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Subintimal Angioplasty of Tibial Vessel Occlusions in the Treatment of Critical Limb Ischaemia: Mid-term Results

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Objectives: *to evaluate the feasibility and preliminary results at 1 year of subintimal angioplasty of tibial occlusions in critical limb ischaemia (CLI).*
Material: *from December 1997 to December 1999, we intended to treat 36 patients and 40 limbs by subintimal angioplasty of occlusions of tibial vessels. Thirty-one had gangrene or ulceration and nine had rest pain. Twenty-seven occlusions were more than 10 cm, 10 were 5 to 10 cm and three were less than 5 cm in length. Three patients had an occluded previous ipsilateral bypass graft. All patients were followed 3 monthly for a median of 10 months by means of clinical and duplex examination.*
Results: *the technical success rate was 78% (31/40). Nine technical failures were treated by conventional surgery or angioplasty of another diseased tibial vessel. The clinical success rate was 68% (27/40). Four below-the-knee amputations were performed despite a patent recanalisation. Primary and secondary patency rates at 12 months were 56% (72% without technical failures). The 12-month limb salvage rate was 81% and survival rate was 78%. Three of five complications were treated by endovascular procedures. The length of occlusion (>10 cm) but not the location of distal re-entry, the type of vessel re-entry and the presence of diabetes are predictors of technical success and patency.*
Conclusions: *subintimal angioplasty can be used to treat tibial occlusions in patients with CLI. Technical failure does not preclude conventional surgery and complications may often be treated by endovascular procedures. However, the durability of angioplasty is as yet uncertain.*

Key Words: Subintimal angioplasty; Tibial vessel occlusions.

Introduction

The treatment of critical limb ischaemia (CLI) resulting from tibial vessel occlusion remains a challenge for vascular surgeons. In most cases CLI affects elderly patients with severe comorbidities. Furthermore, surgery is often complicated by swelling, spreading infection, ulceration, and lack of venous conduit. The prognosis of patients judged as not suitable for reconstruction is poor; at 2 years, only 27% are alive without amputation and 37% are dead.[1]

The purpose of this study is to report our preliminary experience with subintimal angioplasty or percutaneous intentional extraluminal recanalisation (PIER).

Materials and Methods

Sub-intimal angioplasty or PIER was first described in 1987.[2–4] It entails the creation of a dissection with an hydrophilic guide wire in the same plane as surgical endarterectomy. The dissection is extended until the wire re-enters the patent distal artery. This new channel is then opened by means of a balloon angioplasty (PTA), restoring arterial blood flow in the distal vessels.

From December 1997 to December 1999, we intended to treat 36 patients (21 men, median age of 70 years, range 36 and 90) and 40 limbs by a PIER of tibial occlusions. Diagnosis of tibial occlusion was made by conventional angiography and endovascular treatment was attempted during the same procedure in the majority of cases. We included in this study only occlusions recanalised by PIER. Stenosis and short occlusions (opened transluminally) were excluded.

Most of the procedures were performed simultaneously by one surgeon and one radiologist. Indications for PIER were poor general status, poor local conditions (swelling, extended ulcerations) or lack of autogenous conduit. All but two procedures were performed under local anaesthesia through a percutaneous antegrade common femoral puncture using a 5 or 6 French sheath. The two remaining patients had simultaneous above-knee femoropopliteal bypass.

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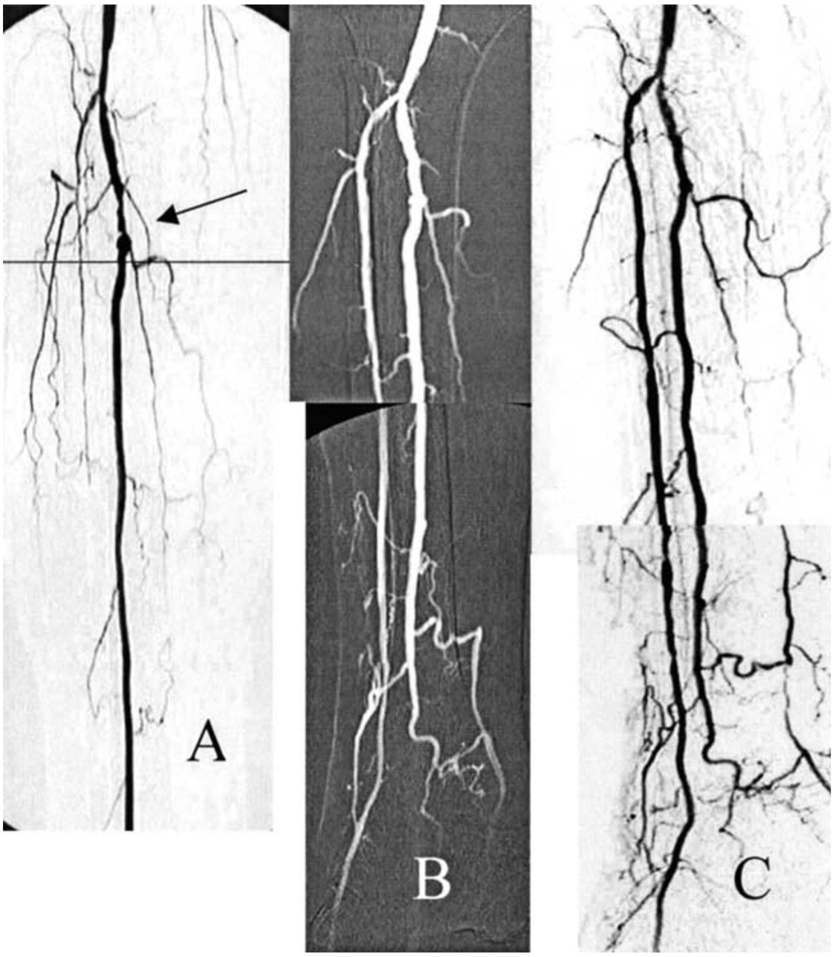


