

Assessment of Primary Patency of the Tibial Vessels After Below the Knee Angioplasty Using Long Peripheral Balloons and Its Effect on Limb Salvage in Comparison to Using Short Balloons for Tibial Angioplasty in Previous Literature

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Aim: To assess the primary patency of the tibial vessels after using long dilatating balloon catheters in below the knee angioplasty in patients with critical limb ischemia, and its effect on limb salvage rates. These results were compared with previous literature results of treating tibial lesions using short balloon catheters.

Patients & methods: Twenty (20) patients with critical lower limb ischemia essentially attending the vascular out-patient clinic and the emergency department of Ain Shams University Hospitals from December 2012 till December 2014 were included in the study. Patients were treated by long balloon catheter and the primary patency of this procedure, and its effect on limb salvage were assessed.

Results: The technical success rate was 95%, while primary patency rate after one year was 75% for patients treated by long balloon catheters for multi-segmental long tibial lesions in below the knee angioplasty. Limb salvage rate was 90% after one year. Comparison with results from previous literature using short balloons in the treatment of tibial lesions revealed no significant difference as regard technical success rate, primary patency rate or limb salvage rate.

Conclusion: Infrapopliteal angioplasty with a long balloon was feasible, with encouraging midterm outcome, in the treatment of severe limb ischemia. The advantage of long balloons is that it can easily treat complex long lesions with a single balloon covering complicated anatomy of the most of the lesion area, resulting in better arterial remodeling, also, decreased procedural time and decreased radiation exposure.

Key words: Below-the-knee lesion, critical limb ischemia, endovascular treatment.

Introduction:

Peripheral arterial disease (PAD) is a major world-wide health problem affecting 12%–14% of the general population, and its prevalence increases with age, affecting as many as 20% of patients older than age 75 years. Several significant risk factors contribute to the development and progress of PAD including diabetes mellitus, hypertension, hyperlipidemia & smoking.¹ Atherosclerosis develops at a younger age in patients with diabetes and progresses rapidly.

Moreover; atherosclerosis affects more distal vessels in patients with diabetes. The profunda femoris, popliteal and tibial arteries are more frequently affected, while the aorta and iliac arteries are minimally narrowed.² Chronic critical lower limb ischemia develops when the arterial blood flow is severely reduced to maintain the necessary requirement of normal tissues metabolism. It can be manifested clinically as rest pain, non-healing wounds or tissue loss (necrosis or gangrene).³

Tibial angioplasty has acceptable rates of

limb salvage in patients with CLI considered to be at high risk for surgery, despite high recurrence rates. The procedure has low morbidity and mortality with lower cost compared with open revascularization. Aggressive angioplasty should be an option to patients who otherwise would face primary amputation.⁴

Infra-popliteal percutaneous transluminal angioplasty (PTA) with new dedicated below-the-knee (BTK), long tapered balloon (>15 cm) in patients with critical limb ischemia (CLI) is feasible, safe and associated with favorable clinical results at both acute and mid-term follow-up.⁵

Patients and methods:

Twenty (20) patients with critical lower limb ischemia were enrolled in the study. Patients included in the study were essentially attending the vascular out-patient clinic and the emergency department of Ain Shams University Hospitals from December 2012 till December 2014. Patients were treated by long balloon catheter and the primary patency of this procedure was assessed and its effect on limb salvage.

The inclusion criteria of these patients were:

1. All patients aging >35 years, presenting with manifestations of critical limb ischemia which is defined as patients presenting with ischemic rest pain and tissue loss in the form of non healing ulcers or gangrene.
2. The diseased segment of the arterial tree of the lower limbs is at the level of the infrapopliteal arterial system (whether single or multiple lesions).
3. The diseased arterial segment may be occlusion(long \leq 5 cm), stenosis(long \leq 5 cm, significant >50% or tight >75%) or both occlusion and stenosis.

