

Assessment of Endovascular Treatment of Tibial Artery Occlusion in Diabetic Patients

Mohamed Abdel-Hamid Abdel-Rahman, Ahmed Saeed Daha,

Mohamed Moukhtar Abdel-Fattah Elbanwany

Vascular Surgery Department, Faculty of Medicine, Al-Azhar University

ABSTRACT

Background: Globally, over 170 million people have diagnosed DM, and by the year 2030, the prevalence is estimated to raise 2.5-fold. Diabetes mellitus (DM) is one of the strongest predictors of peripheral arterial occlusive disease and a significant risk factor for progression of asymptomatic disease or claudication into critical limb ischaemia (CLI). Critical limb ischaemia is the most advanced stage of peripheral arterial occlusive disease. The prognosis is poor, with amputation rates up to been 30% and mortality up to 25 % after 1 year.

Aim of the Work: The aim of this work is to evaluate the role of endovascular treatment of tibial artery occlusive disease in diabetic patients, as regard to efficacy, safety, as well as complications. **Patients and Methods:** This is prospective cohort study, diabetic patients with peripheral arterial occlusive disease (affecting tibial arteries), it is the study of 20 patients, Al-Azhar University Hospitals. Patients with Critical limb ischaemia (CLI) with Computerized Topographic Angiography (CTA) evidence of significant isolated tibial artery occlusive disease (anterior or posterior or both). Patients with generally adequate state of cardiac, respiratory and renal conditions that allow the procedure.

Results: The present study was conducted on 20 diabetic patients, 11 males (55%) and 9 females (45%). Their age ranged between 50 years and 87 years with a mean age of 66.7 ± 12.35 . All 20 diabetic patients had tibial disease which ranges from segmental stenosis to total occlusion. The procedure time was estimated from the time of infiltration of local anaesthesia to the end of the procedure; It ranged from 45 min to 120 minutes with mean \pm SD (88.9 ± 20 . min). The hospital stay ranged from 1 to 21 days with mean \pm SD (5.5 ± 6.8). **Conclusion:** Tibial angioplasty demonstrated its feasibility, safety and effectiveness in the treatment of diabetic patients with CLI. Limb salvage should be the main goal in patients with CLI due to infrapopliteal occlusive disease. With a prompt diagnosis, treatment can be started early and serious consequences may be avoided. Revascularisation that can prevent amputation is the ultimate treatment strategy.

Keywords: Endovascular Treatment, Revascularisation, Tibial Artery Occlusion.

INTRODUCTION

Globally, over 170 million people have diagnosed DM, and by the year 2030, the prevalence is estimated to raise 2.5-fold⁽¹⁾.

Diabetes mellitus (DM) is one of the strongest predictors of peripheral arterial occlusive disease and a significant risk factor for progression of asymptomatic disease or claudication into critical limb ischaemia (CLI)⁽²⁾.

Critical limb ischaemia is the most advanced stage of peripheral arterial occlusive disease. The prognosis is poor, with amputation rates up to been 30 % and mortality up to 25 % after 1 year⁽³⁾.

Diabetic patients who develop CLI are more prone to ischaemic events with an impaired functional status. Approximately 80 % of diabetes related lower limb amputations are preceded by a diabetic foot ulcer⁽⁴⁾.

Treatment of CLI aims at wound healing, improvement in quality of life, limb loss prevention, and prolonged survival. Current strategies propose open or endovascular revascularization of tibial arteries with runoff

through the ankle, but not specifically targeted to the location of ischaemia⁽⁵⁾.

To achieve healing of an ischaemic foot ulcer and save the leg from amputation, revascularization, endovascular or open surgery, with sufficient wound perfusion is necessary. In recent years, selection of the artery for revascularization has been the subject of discussion, the angiosome concept has been introduced⁽⁶⁾.

AIM OF THE WORK

The aim of this work is to evaluate the role of endovascular treatment of tibial artery occlusive disease in diabetic patients, as regard to efficacy, safety, as well as complications.

PATIENTS AND METHODS

- **Study design:** this is prospective cohort study. **The study was approved by the Ethics Board of Al-Azhar University.**
- **Study population:** diabetic patients with peripheral arterial occlusive disease (affecting tibial arteries).

- **Patient's number:** it is the study of 20 patients.
- **Study venue:** Al-Azhar University Hospitals.

Inclusion criteria in the study:

- Patients with Critical limb ischaemia (CLI) with Computerized Topographic Angiography (CTA) evidence of significant isolated tibial artery occlusive disease (anterior or posterior or both).
- Patients with generally adequate state of cardiac, respiratory and renal conditions that allow the procedure.

Exclusion criteria from the study:

- Patients with multi-level arterial lesions i.e. aorto-iliac, femoro-popliteal combined with tibial arterial lesion.
- Inevitable amputation.
- Acute on top of chronic ischaemia.
- Buerger's disease
- Highly calcific lesions
- Patients with creatinine > 1.7 mg/dl.
- Poor general condition (decompensated heart failure, stroke, bed ridden).

