Outcomes of infrapopliteal angioplasty in patients with critical limb ischemia

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Abstract

Background: Critical limb ischemia is the natural endstage in many patients with atherosclerotic chronic lower limb ischemia. Most of these patients are risky for major surgical revascularization procedures. Infrapopliteal angioplasty can represent an alternative procedure to the popliteal to distal bypasses in such group of patients.

Aim of the study: To evaluate the efficacy ofinfrapopliteal angioplasty in management of patients with critical limb ischemia.

Patients and methods: 48 limbs in 47 patients with critical limb ischemia, secondary to atherosclerosis involving the tibial vessels, underwent treatment with tibial angioplasty.Immediate technical success, sustained clinical improvement based on Rutherford upward categorical shift, and limb salvage rates were assessed and recorded.

Results: 75% of involved patients belonged to category 4-6 of Rutherford classification. 63% had pure tibial disease and 37% had a concurrentfemoropopliteal multilevel disease. 92% of tibia/lesions were classified as TASC D lesions. Immediate technical success was recorded in 44 limbs (91.6%). Sustained clinical improvement and limbs salvage rates were 100%, 92%, 84% and 77% at 1, 3, 6 and 12 months, respectively.

Conclusion: Infrapopliteal angioplasty represents an effective method in treating patients with critical/ower limb ischemia.

Introduction:

Patients with critical limb ischemia (cLn represent the most advanced stage of chronic ischemia. These patients often have diffuse disease affecting multiple levels including the infrapopliteal vessels.l

A substantial portion of these patients, requiring arterial revascularization, do not have adequate saphenous vein, and the alternative conduits have inferior patency and limb salvage rates.[2]

CLI also reflects an advanced, systemic form of atherosclerotic disease that renders the patients at high risk for complications after open surgical revascularization.[3]

Aim of the study:

Was to evaluate the efficacy and safety of infrapopliteal angioplasty in the management of patients with CLI.

Patients and methods:

A prospective study involved 48 limbs in 47 patients was done in Ain Shams University hospitals and Al-Ahssa Hospital, Saudi Arabia, during the period between March 2008 and March 2010 analyzing the outcomes of infrapopliteal angioplasty.

All patients enrolled in this study had one of the presentations of CLI that was defined by the European consensus document as the presence of ischemic rest pain requiring opiate analgesia for at least 2 weeks, ankle systolic pressure lower than 50 mmHg and/or toe systolic pressure lower than 30 mmHg or the presence of ischemic ulcer or foot gangrene.[4]

The expected underlying pathology was atherosclerosis and the involved vessels were either the tibial vessels alone or in concurrent with femoropoplitealleslons.

Any patient had one of the following criteria was excluded from the study:

1- Patients not fulfilling criteria of CLI.
2- Patients with functionally unsalvageable limbs.
3- Underlying pathology rather than atherosclerosis e.g. Burger's disease.
4- Patients with no runoff.
5- Patients with chronic renal impairment with S.creatinine>1.5 mg% (contraindication for usage of contrast).

All patients were submitted to a thorough physical examination with special care to the pulse deficits, Doppler evaluation and ankle brachial index (ABI).

The tibial disease was evaluated using multislice CT angiography or digital subtraction angiography.

The lesion anatomy (presented in the angiography) was assessed according to the Trans-Atlantic Inter-Society Consensus II (TASC II) criteria5 as shown in Table(l).

Table (1): TASC II classification for infrapopliteallesions.

Classification	Lesion characteristics
TASCA	Single stenosis < I em long.
TASCB	Multiple focal stenosis < 1 em long or 1 or 2 stenosis < 1 em long involving the trifurcation.
TASCC	Stenosis I to 4 em long, occlusion 1 to 2 em long or extensive disease involving the trifurcation.
TASCD	Occlusion > 2 em long or diffusely disease artery.

The lesions were classified according to the target vessel to be treated which was the most likely to provide an inline flow down to the foot. In case of the presence of simualtneous stenotic and occlusive lesions or two lesions of the same type but with varying lengths, we classified the lesion according to the most severe lesion type.

Periprocedure medications:

All patients were given clopidogril 75 mg/day one week before the procedure. If it was not possible to start clopidogril before the procedure, it was given as a loading dose of 300 mg once at the morning of the procedure. Clopidogril was maintained as 75 mg daily for 3 months combined in the first week with a weight based dose of low molecular weight heparin (LMWH) in therapeutic doses.

After 3 months all patients were maintained on aspirin 100mg daily for life.