4. Patients unfit or refusing surgical infrapopliteal reconstruction.

The exclusion criteria were:

1. Patients presenting with acute lower limb ischemia.
2. Patients refusing to be included in the study.

3. Patients with associated suprapopliteal arterial diseases.

4. Patients with chronic renal impairment (not on hemodialysis)

Every patient was subjected to:

1. History taking: In the form of: (1) Personal history including special habits specially smoking history; (2) Complaint: With special attention to onset, course, and duration of the complain; (3) History of present illness

2. Clinical examination: Including general and local examination with recording of the ankle/brachial index of the affected side

3. Laboratory investigation: With special attention to kidney functions.

4. Duplex Scanning and or CT angiography

5. All patients were given Clopidogrel (Plavix) 150 mg 6 hours before the procedure.

Procedure:

1. The procedure was done under local infiltration anesthesia with antegrade puncture of the common femoral artery of the affected site while the patient was in the supine position.

2. Seldinger technique was used with introduction of a 6 F (Prelude[®], MeritMedical) sheath. Diagnostic angiogram was done to select the area for intervention using non ionic contrast media, evaluation of the lesion was done again to be sure that it still matches the criteria for intervention.

3. A 0.018 J shaped guide wire (Terumo[®], Terumo corporation) was manipulated to cross the lesion as much as possible distal to the lesion, this negotiation with the lesion was done by a combination of 4F or 5F guiding catheter (Performa[®], MeritMedical).

4. After crossing the lesion, the balloon was introduced. Balloons were from 2-4 mm in diameter with length ranging from 150-300 mm according to length of the lesions. The length of the balloon extends over the entire length of the lesion. The balloon catheter was advanced into position over the guide wire using fluoroscopy with the aid of "road map". The balloon was slowly inflated by diluted

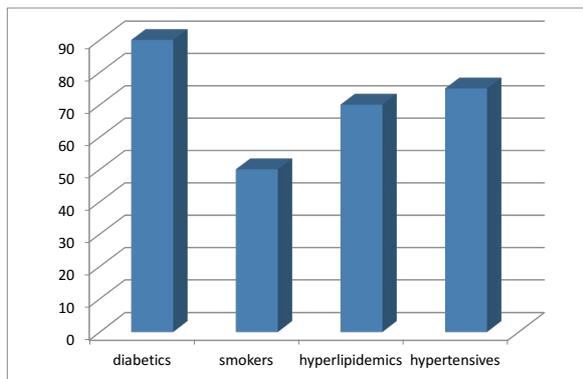


Figure (1): Risk factor assessment of the study group.

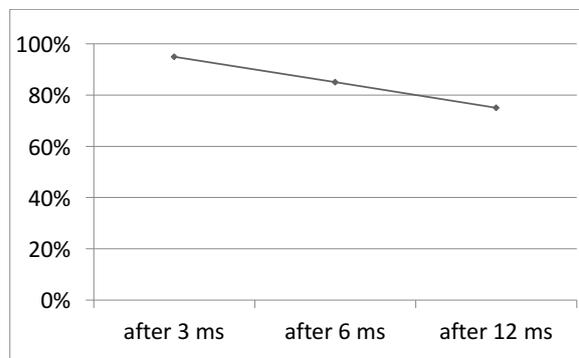


Figure (2): Primary patency rate over one year.