Methods

After taking of written consent from all 20 patients. They were subjected to the following:

1-Clinical data for every patient was recorded in a printed vascular Sheet:

A-History:

Personal history: Name, Age, Sex, Occupation, Residence and Special habits.

Complaint: Rest pain or Tissue loss.

Present history: Analysis of complaint: Onset, Course. Duration Risk factors Diabetes Smoking Hypercholesterolaemia, Ischaemic heart disease, Hypertension, Renal impairment

Past history: Neurological, Cardiac, Operations, Drug intake, Hepatic disease, Lung disease, Similar conditions, Vascular procedure or Allergies.

▪ **Family history**

B-Examination:

I. General examination: Temperature, Respiration, Pulse, Weight, Head and neck, Heart and Abdomen.

Statistical Methods

All the collected data were coded on the computer and the statistical analysis was done using SPSS program (Statistical Package for Social Science).

RESULTS

Table (1): Distribution of the studied patients regarding their age and sex.

Sex	N.	(%)	Age	
			Range	Mean±S.D.
Male	11	(62%)	50 – 87	68.2±12.33
Female	9	(38%)	55 – 84	67.5±11.95
Total	20	(100%)	50-87	66.7±12.35

There was a statistically significant difference (P-value<0.014) between the outcome of PTA and the age of patients where the outcome of PTA was more worse in patients over 70 years than in those under 70 years, but the outcome was not affected by sex (P-value>0.66).

Table (2): Duplex grades of stenosis in 20 patients.

Category	N	%
A (stenosis 50-70%)	3/20	15%
B (stenosis 70-90%)	5/20	25%
C (stenosis >90%)	12/20	60%

The pre-intervention mean ABPI for the entire group was 0.32±0.2.

Table (3): Localization, number of arteries and nature of treated lesions in the infragenicular arteries:

Artery	No.	(%)	Stenosis (n)	Occlusions (n)
TP Trunk	5	25%	4	1
ATA	8	40%	5	3
PTA	6	30%	4	2
PA	12	60%	9	3

Most of the lesions were in the peroneal and anterior tibial arterial territories (60% and 40%, respectively).

Table (4): Results of PTA in studied patients (Angiographic patency)

Result of PTA	Angiographic Patency Rate (APR)				
	N	(%)	A	B	C
Optimal (<30%)	9	45 %	2	4	7
Suboptimal (30-50%)	4	20 %	1	1	1
Failure	7	35%	0	0	4
Total	20	100 %	3	5	12

Procedure success was defined as: PTA resulting in less than 50% residual stenosis of the original lesion after dilatation.

Table (5): Analysis of the clinical factors in relation to PTA outcome:

Presenting complaint	Success		Failure		Total	
	N	(%)	N	(%)	N	(%)
Rest pain	2	66.7%	1	33.3%	3	15%
Minor tissue loss (Non healing ulcer or focal gangrene with diffuse pedal ischaemia).	11	64.7%	6	35.3%	17	85%
P	0.36					

Clinical successes were defined as relief of rest pain or improve healing of the ulcer and limb salvage, based on Rutherford categories.

Table (6): Ankle brachial pressure index (ABPI) in the studied patients group pre and post operative excluding patients with sever calcifications.

	Pre PTA	Immediately after PTA	After one month post PTA	After 3 months	After 6 months	P
Mean ±S.D.	0.29 ±0.2	0.58±0.17	0.62±0.18	0.70±0.19	0.75±0.20	<0.001

The pre-intervention mean ABPI for the entire cohort (**excluding patients with sever calcifications**) was 0.29±0.2, which improved to 0.58±0.17 immediately post-intervention (P<0.001). When evaluated after 1 months post-procedure, it improved to 0.62±0.19 (P<0.001), after 3 months to 0.70±0.20, after 6 months to 0.75±0.20. (P< 0.001).

Table (7): Analysis of the relationship between pattern of waves pre and post PTA by colour duplex:

Pattern of the waves	Success		Failed		Total	
	N	(%)	N	(%)	N	(%)
Monophasic	9	75%	3	25%	12	60
Biphasic	8	100%	0	0	8	40
P	<0.05*					

There was statistically significant improvement in the type of wave pattern by duplex scan pre-PTA and post-PTA.

Table (8): Primary patency rate after 1 month was 80%, while after 6 months was 70%.

Primary Patency rate	N.	(%)
After one month	14	70
After 3 months	14	70
After 6 Months	12	60

Patency at follow-up was documented by means of colour duplex ultrasound: < 50% diameter reduction (peak systolic velocity index < 2.4), 50% or more diameter reduction (peak systolic velocity index > 2.4) and complete occlusion. Primary patency at 1 and 3 months was defined as Freedom from restenosis (Ultrasound patency); restenosis was defined by a peak systolic velocity index > 2.4 at the target lesion.