Fig. 1. (A) Angiography of the tibial vessels: occlusion of both anterior and posterior tibial arteries with a thigh stenosis of the tibio-peroneal trunck (arrow). Conventional angioplasty of this lesion had no effect on healing of malleolar ulcers. (B) Angiography after subintimal recanalisation of the all length of the anterior tibial artery with pedal re-entry: complete healing of the ulcers. (C) Angiography 22 months after the procedure: the recanalisation is still patent and there is no recurrence of ulcers.

There were 31 cases of gangrene or ulceration (78%) and nine cases of rest pain. Twenty-six patients were diabetic (72%), 21 had coronary disease, 14 had hypertension and seven had renal failure (four were on chronic haemodialysis). Three had an occluded previous bypass at the same limb.

The length of the occlusion was less than 5 cm in three cases, between 5 and 10 cm in 10 cases and more than 10 cm in 27 cases (68%). The PIER technique involved tibial artery alone in 32 cases and popliteal artery extending into crural vessels in eight cases. The re-entry site was tibial in 24 and pedal in 16 cases (Fig. 1 and Table 1). In six cases, two different crural vessels were recanalised.

The recanalisation was performed with an angled 0.035 glidewire (Terumo, Japan) and a 4 or 5F multipurpose catheter. After re-entering the vessel lumen distal to the occlusion with the catheter, a 200 cm 0.018 wire was placed (V-18 Control Wire, Boston Scientific, Watertown, MA, U.S.A.). Angioplasty was performed with a 3 or 2.5 mm diameter balloon (40 mm of length) for crural vessels and a 3–4 mm by 40 mm balloon for below-the-knee popliteal arteries (Symmetry stiff or Bijou, Boston Scientific).

Occlusions were rarely isolated and a complementary procedure was performed in 25 cases of the 31 successful procedures (81%) (Table 2). After the procedure, systemic anticoagulation was administered for 24 to 48 h and aspirin was started. Before discharge, patency was confirmed by duplex examination. All patients were followed by clinical and duplex examination at 1 month and then 3 monthly for a median of 10 (range 0.5–24) months.

Technical success was defined as flow on angiography at the end of the procedure and on duplex examination before discharge. Clinical success was defined as relief of rest pain as well as healing of the ulceration, or minor amputation allowing walking

Table 1. Successful recanalisations: localisation of the re-entry, run-off and the late occlusions.

Location of distal re-entry	Success/ attempt	Vessel of re-entry	*n* (X)	Run-off	*n*	Late reocclusion (X)	Time of reocclusion
Tibial vessel (calf level)	21/24	Anterior tibial	3 (1)	Pedal	3	0	
		Posterior tibial	5 (2)	Posterior tibial	5	1 (1)	3 m
		Peroneal	9 (3)	Pedal	5	2 (2)	1 m/8 m
				Posterior tibial	2	1	6 m
				Pedal + posterior tibial	2	1	3 m
		Anterior tibial + tibio-peroneal trunck	1 (1)	Pedal + peroneal	1	0	
		Anterior tibial + peroneal	2	Pedal	2	0	
		Posterior tibial + peroneal	1	Posterior tibial	1	1	13 m
Distal vessel (below ankle level)	10/16	Pedal	4			0	
		Posterior tibial	4			1	6 m
		Pedal + posterior tibial	1			1*	15 m
		Pedal + peroneal	1			0	

* = occlusion of only one of the two vessels recanalised.
(X) = number of recanalisations of popliteal occlusion extending into thee crural vessels.

without prosthesis. Recanalisations which were occluded or required subsequent procedures to maintain or restore patency were considered as failures. A successfully revised (PTA or new recanalisation) recanalisation contributed to secondary patency, while surgical revascularisation was considered as failure. Any limb amputated at or above the ankle was regarded as lost. Limb salvage and survival were calculated from the first procedure in patients having two procedures.