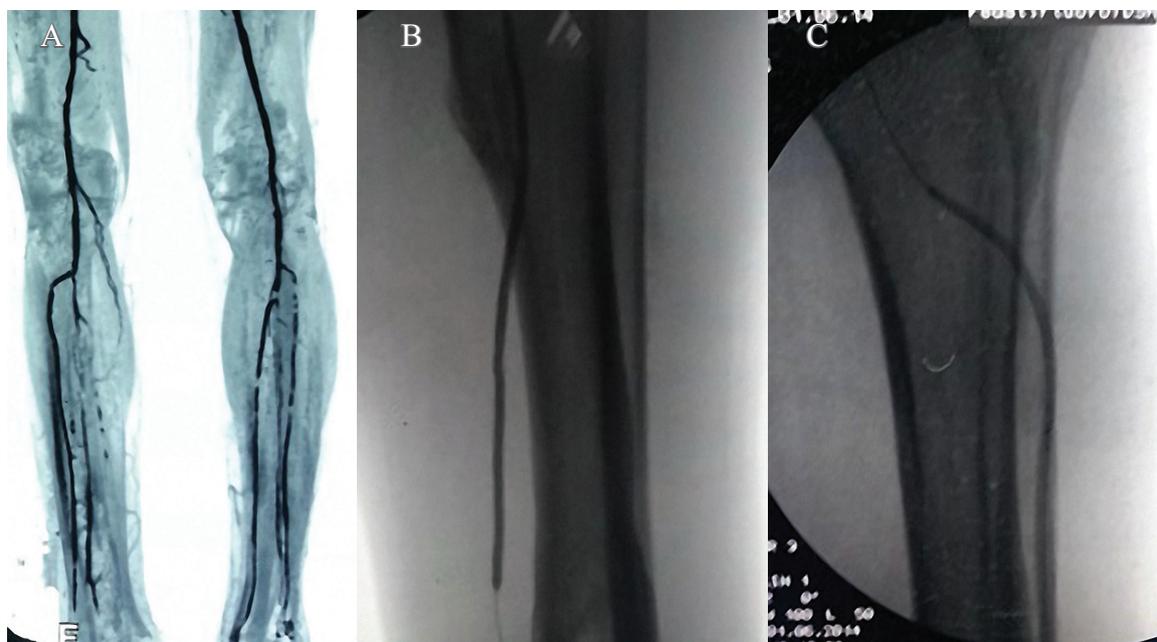


Figure (3): A: A CT angiography showing a multisegmental lesions involving the Anterior tibial, and posterior tibial vessels in a patient with left foot infected ulcer in need of urgent debridement. B: Dilatation of the posterior tibial artery using 3 x 200 mm balloon. C: Dilatation of the anterior tibial artery using 3 x 200 mm balloon.

Table (1): Age distribution of the study group.

Age group	No.	%
45-55 years	3	15%
56-66 years	9	45%
67-80 years	8	40%

Table (2): Co-morbidities of the study group.

		No.	%
Cardiac(CAD)		6	30%
Previous amputation	Minor	3	15%
	Major	2	10%
Cerebrovascular		3	15%

Table (3): Overall of limb salvage.

Outcome = 20	No.	%	Total
Free of amputation	7	35%	90%
Minor amputation	11	55%	
Major amputation	2	10%	10%

Table (4): Results from previous studies showing initial success rate, primary patency and limb salvage rate using short balloons for treating infrainguinal lesions

Study	No. Of PTs	Maximum length of balloon(mm)	Initial success rate	Primary patency rate	Limb salvage rate
Conrade et al 2009.6	144	≤ 3×100	95%	70%	86%
Bosiers et al 2006.7	443	≤ 3×100	85%	74%	96%
Dorros et al 2001.8	235	≤ 3×80	94%	75%	91%
Iida et al 2013.9	314	3×100 3×120	93%	74%	80%
Peregrin et al 2010.10	1268	3)×20 to100)	89%	73%	80%
Total (X±SD)			91.2%	73.2%	86.6%

Table (5): Comparing the technical success rate, primary patency rate, and limb salvage rate between our study and the mean values of previous literature.

Outcome	Our study	Mean values of previous literatures	X ² -test	P-value
Initial technical success rate	95%	91.2%	0.078*	> 0.05
Primary patency rate	75%	73.2%	0.063*	> 0.05
Limb salvage rate	90%	86.6%	0.069*	> 0.05

contrast solution under fluoroscopy, using an inflation device.

5. Inflation pressure ranging from 6–10 atmospheres. Inflations were generally held for 30–90 seconds and were repeated once if there was evidence of persistent or residual stenosis after the initial inflation.

6. Completion angiography was done for evaluation of angioplasty results. Technical success was defined as improvement of luminal diameter of more than 50% or less than 30% residual stenosis.

7. Manual compression of the puncture site: Immediately after removal of the sheath for 15 to 20 minutes (it was done immediately after the procedure).