DISCUSSION

Diabetic patients are more likely to develop CLI and its serious complications including gangrene, and to have higher morbidity and mortality.

Also, diabetes mellitus is one of the possible determinant factors of graft failure in patients with CLI. For these reasons, Tibial angioplasty is currently proposed as the primary treatment for CLI in diabetic patients. Tibial angioplasty, however, has been criticized because of the small diameter and length of the treated vessel, both of which have a tendency towards a high restenosis rate; furthermore, it is not clear whether the clinical success of Tibial angioplasty is due solely to technical success ⁽⁷⁾.

A recent meta-analysis of Tibial angioplasty for CLI reports that the durability of PTA is limited compared with bypass surgery. Nevertheless, for this kind of patients, the main result is not to avoid restenosis and maintain distal pulse, but to restore a straight line blood flow (sometimes as a “temporary bypass”) for the time that is necessary to provide wound healing and limb salvage, favouring the treatment of infections where needed ⁽³⁾.

According to TASC II, there is growing evidence supporting this treatment for limb salvage in patients who have stenotic or occluded tibial arteries, but only when there is presence of distal run-off in the foot in patients at high surgical risk. There is 90% success rate in immediate outcomes of the endovascular treatment of distal lesions ⁽⁷⁾.

Studies have shown that the most important aspect of life quality for CLI in diabetic patients is actually that of limb salvage. Compared to other markers such as rest pain and ulcer healing, it is believed that limb salvage should be the goal in most patients with CLI. Hence, leaving the patient with an ambulatory foot should be the paramount goal ⁽⁹⁾.

Long-term patency is not as relevant in this patients, because less blood flow is generally required to maintain tissue integrity than to achieve wound healing. Therefore, temporary 6 months restoration of straight-line flow to the foot may be sufficient to relieve CLI, while collateral flow may be all that is necessary to preserve tissue integrity. Because of this, the long-time patency in the treated segments wasn't the primary objective of this study.

This study was concentrating on the outstanding role of Tibial angioplasty for the management of critical lower limb ischemia in diabetic patients

The present study demonstrates technical success as well as safety, efficacy and practicability and estimates the early results as limb salvage and patency rates of Tibial balloon angioplasty for diabetic patients with critical lower limb ischaemia.

In this study, patients age ranged between 50 years and 87 years with a mean age 66.7 ± 12.35 .

The higher mean age and the greater prevalence of diabetic, renal, cardiac, and hypertensive identify a very fragile population at high surgical risk, for which endovascular treatment represents the hope to avoid amputation, and improve functional status and quality of life.

Analysis of the effects of various **demographic factors** like; age, sex, D.M., smoking, hypertension, dyslipidaemia, associated diseases (cardiac, renal, CVD), the presence of more than one risk factor had revealed that: age > 70 years had poor outcomes due to the severity of the atherosclerotic disease affecting the patients; Also the association of more than one risk factor has a highly significant poor prognosis.

In this study, the pre-intervention mean ABPI for the entire cohort excluding patients with severe calcifications was 0.29 ± 0.2 , which improved to 0.62 ± 0.17 one month post-intervention ($P < 0.001$). When evaluated after 3 months post-procedure, it improved to 0.70 ± 0.19 ($P < 0.001$) and after 6 months to 0.75 ± 0.20 .

In **3** diabetic patients (15%) there was severe medial calcifications affecting the tibial vessels and the ABPI was falsely elevated (> 1.2), so that evaluation of those patients with ABPI was not statistically significant.

Technical success was defined as: PTA resulting in less than 50% residual stenosis of the original lesion after dilatation.

In this study, the primary technical success rate was achieved in 13 patient (80%). 9 of them (45%) had optimal technical success, 4 patients (20%) had suboptimal technical success and 7 patients (35%) had technical failure.

In this study, Clinical success was defined as relief of rest pain or healing of the ulcer and limb salvage, based on Rutherford categories. Of 4 patients (15%) suffering from rest pain, 3 patients (75%) become asymptomatic and 1 patient (25%) underwent BK amputation. Of 17 patients (85%) suffering for minor tissue loss, improve Healing was achieved in 9 patients (69.2%) and 4 patients (30.8%) underwent major amputations.

Undoubtedly, clinical success has little correlation with patency of the treated vessel. The term patency derives from surgical revascularization literature and is used to describe the presence of uninterrupted flow. By definition, the term reflects the findings of objective imaging such as duplex ultrasound, digital subtraction angiography, computed tomographic or magnetic resonance angiography ⁽¹⁰⁾.

