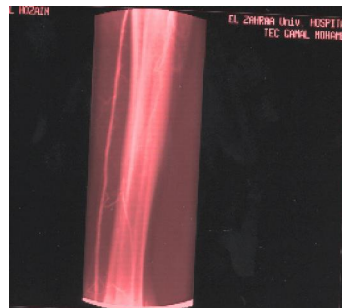
Table (2): Relation between type of stenosis and primary patency rates

Type of stenosis	Number of lesions (22)	Primary patency rates									
		1 month		3 months		6 months		12 months		24 months	
		No.	%	No.	%	No.	%	No.	%	No.	%
Focal stenosis	14	14	100	13	92.5	12	85.7	11	78.5	10	71.4
Multiple stenosis	8	7	87.5	7	87.5	6	75	5	62.5	5	62.5

There was a significant relation between the type of stenosis and patency rates, multiple stenosis showed lower patency rates than that of focal stenosis.

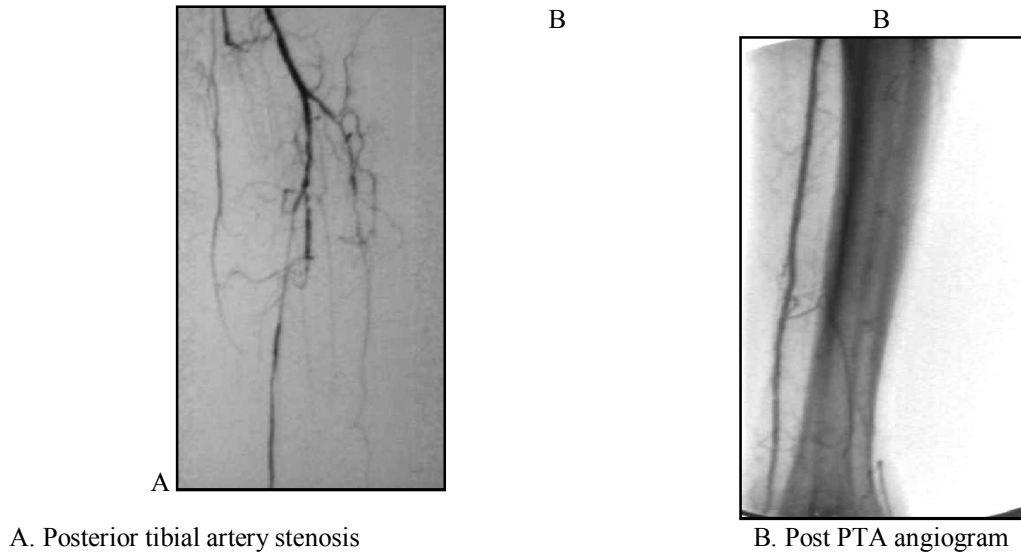
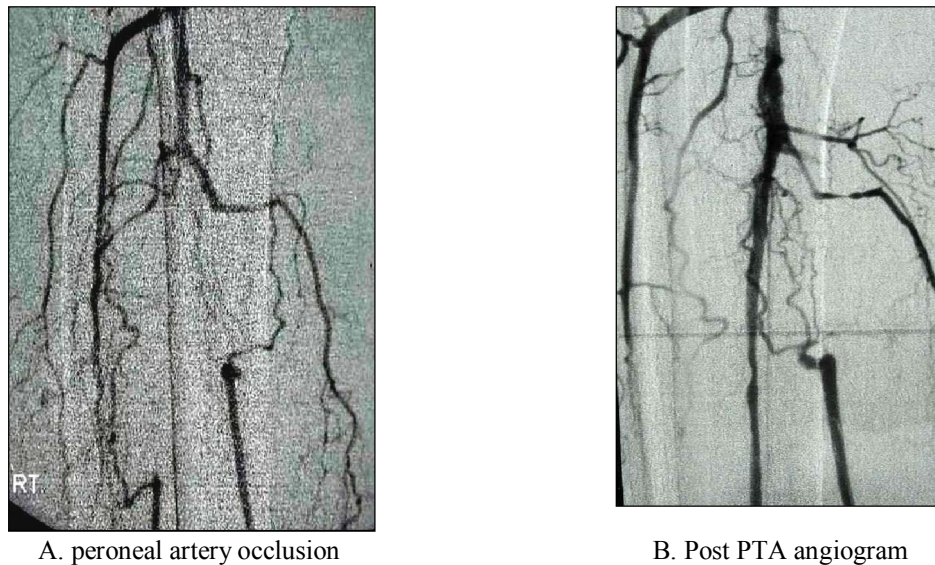


A. left posterior tibial artery occlusion



B. Post PTA angiogram

Fig. (1)

**Fig. (2)****Fig. (3)**

4. Discussion

Bypass surgery using outflow vessels in the distal ankle and foot is considered the standard of care in patients with critical limb ischaemia due to below knee vessel disease¹⁷.

However it needs a good vein conduit and at least one open foot artery, and is associated with 0.9% perioperative mortality, 3% myocardial infarction or acute congestive heart failure, and 6.6% early reoperation for graft thrombosis, postoperative bleeding or infection¹⁸.

For these reasons, infrapopliteal PTA is currently proposed as the primary treatment for critical limb ischaemia¹⁹.

Many published papers have described interesting finding concerning the efficacy of the endovascular treatment of peripheral artery disease²⁰⁻²³.

The technical success rate in this study was 92.5%, technical failure occurred in three lesions due to inability to cross a highly calcified total occlusion, femoro- distal bypass was done using *in situ* great saphenous vein graft after one week of intervention with successful outcome.

Johnston²⁴ reported that the technical success rate in stenosis is greater than 90% and in occlusions 80.8%. Greenfield²⁵ reported that the technical success rate was 88%.

In our study, the primary patency rate in stenosis is better than that in occlusion and in focal stenosis than that of multiple stenosis, also the primary patency

rate in short segment of occlusion (less than 5cm) is better than that of long segment of occlusion (more than 5 cm).

The primary patency rate in stenosis is better than that with occlusion²⁶.

The cumulative clinical success in single stenosis is higher than that of multiple stenosis²⁷.

The treatment of longer (> 5cm) stenotic or occlusive lesions is often more complex, associated with worse prognosis and require more experience with good quality imaging equipment²⁸.

In our study, the limb salvage rates were 95, 95, 90, 85 and 80% at 1, 3, 6, 12 and 24 months, respectively.

Schwarten²⁹ Performed 146 infrapopliteal angioplasties on 96 patients and reported 1 and 2 years limb salvage rates of 88% and 83% respectively.

Ingle *et al.*,³⁰ found that the limb salvage rate of 85% after one year.

Conclusion:

Limb salvage should be the goal in patients with critical limb ischaemia caused by infragenicular occlusive diseases, as amputation has a serious impact on the patient's quality of life, any type of revascularization that can preserve the limb has to be considered. Angioplasty can be considered the first line therapeutic modality especially in stenotic and short occlusive lesions, lack of venous conduit, spreading infection and in elderly patients who are unfit for surgery, also morbidity and mortality rates are lower with angioplasty than with traditional bypass surgery. Angioplasty do not prohibit future bypass surgery or additional treatments and therefore be considered the primary approach in this group of patients.

A combination of angioplasty and surgery is often required for complex or multilevel disease, skills in both treatment modalities are required to provide optimal treatment for all patients. Immediate angiographic success can only be determined using flow and not static angiographic images, long-term outcome is best if straight line flow to the foot is obtained in at least one vessel.

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