8. In the immediate post procedure period, the patient was followed up for pedal

pulsations, temperature, color of skin, motor power, capillary refilling, together with measurement of Ankle/Brachial index(ABI). If the patient was in need of urgent debridement it was done in the setting of the angioplasty, otherwise debridement was postponed till the 3rd day postprocedural.

9. All patients were maintained on Clopidogrel 75 mg once daily, together with acetyl salicylic acid 100 mg and a lipid lowering agent for at least 6 months.

10. Follow up was done weekly for 4 weeks postoperatively then followed up every month for 4 months, then every couple of months for one year, which was in the form of clinical examination to assess improvement of symptoms, ankle/brachial index to compare with the preprocedural one,

and duplex scanning.

Results:

This study was conducted on 20 patients From December 2012 till June 2014. Patients included in the study were essentially attending the vascular out-patient clinic and emergency department at Ain Shams University Hospitals treated by tibial angioplasty with long balloon catheter.

The patients included in the study were 15 males versus 5 females with a percentage of 75% and 25% respectively. The mean age of patients was 64 ± 11.1 years (ranging from 45 to 80 years). The distribution of the age groups of the patients are shown in **Table (1)**:

Assessment of risk factors for the studied group together with the associated comorbidities are shown in **Figure (1)** and **Table (2)** respectively.

Of the studied group, only one patient had rest pain on the left side lower limb of more than two weeks not responding to analgesia. Nine of the studied patients (45%) had minor tissue loss or gangrene, (15%) had major tissue loss.

The site and the degree of the lesions was found to be, one (5%) of our patients had lesions only in the anterior tibial artery, Two (10%) affect only posterior tibial artery and seventeen (85%) patients with a combined infrapopliteal arterial lesions, twenty eight (53.8%) of the lesions were stenosis of arterial segments (28.8% with significant stenosis less than 75% luminal reduction and 25% with tight stenosis more than 75% luminal reduction) and twenty four patients (46.2%) of the lesions were arterial occlusions (13.5% with short occlusion less than or equal 2cm in length and 32.7% with long occlusion more than 2cm length).

The technical success rate was 95% as the procedure succeeded in nineteen patients and failed in one patient (severely calcified long occlusions) who underwent below knee amputation, follow up was done by duplex examination and assessment of ABI, after six months the primary patency rate was 85% as another patient underwent below knee amputation and recurrence of rest pain

(restenosis) had occurred in another patient, after 12 months of follow up we recorded two cases with restenosis and decrease of ABI so the primary patency rate after 12 months was 75%, as shown in **Figure (2)**.

55% of our patients (11) underwent minor amputations (1 tarso-metatarsal, 2 middle toes, 2 the 2nd and 3rd toes, 1 little toe, 2 the lateral 2 toes, 1 the 2nd toe and 2 big toe), 35% (7) of our patients treated were free of amputation. While only two patients in this study underwent major amputations (below knee amputation).

The comparison between our study and previous studies that used short balloon catheters (≤ 12 cm in length) in treatment of tibial arterial lesions, is shown in **Table (4)**.

The mean results of those 5 studies were compared with the results of our study and the P-value was calculated by Fisher-exact test, and the result was found to be non significant as shown in **Table (5)**.

Discussion:

This study is concerned with the primary patency of Angioplasty with long balloon catheters for long multi-segmental tibial lesions in patients with critical lower ischemia, and its effect on quality of life and limb salvage & comparing its results to previous studies had used short balloon catheters.

Follow up of the patients was done by clinical examination and assessment of improvement of patient complaint (rest pain), and healing of ulcers, full pulse examination of the lower limb arterial system for all patients with recording of the ankle brachial pressure index, limb salvage rate, Lower limb arterial duplex.

Follow up over 12 months revealed patency rate of (75%), and limb salvage among overall patients (90%).

The immediate technical success in our series for PTA was 95%, 55% underwent minor amputation.