Procedure:

An arterial access was obtained using a 6F sheath through an antegrade ipsilateral approach. Retrograde contralateral access was used; if there was a concurrent proximal superficial femoral artery (SFA) lesion.

Lesions were crossed with a 0.035 inch hydrophilic wire. A 0.014 or 0.018 inch platinum tipped wires were used if the 0.035 wire could not be navigated through the lesion.

Subintimal procedures Figure(l) were used only if the transluminal approach failed Figure(2).

All patients were anticoagulated with systemic heparin during the procedure.

Angioplasty was performed using a balloon diameter of 2-3 mm, whereas 4 mm balloon diameter was used in the tibioperoneal trunk. Long balloons (10-22 em) were used to prevent arterial injury or dissection.

The development of flow limiting dissection or persistence of> 30% residual stenosis were the indications for using nitinol self-expandable stents (at level of tibioperoneal trunk) or coronary balloon mounted stents (distally at tibial vessels).

Defmitions used:

-Technical success: No or residual stenosis of < 30% with an inline flow in at least one tibial vessel down to the foot.
-Multilevel intervention: Femoropopliteal

interventions in conjunction with tibial interventions.

-Multivessel intervention: Intervention in more than one tibial vessel.

-Clinical success: Improvement of rest pain or progressive healing of the wounds.

Postoperative follow up:

All patients were followed up for one year. Failure of primary patency was considered if symptoms recurred in the face of worsening ABI due to recurrence of the lesions.6

Patients with recurrent symptoms secondary to progression of the disease in the iliac or femoropopliteal segments were considered as clinical failures but not failure of primary patency.

Also, patency was considered to be failed if surgical bypass was needed to save the limb or post procedure major amputation was needed.

Statistical method used:

Kaplan-Meier methodology was used to assess the outcomes of the procedure.

Results:

In this study, the tibial angioplasty was used to treat 48 limbs in 47 patients. The demographic and clinical data of these patients are summarized in Table(2).

Table (2): Demographic data of the patients.

Variable (n=47 patients)	Number(%)
Average age	65 years ±10
Male gender	33 (70%)
Diabetes mellitus	47(100%)
Hypertension	35(74%)
Ischemic heart disease	30 (63%)
Congestive heart failure	4(8%)
Current smoker	33(70%)
Hyperlipidemia	30(63%)

Clinical stratification of the patients enrolled in our study, according to Rutherford categories,? showed 2 patients (4%) enrolled as category 4 (rest pain), 10 patients (21%) as category 5 (minor tissue loss) and 36 patients (75%) as category 6 (major tissue loss).

30 patients (63%) had pure tibial disease and 18 patients (37%) had a concurrent femeropopliteal multilevel disease. The anterior tibial artery was the most commonly treated artery with a 64% predominance, the posterior tibial artery was our target vessel in 54% of treated limbs and the peroneal artery in 56% of the cases.

Table(3) summarizes the lesion characteristics and the procedures done in the treated 48 limbs.

Table (3): Lesion characteristics and procedures done.

Variable (n=48 Limbs)	Number (o/o)
Lesion characteristics	n=48
-TASCA	1(2%)
-TASCB	1(2%)
-TASCC	2(4%)
-TASCD	44(92%)
Tibial lesion characteristics	
-Stenosis (mean length 4 em)	4(8%)
- Occlusion (mean length 15 em)	44(92%)
Femeropoplitealleslon characteristics	n=l8
-Stenosis	0
-Occlusion	18(100%)
Multivessel intervention	n=31
- Three vessels	5(16%)
- Anterior tibial and peroneal	9(29.5%)
- Anterior tibial and posterior tibial	8(25%)
- Posterior tibial and peroneal	9(29.5%)
Single vessel run off	n=l7
- Anterior tibial only	9(53%)
- Posterior tibial only	4(23.5%)
- Peroneal only	4(23.5%)
Stents placed	n=l4
- Femoropoplitealleslons	13(72%)
-Tibial lesions (ATA)	1 (2%)
Mutlilevel intervention	n=l8

We achieved an immediate technical success in 44 limbs (91.6%) with only 4 failures. In these failures, the tibial vessels were totally occluded and calcified that can't be crossed by the wires. Two of these patients underwent surgical bypass while the other two patients had primary amputations.

(A) (B) (C) (D)

(E) (F)

Figure (1): (A) Anterior tibial artery occlusion just distal to the origin, (B) Guide wire loop in the subintimal space, (C) Successful anterior tibial artery re-canalization, failed attempt for posterior tibial artery canalization, wire loop in the subintimal space (D) Patent dorsalis pedis artery, (E) Gangrenous third toe (before re-canalization), (F) Minor amputation of the second and third toes, arrest of gangrenous process with proximal limb salvage.