In this study, the primary patency rate was (70%) at 1 and 3 months and (60%) at 6 months

This result reflects a decline of patency rate by time, however the long-term complete patency of the treated vessels less important in such patients than in those with coronary, carotid or renal arterial disease: the re-canalization temporarily increases blood flow to the foot and has a positive effect in eradicating infection and healing ulcers and surgical wounds, thus the rate of major amputations in this study still low after 12 months of angioplasty.

There are differences in primary patency between studies in literature that may be due to the heterogeneity of the patient groups rather than to the differences in angioplasty technique.

Earlier reports have even greater variability in outcomes with less objective measurement criteria to assess re-stenosis or occlusion. In **2001, Lofberg et al.** ⁽⁸⁾ reported 86 infrapopliteal interventions for CLI, defining clinical success as symptomatic improvement and an increase in ABI of > 0.1 . Rates for 1-, 2-, and 3-

year clinical success were 51%, 36%, and 36%, respectively, and 3-year limb salvage was 72%.

In this study, Patency at follow-up was documented by means of colour duplex sonography: <50% diameter reduction (peak systolic velocity index < 2.4), 50% or more diameter reduction (peak systolic velocity index > 2.4) and complete occlusion. Primary patency at 1 and 3 months was defined as Freedom from restenosis (Ultrasound patency); restenosis was defined by a peak systolic velocity index > 2.4 at the target lesion.

CONCLUSION

On the basis of the obtained results, it can be concluded that:

- Tibial angioplasty demonstrated its feasibility, safety and effectiveness in the treatment of diabetic patients with CLI.
- Limb salvage should be the main goal in patients with CLI due to infrapopliteal occlusive disease. With a prompt diagnosis, treatment can be started early and serious consequences may be avoided. Revascularisation that can prevent amputation is the ultimate treatment strategy.
- Tibial angioplasty is a low-risk and minimally invasive procedure, which rarely compromises a later surgical procedure, and at the same time preserves the saphenous vein for future coronary or lower extremity distal bypass surgery.
- Tibial angioplasty showed favorable clinical outcomes in terms of technical success, primary patency, high rate of limb salvage and amputation-free survival.
- It carries a lower morbidity and mortality and shorter hospital stay compared with surgery but with high cost.
- All the above reasons are encouraging and support the endovascular revascularization as the first treatment option in all patients with CLI who would otherwise be offered distal bypass surgery or amputation, as failure rarely precludes surgery.
- Correct pre-procedural investigation and planning, appropriate revascularization techniques and adequate post-procedural follow-up and medical management are crucial to the desired clinical outcome.

- Although it is still a technically challenging procedure, more aggressive treatment with advanced devices and more clinical experience would allow the interventionist to treat increasingly complex and diffuse patterns of disease.

REFERENCES

1. **Armstrong DG, Kanda VA, Lavery LA *et al.* (2013):** Mind the gap: disparity between research funding and costs of care for diabetic foot ulcers. *Diabetes Care*, 36(7):1815e7.
2. **Thiruvoipati T, Kielhorn CE, Armstrong EJ (2015):** Peripheral artery disease in patients with diabetes: epidemiology, mechanisms, and outcomes. *World J Diabetes*, 6(7):961e9.
3. **Norgren L and William R (2007):** Inter-society consensus for the management of peripheral arterial disease (TASC II). *Eur.J.Vasc.Endovasc.Surg.*, 43: 71-75.
4. **Hingorani A, LaMuraglia GM, Henke P *et al.* (2016):** The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *Journal of vascular surgery*, 63(2), 3S-21S.
5. **Bosanquet DC, Wright AM, White RD, Williams IM (2016):** A review of the surgical management of heel pressure ulcers in the 21st century. *Int Wound J.*, 13:9-16.
6. **Attinger CE, Evans KK, Bulan E *et al.* (2006):** Angiosomes of the foot and ankle and clinical implications for limb salvage: reconstruction, incisions, and revascularization. *Plast Reconstr Surg.*, 117(7):261Se93S.
7. **Bosiers M, Hart J, Deloose K *et al.* (2009):** Endovascular therapy as the primary approach for limb salvage in patients with critical limb ischemia: experience with 443 infrapopliteal procedures. *Vascular*, 14: 63-69.
8. **Lofberg A, Karacagil S and Ljungman C (2001):** Percutaneous transluminal angioplasty of the infrapopliteal arteries in limbs with chronic critical lower limb ischemia. *J Vasc Surg.*, 34(1):114-121.
9. **Sigala M, Sigalas B, Langer P *et al.* (2005):** Transluminal angioplasty of isolated crural arterial lesions in diabetics with critical limb ischemia. *Vasa.*, 34(3), 186-191.
10. **Sensier Y, Fishwick G, Owen R *et al.* (1998):** A comparison between colour duplex ultrasonography and arteriography for imaging infrapopliteal arterial lesions. *European journal of vascular and endovascular surgery*, 15(1): 44-50.