A study by Jue Wang et al., showed immediate technical success rate of 92.5%, limb salvage rate of 94% and patency rate of (59%) over 12 months follow up, 11% underwent minor amputation.¹¹

In another study by Gandini et al., showed that 93.5% with immediate technical success rate, 100% limb salvage rate and patency rate of (77.4%) over 12 months follow up, 16.1% underwent minor amputation.⁵

In a retrospective study, patients experiencing CLI had endovascular treatment including Below The Knee (BTK) Percutaneous Transluminal Angioplasty. Limb Salvage Rate (LSR) for patients who had a successful procedure was 87% at 1 year and 3 years. Two-thirds of patients had total vessel dilatation with improved LSR at 1 year and 3 years 89%.¹²

After 12 months follow up of our patients, the data was collected and analysed statistically and then compared with previous literatures concerned with treatment of infrapopliteal arterial lesions by shorter balloon catheters angioplasty.

Conrade et al performed a retrospective review of below-knee percutaneous interventions in 144 patients with CLI. Patients were treated with angioplasty by balloon length not exceeds 10 cm . The initial success rate was 95%, the overall primary patency rate at 1 year was 70 % and The overall limb salvage rate for 1 year was 86%.⁶

Bosiers et al., performed angioplasty between September 2002 and June 2005, 443 patients (355 Rutherford category 4, 82 category 5, 6 category 6) underwent intervention for 681 BTK lesions. Patients were treated with angioplasty by balloon length not exceeding 10 cm . The initial success rate was 85%, the overall primary patency rate at 1 year was 74 % and The overall limb salvage rate for 1 year was 96%.⁷

Dorros et al., performed a prospective, nonrandomized, consecutive series of tibioperoneal vessel angioplasty for 235 patients. Patients were treated with angioplasty by balloon length not exceeding 8 cm. The initial success rate was 94%, the overall primary patency rate at 1 year was 75 % and The overall limb salvage rate for 1 year was 91%.⁸

In Iida et al., A prospective multicenter study was conducted to evaluate the clinical

outcomes of 314 Japanese critical limb ischemia patients. Patients were enrolled from December 2009 to July 2011 and were followed-up for 12 months. Patients were treated with angioplasty by balloon length 10 &12 cm. The initial success rate was 93%, the overall primary patency rate at 1 year was 74% and the overall limb salvage rate for 1 year was 80%.⁹

From 1999 to 2007 Peregrin et al., performed infrapopliteal angioplasty as a primary procedure in a total of 1445 lower limbs of 1268 patients. Patients were treated with angioplasty by ballon length ranged from 2 to 10 cm. The initial success rate was 89%, the overall primary patency rate at 1 year was 73 % and The overall limb salvage rate for 1 year was 80%.¹⁰

Conclusion:

Endovascular treatment of below the knee lesions is a valid and robust therapy for critical limb ischemia, with excellent results (either long or short balloon catheters as there is no significant difference in their results). We anticipate that endovascular intervention will become the primary treatment for below the knee lesions in CLI patients, with 1-year primary patency, limb salvage, and survival rates that compare favorably with published surgical data.

Infrapopliteal angioplasty using long balloon catheters can be performed safely with favorable results in patients, with accepted primary patency rates in comparison to using short balloons.

Advantages of long balloon catheters includes decreased procedural time, decreased radiation exposure, less vessel occlusion time and risk of thrombosis, Less risk of emboli resulting from advancing or withdrawing winged balloons across diseased segments and less risk of dissection as dilation is from normal segment distally to normal segment proximally

Infrapopliteal angioplasty with a long balloon was feasible, with encouraging midterm outcome, in the treatment of severe limb ischemia. The advantage of long balloons is most clearly evident in cases of

complex distal revascularization such as those involving the pedal arch. In these cases, the diseased arch can be easily treated with a single balloon covering complicated anatomy of the most of the lesion area, resulting in better arterial remodeling, also, decreased procedural time and decreased radiation exposure. The limited sample size in this study does not enable however a definitive appraisal of the clinical role of this type of balloon catheters so Further studies are necessary to evaluate long-term outcome.

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