(A) *(B)* *(C)*

(D) *(E)*

Figure (2): (A) Left posterior tibial artery showing significant stenosis (1em) at lower 1/3 and complete occlusion (3cm) distally. (B) Balloon dilatation. (C) Successful regaining of straight-line blood flow through the stenotic and occluded segments. (D) Left transmetatarsal amputation one day after PTA. (E) Complete healing of the stump 3 months after PTA.

Clinical improvement was observed in 35 limbs based on Rutherford upward categorical shift with absence of rest pain and/or progressive tissue healing together with improved ABI.

Sustained clinical improvement based on Rutherford upward categorical shift is represented by the Kaplan-Meier curve **Figure(3)** which shows a sustained clinical improvement of 100%, 92%, 84% and 77% at 1, 3, 6 and 12 months, respectively.

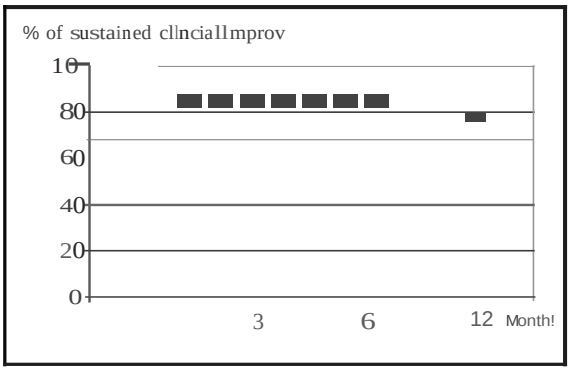

Figure (3): Kaplan-Meier curve showing sustained clinical improvement.

Follow up of the haemo-dynamic outcome showed an improvement in 95%, 85%, 71% and 42% of patients at 1, 3, 6, and 12 months, respectively.

The limb salvage rate in technically successful cases was 100%, 92%, 84% and 77% at 1, 3, 6 and 12 months, respectively.

Table(4) shows the end points of the study and their incidence.

Table (4): End points of the study.

Endpoint	Number(%)
Below knee amputation	3(6%)
Above knee amputation	1(2%)
Surgical bypass	2(4%)
Death	7(15%)

Complications:

The overall mortality was 7(15%), however the deaths were due to progression of concurrent comorbidities as cardiac and pulmonary diseases. No cases developed large groin hematoma. Contrast nephropathy occurred in 4(8%) patients and non of them required dialysis.

Discussion:

Bypass surgery using the outflow vessels in the distal ankle and foot was considered the standard line of treating patients with CLI secondary to tibial disease.8 However, it needs good vein conduit and is associated with 0.9% perioperative mortality, 3% cardiac morbidities and 6.6% graft thrombosis.9

For these reasons, in:frapopliteal angioplasty is currently proposed as the primary line of treatment of patients with CLI.lO

This study was conducted on a selected patient population with CLI secondary to infragenicular arterial disease in order to precisely evaluate the clinical outcomes of angioplasty in tibial vessels.

Our studied population consisted of a very homogenous group of predominantly male patients with a mean age of *65* years and or remarkable association of diabetes mellitus, hypertension and ischemic heart disease with in:fragenicular diffuse multiple occlusive lesions rather than focal stenotic lesions.

The limb salvage rate at one year in this study was higher than that of the patency rate. This can be explained as the temporarily recanalized vessels increase the blood flow to the foot that had a positive effect in eradicating infection and healing ulcers. The healed foot has a lower oxygen demand, so less blood flow is generally required to maintain tissue integrity and keep the limb asymptomatic.ll

The results obtained by a study done by Soder et al.ll on 72 limbs showed an initial technical success rate of 61% and 18 months patency and limb salvage of 48% and 80%, respectively.

Similarly, Vraux et al.,12reported a technical success rate of 78% and a one-year primary patency rate of 58%.

In our study, the initial success was 91.6% which was higher than the previous trials.This may be explained by the advances in the wire's and balloon's technology nowadays which was not present in previous trials that were done on year 2000.

Our results were similar to that obtained by a large trial done on 443 patients by Boisers et ai.,lO who reported a one-year patency of 74% and limb salvage rate of 96%. These results led them to predict that tibial angioplasty would become the first line therapy for CLI.

Conclusion:

Angioplasty of the infragenicular vessels represents an effective method in treatment of CLI and should be the first treatment option in those patients who would, otherwise, be offered distal bypass surgery or amputation,

taking into consideration the fragile nature and co-morbidities in such patient population.

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