Patency, limb salvage and survival rates were analysed by the Kaplan–Meier method using standardised reporting criteria[5] and were based on intention to treat. Comparison between groups were made by Fisher exact test. Comparison between patency and limb salvage rates were made by the log-rank test of significance.

Results

Primary technical success was 78% (31/40). There were nine technical failures (all in the subgroup of occlusions of more than 10 cm) rendering the completion of the procedure impossible (Table 3).

Table 2. Type and number of complementary procedures.

Type of procedure	*n*
Proximal surgery	1
Proximal PTA*	11
Distal PTA	3
PTA of another tibial trunk	7
Proximal stent	1
Proximal PIER†	1
Thrombolysis	1
Total	25 (80.6%)

*PTA = angioplasty.
† PIER = percutaneous intentional extraluminal recanalisation.

The clinical success was 68% (27/40). Despite technical success and patent recanalisation, there were four below-the-knee amputations. The remaining had relief of rest pain, or healing of their ulceration or minor amputation without residual rest pain.

Five complications were encountered (16%): 2 distal embolisms treated by percutaneous thromboaspiration and 1 by surgical embolectomy; 1 arterial perforation treated by creating an another channel of recanalisation excluding the perforation during the same procedure and 1 common femoral artery false aneurysm. Including the nine technical failures, the 1-year patency rates were 56% ($\pm$13%) (Fig. 2). Eight late occlusions were encountered. Five were treated conservatively at 3, 6, 6, 8 and 15 months and the gangrene or ulcers healed. Two were treated by a new recanalisation with the same technique (1 and 13 months), the first one reoccluded at 1 month and treated conservatively, the second one is still patent after 10 months. One underwent a femoroperoneal bypass (3 months).

Limb salvage rate at 1 year was 81% ($\pm$9%) (Fig. 3). Among the 31 technical successes, four below-knee amputations were performed even though the recanalisation was patent. Three below-the-knee amputations were performed of the nine technical failures (Table 3). The survival rate at 1 year was 78% ($\pm$9%): six of seven deaths were from cardiac origin and two followed shortly after an amputation.

Discussion

Bolia *et al.*[2–4,6–8] reported 28 cases of infrapopliteal occlusion treated by subintimal angioplasty for CLI

Table 3. Technical failures: localisation, cause and treatment.

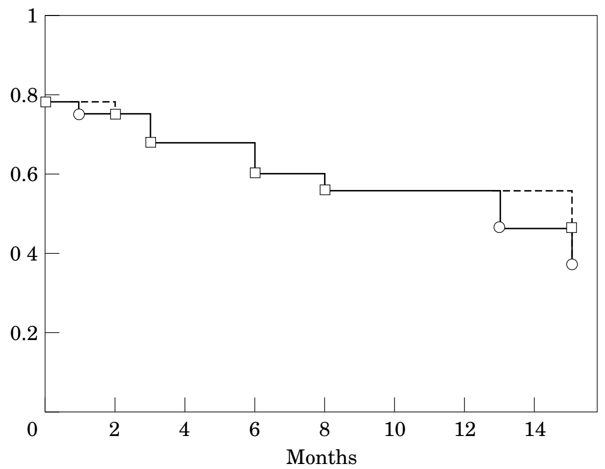
Location of distal re-entry	Failure/ attempt	Vessel of re-entry	Cause of failure	Conditions	Treatment
Tibial vessel (calf level)	3/24	Peroneal into posterior tibial artery	Two failures of catheter progression One poor distal run-off	One* Buerger disease One calcification One small peroneal artery	Declined a new peroneal bypass PTA of multiples stenoses of posterior tibial Conventional PTA of short occlusion of large anterior tibial
Distal vessel (below ankle level)	6/16	Pedal	Three failures of catheter progression	Calcifications	Two pedal bypass (1 occluded at 6 m and BK amputation) One PTA of stenoses of peroneal
		Collateral of pedal artery	Three poor distal run-off	Absence of pedal arch in diabetic patients	Two BK amputations despite surgical exploration One PTA of tibio-peroneal trunk into peroneal
Fisher test	NS				

* = recanalisation of popliteal occlusion extending into the tibio-peroneal trunk and proximal peroneal artery.

Table 4. Influence of factors on technical failures, clinical success and late occlusion.

	n	Technical failures	Statistical*	Clinical success (failures)	Statistical*	Late occlusion/ Technical success	Statistical*
Diabetic	28	7 (25%)	NS	17 (4)	NS	4/21	NS
Non-diabetic	12	2 (17%)		10 (0)		4/10	
>10 cm	27	9 (33%)	$p=0.05$†	17 (1)	NS	5/18	NS
<10 cm	13	0 (0%)		10 (3)		3/13	
Tibial re-entry	24	3 (13%)	NS	20 (1)	NS	6/21	NS
Distal re-entry	16	6 (38%)		7 (3)		2/10	
Indirect distal flow	12	3 (25%)	NS	9 (0)	NS	4/9	NS
Direct distal flow‡	28	6 (21%)		18 (4)		4/22	
Popliteal into crural artery	8	1 (13%)	NS	7 (0)	NS	2/7	NS
Crural artery	32	8 (25%)		20 (4)		9/24	

* Fisher exact test.
† Statistical signification, but 4 of the technical failures were secondary to poor distal run-off and not secondary to length of the occlusion.
‡ Indirect distal flow is flow into a peroneal artery and then into a pedal and/or a distal posterior tibial artery. Direct distal flow is flow directly into pedal or distal posterior tibial artery.

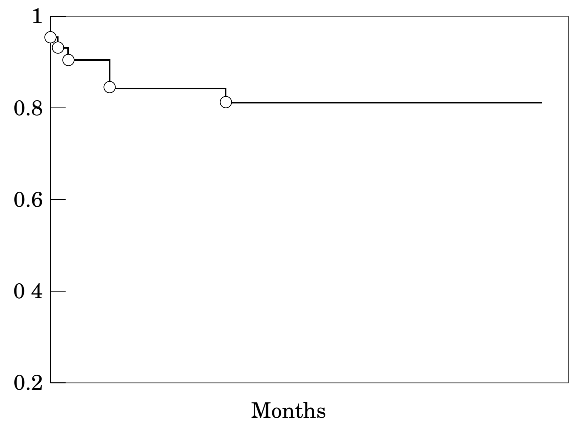


Number at risk

Primary
40 25 19 18 14 13 8 5

Secondary
40 26 19 18 14 13 8 6

Fig. 2. Cumulative primary (—) and secondary (– – –) patencies including the nine technical failures (standard error >10% after 12 months).



Number at risk
40 32 29 26 23 21 15 10 10

Fig. 3. Limb salvage rate including the nine technical failures (standard error >10% after 12 months).

with technical success of 82%, 1-year haemodynamic and symptomatic patencies of 53% and 56% respectively, a 1-year limb salvage rate of 85% and 1 year survival rate of 81%.

Our series confirms these promising results: technical success of 78%; clinical success of 68%; primary and secondary patency rate of 56%; limb salvage rate of 81%; and survival rate of 78%. These results are preliminary results and the trend has to be confirmed by long-term results.

Theoretically, the sub-intimal channel is free of atherosclerotic disease and may be recovered by a new intima. This could possibly explain the more favourable results than those of conventional techniques and that longer occlusions can be treated.

Two important points were underlined by our study. First, as evocated by Criado *et al.*[9] and by Bell *et al.*,[10] technical failure does not preclude conventional surgery.

Secondly, even after late re-occlusion, half of the patients (five of the eight occlusions) can be treated medically: gangrene or ulcers healed.

As a result, our management of CLI has changed such that surgery is attempted first only in good risk patients. In the rest, subintimal angioplasty is attempted first and surgery is only performed if the procedure fails. Diabetes is not a contraindication (Table 4). Technical success for diabetic patients is 75% (NS). One-year results are 50% for secondary patency rate and 72% for limb salvage rate (NS). However, we now consider lack of run-off as a contraindication for attempt of the recanalisation, because failure can precipitate ischaemia without any surgical alternative.[10]

The location of the distal re-entry, the type of vessel re-entry and the beginning of the occlusion did not affect the outcome. Only the length of the occlusion affected the technical failure rate (Table 4).

However, not all are agreed that there is a rate for PTA in CLI. Parson *et al.*[11] reported 66 cases of tibial artery PTA for CLI. The 1-year cumulative patency rate was 13% and the 1-year limb salvage rate was 25%. Treiman *et al.*[12] reported 25 cases of PTA for localised stenosis of below-knee popliteal artery or tibioperoneal trunk. The clinical and haemodynamic success was 59%, 32% and 20% at 1, 2 and 3 years, respectively. They concluded that PTA was associated with a high rate of recurrence requiring subsequent intervention.

However, Marzelle *et al.*[13] reported 200 cases of endovascular treatment (with 81 lesions of tibial arteries of the 287 lesions treated) with 1 and 4-year primary patency rates of 61% and 52%, and limb salvage rates of 87% and 82% respectively. Criado *et al.*[9] report 26 cases of PTA of stenoses or short occlusions (<3 cm) of crural arteries with a technical success rate of 77% and long term limb salvage rate of 80%.

Our experience leads us to conclude that subintimal angioplasty of tibial vessel occlusions yields acceptable short-term results in the treatment of CLI.

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